

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

S/N	NDA REGISTRATION NUMBER	LICENSE HOLDER	LOCAL TECHNICAL REPRESENTATIVE	NAME OF DRUG	GENERIC NAME OF DRUG	STRENGTH OF DRUG	MANUFACTURING SITE	COUNTRY OF MANUFACTURE	DOSAGE FORM	PACK SIZE	REGISTRATION DATE
1	NDA/MAL/HDP/002	ABACUS PARENTERAL DRUGS LIMITED.	ABACUS PARENTERAL DRUGS LIMITED	X-SONE-N	DEXAMETHASON E+NEOMYCIN	0.1W/V+ 0.35W/V	ABACUS PARENTERAL DRUGS LTD.PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL,1.0X5.0 ML VIAL	01/07/2011

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2	NDA/MAL/HDP/003	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	UMOXIL CLAV 625	AMOXICILLIN + CLAVULANATE POTASSIUM	500 MG + 125 MG	UNI MEDICOLABS21-22 PHARMACY SELAQUI DEHRADUN 248197	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2015
3	NDA/MAL/HDP/006	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DIAMIDE	GLIBENCLAMIDE + METFORMIN HYDROCHLORIDE	5MG + 500MG	HOVID BERHAD, LOT 56442, 7 1/2 MILES JALAN IPOH/CHEMOR 31200, CHEMOR PERAK	MALAYSIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X12.0 TABLET BLISTER	01/07/2014

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4	NDA/MAL/HDP/007	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	PROCIP SYRUP	CYPROHEPTADINE HYDROCHLORIDE	2MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE	01/07/2013
5	NDA/MAL/HDP/012	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	PENGESIC SR	TRAMADOL HYDROCHLORIDE SR	100MG	HOVID BHD LOT 56442, 7.5 MILE JALAN IPOH/CHEMOR, 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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6	NDA/MAL/HDP/0013	ORGANON SOUTH AFRICA (PTY) LTD	SURGIPHARM (U) LIMITED	IMPLANON NXT	ETONOGESTREL	68MG	N.V. ORGANONKLOOSTER STRAAT 6, 5349 AB OSS, THE NETHERLAND	NETHERLANDS	PARENTERAL RETARD IMPLANTS	1.0X68.0 MG IMPLANT	01/07/2015
7	NDA/MAL/HDP/0016	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	CODIMEX-CT TABLETS	CETIRIZINE DIHYDROCHLORIDE	10MG	REGAL PHARMACEUTICALS LIMITED PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014

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8	NDA/MAL/HDP/0017	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS LIMITED	S-HYDRO	HYDROCORTISON E	100MG	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X7.5 ML VIAL, 1.0X50.0X100.0 MG VIAL	01/07/2011
9	NDA/MAL/HDP/0021	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	QUINS	QUININE DIHYDROCHLORIDE	300MG/ML	SAKAR HEALTHCARE PVT. LTD PLOT 10/13 SAKHEJ-BAVLA ROAD, AHMEDABAD, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X2.0 ML AMPOULE, 1.0X2.0X5.0X2.0 ML AMPOULE	01/07/2013

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10	NDA/MAL/HDP/0022	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	QUININE SULPHATE	QUININE SULPHATE	300MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2009
11	NDA/MAL/HDP/0024	KOPRAN LIMITED	TATA UGANDA LIMITED	AMPICLOXA	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	KOPRAN LIMITED VILLAGE-SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1997

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12	NDA/MAL/HDP/030	UNOSOURCE PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	TRADMIN	TRAMADOL HYDROCHLORIDE	50MG/ML	AKUMS DRUGS & PHARMACEUTICALS LTD. -PLANT III,PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL,RANIPUR, 249 403	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE	01/07/2015
13	NDA/MAL/HDP/031	MANKIND PHARM LTD	TATA UGANDA LIMITED	CEFTATIME-SB 1.5	CEFTRIAZONE+SULBACTAM	1000MG+500MG	MANKIND PHARMA LTD-VILLAGE KISHANPURA P.O JAMNI WALA TEHSIL PAONTA SAHIB DISTT SIRMOUR 173025 HIMACHAL PRADESH	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.5 G VIAL	01/07/2015

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14	NDA/MAL/HDP/0033	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYVATE CREAM	BETAMETHASONE VALERATE	0.1%W/W	ELYS CHEMICAL INDUSTRIES LIMITED- ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997
15	NDA/MAL/HDP/0041	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RECIM	CIMETIDINE	200MG	RENE INDUSTRIES LIMITED PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013



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16	NDA/MAL/HDP/0045	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOMOL CAPLETS	PARACETAMOL	500MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/2007
17	NDA/MAL/HDP/0051	H. LUNDBECK A/S	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CLOPIXOL ACUPHASE	ZUCLOPENTHIXOL ACETATE	50MG/ML	H. LUNDBECK A/S OTTILIAVEJ 9,2500 VALBY	DENMARK	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE	01/07/2015

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18	NDA/MAL/HDP/0052	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	DISPERCAM	PIROXICAM	0.5%W/V	MEDICAL UNION PHARMACEUTICAL CO.PLANT: ABUSULTAN, ISMAILIA, EGYPT	EGYPT	TOPICAL EXTERNAL GELS AND SOLS	1.0X15.0 G TUBE,1.0X30.0 G TUBE	01/07/2014
19	NDA/MAL/HDP/0053	H. LUNDBECK A/S	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	FLUANXOL DEPOT	FLUPENTIXOL DECANOATE	20MG/ML	H. LUNDBECK A/S ,,OTTILIAVEJ 9, DK-2500, VALBY-COPENHAGEN	DENMARK	PARENTERAL RETARD AMPOULES	1.0X1.0 ML AMPOULE	01/07/2015

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20	NDA/MAL/HDP/0054	GOOD DAY PHARMACY LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	FUNGOAL	CLOTRIMAZOLE	1%W/W	KREMOINT PHARMA PVT LTD--B-8 ADDITIONAL AMBERNATH MIDC OPP. ANAND NAGAR POLICE CHECK POST AMBERNATH (E) DIST THANE 421 506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2013
21	NDA/MAL/HDP/0055	H.LUNDBECK A/S	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CLOPIXOL DEPOT	ZUCLOPENTHIXOL DECANOATE	200MG/ML	H. LUNDBECK A/S ,,OTTILIAVEJ 9, DK-2500, VALBY-COPENHAGEN	DENMARK	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE	01/07/2015

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22	NDA/MAL/HDP/0056	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DYNAPAR QPS	DICLOFENAC	4%W/V	TROIKAA PHARMACEUTICALS LTDTHOL VILLAGE, DIST. MEHSANA-382728, GUJARAT, INDIA TROIKAA PHARMACEUTICALS LTDBLOCK NO. 2019, 2020, 2023, VILLAGE VIROCHANNAGAR, TAL-SANAND CITY: AHMEDABAD, DIST. AHMEDABAD-382170, GUJARAT STATE	INDIA	TOPICAL EXTERNAL SPRAYS WITHOUT GAS	1.0X30.0 ML BOTTLE,1.0X15.0 ML BOTTLE	01/07/2015
23	NDA/MAL/HDP/0058	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	WATER FOR INJECTION B.P.	WATER FOR INJECTION	N/A	ACULIFE HEALTHCARE PVT. LTDVILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0 ML AMPOULE,1.0X10.0 ML AMPOULE	01/07/1997

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24	NDA/MAL/HDP/0059	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	VAGIBACT CREAM	CLINDAMYCIN PHOSPHATE	2%W/W	NABIQASIM INDUSTRIES (PVT) LTDV17/24,KORANGI INDUSTRIAL AREA, KORANGI, KARACHI-PAKISTAN.	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X40.0 G TUBE + 1 APPLICATOR	01/07/2006
25	NDA/MAL/HDP/0060	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GONAL-F PEN 300 IU/0,5 ML (22 µG/0,5 ML)	FOLLITROPIN ALFA	22 µG/0,5 ML	MERCK SERONO SPA (BARI)-VIA DELLE MAGNOLIE, 15 (LOC FRAZ ZONA INDUSTRIALE) 70026, MODUGNO, BARI MERCK SERONO S.A - SUCCURSALE D'AUBONNE, ZONE INDUSTRIELLE DE L'OURIETTAZ, 1170 AUBONNE, SWITZERLAND	ITALY SWITZERLAND	PARENTERAL ORDINARY PRE-FILLED PENS	1.0X1.0 CARTRIDGE PREFILLED PEN + 8 NEEDLES FOR INJECTION	01/07/2015

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26	NDA/MAL/HDP/0063	HETERO LABS LTD	AIVEEN (U) LIMITED	ABACAVIR SULPHATE + LAMIVUDINE	ABACAVIR SULFATE + LAMIVUDINE	600MG + 300MG	HETERO LABS LTD. UNIT (V)439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2015
27	NDA/MAL/HDP/0064	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GONAL-F PEN 450 IU/ IE 0,75 ML (33 µG)	FOLLITROPIN ALFA	33µG/ 0.7ML	MERCK SERONO SPA (BARI)-VIA DELLE MAGNOLIE, 15 (LOC FRAZ ZONA INDUSTRIALE) 70026, MODUGNO, BARI MERCK SERONO S.A. (MSA) - 1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND	ITALY SWITZERLAND	PARENTERAL ORDINARY CARTRIDGES	1.0X1.0 CARTRIDGE PREFILLED PEN + 12 NEEDLES FOR INJECTION	01/07/2015

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28	NDA/MAL/HDP/0065	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	ALENDRONATE 70MG	ALENDRONATE SODIUM	70MG	HOVID BHDLOT 56442 7 1/2 MILES JALAN IPOH / CHEMOR 31200 CHEMOR	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	01/07/2015
29	NDA/MAL/HDP/0067	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	ARTEES	ALPHA-BETA ARTEETHER	75MG/ML	SAKAR HEALTHCARE PVT LTD - (406, SILVER OAKS COMMERCIAL COMPLEX,)	INDIA	PARENTERAL ORDINARY AMPOULES	1X3.0X2.0 ML AMPOULE	01/07/2013

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30	NDA/MAL/HDP/0071	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SUMAFIX 100	SUMATRIPTAN SUCCINATE	100 MG	AUROBINDO PHARMA LIMITED (UNIT III) AURO HOUSE, 313, BUCHUPALLY, QUTHUBULLAPAR(M), RR DISTRICT HYDERABAD-500090, ANDHERA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X4.0 TABLET BLISTER	01/07/2014
31	NDA/MAL/HDP/0075	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS LTD	SYNRIAM	ARTEROLANE MALEATE + PIPERAQUINE PHOSPHATE	150 MG + 750 MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED INDUSTRIAL AREA 3, A.B. ROAD, DEWAS 455001, MADHYA PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER	01/07/2014



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32	NDA/MAL/HDP/0077	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	X-SONE	DEXAMETHASON E SODIUM PHOSPHATE	0.1 % W/V	ABACUS PARENTERAL DRUGS LTD.PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL	01/07/2015
33	NDA/MAL/HDP/0079	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	REVOKE 72	LEVONORGESTREL	750MCG	MYLAN LABORATORIES LIMITED..PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, AHMEDABAD, GUJARAT, INDIA 382213 MYLAN LABORATORIES LIMITED.-PLOT NO. 1606-1609	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	01/07/2014

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34	NDA/MAL/HDP/0083	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ZINNIA-F	LEVONORGESTREL & ETHINYLESTRADIOL + FERROUS FUMARATE	150MCG + 30MCG + 75MG	MYLAN LABORATORIES LIMITED..PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, AHMEDABAD, GUJARAT, INDIA 382213 MYLAN LABORATORIES LIMITED.-PLOT NO. 1606-1609	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X28.0 TABLET BLISTER	01/07/2014
35	NDA/MAL/HDP/0088	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	D-LYTE CO-PACK	ANHYDROUS GLUCOSE+SODIUM CHLORIDE+TRISODIUM CITRATE+POTASSIUM CHLORIDE/ZINC, ANHYDROUS GLUCOSE+SODIUM CHLORIDE+TRISODIUM CITRATE+POTASSIUM CHLORIDE/ZINC A	2.7MG+0.52MG+0.58MG+0.30MG+20MG PER 200ML,6.75MG+1.30MG+1.45MG+0.75MG+20MG PER 500ML SACHET,13.5MG+2.60MG+2.90MG+1.50MG+20MG PER 1000ML SACHET	AGOG PHARMALTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY COMBINATION PACK POWDERS/GRANULES	4.0X500.0 ML SACHET + 1*10 BLISTERS,10.0X200.0 ML SACHET + 1*10 BLISTERS,2.0X1000.0 ML SACHET + 1*10 BLISTERS	01/07/2015

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36	NDA/MAL/HDP/0097	MSN LABORATORIES LTD	METRO PHARMACEUTICALS LIMITED	SAFELEVO 750	LEVOFLOXACIN	750MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER, 1.0X1.0X10.0 TABLET BLISTER	01/07/2013
37	NDA/MAL/HDP/0098	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	ATOREM 10	ATORVASTATIN	10MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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38	NDA/MAL/HDP/0101	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOTETRA CAPSULES	TETRACYCLINE HYDROCHLORIDE	250MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER,1.0X500.0 CAPSULE CONTAINER,1.0X1000.0 CAPSULE CONTAINER,1.0X1000.0 CAPSULE CONTAINER,1.0X1000.0 CAPSULE BLISTER	01/07/1998
39	NDA/MAL/HDP/0102	MSN LABORATORIES PRIVATE LIMITED,	METRO PHARMACEUTICALS LIMITED	SILMELT 100	SILDENAFIL CITRATE	100MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X2.0 TABLET BLISTER	01/07/2014

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40	NDA/MAL/HDP/0103	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	ATOREM 20	ATORVASTATIN	20MG	MSN LABORATORIES LTD PLOT NO.42, ANRICH INDUSTRIAL ESTATE	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
41	NDA/MAL/HDP/0104	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	SILMELT 50	SILDENAFIL CITRATE	50MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X2.0 TABLET BLISTER	01/07/2014

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42	NDA/MAL/HDP/0105	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOSPRIN TABLETS	ACETYL SALICYLIC ACID	300MG	AGOG PHARMA LTD PLOT NO.33, SECTOR II, VASAI, TALUKA INDL CO-OP ESTATE LTD, GAURAI PADA, VASAI(E) DIST. T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER, 1.0X500.0 TABLET CONTAINER, 1.0X100.0 TABLET CONTAINER	01/07/1998
43	NDA/MAL/HDP/0110	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SAFETELMI 40	TELMISARTAN	40MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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44	NDA/MAL/HDP/0111	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SAFETELMI 80	TELMISARTAN	80MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
45	NDA/MAL/HDP/0112	NORVATIS PHARMA AG	SURGIPHARM (U) LIMITED	EXFORGE 5MG/160MG	AMLODIPINE + VALSARTAN	5 MG + 160 MG	NOVARTIS PHARMA STEIN AGH-4332 STEIN SCHAFFHAUSERTRASSE	SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2007

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46	NDA/MAL/HDP/0114	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	BREATHEZY 4	MONTELUKAST SODIUM	4MG	MSN LABORATORIES LTD PLOT NO. 42 INDUSTRIAL ESTARE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
47	NDA/MAL/HDP/0116	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	BREATHEZY CW 5	MONTELUKAST SODIUM	5MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013



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48	NDA/MAL/HDP/0 118	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZOCEF 750MG	CEFUROXIME SODIUM	750MG	SANCE LABORATORIES PVT LTDVI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X750.0 MG VIAL + 1 AMPOULE WFI	01/07/2013
49	NDA/MAL/HDP/0 119	DAWA LIMITED	SUPER MEDIC LTD	DACOLD	CAFFEINE ANHYDROUS+CHL ORPHENIRAMINE MALEATE+PARAC ETAMOL+PSEUDO EPHEDRINE	30MG+4MG+400M G+30MG	DAWA LIMITED BABA DOGO RWARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013

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50	NDA/MAL/HDP/0 121	SHELYS PHARMACEUTICAL S LTD	BETA HEALTHCARE UGANDA LIMITED	PEDZINC	ZINC SULPHATE	20MG	BETA HEALTH CARE INTERNATIONAL LIMITED/-PLOT NO. LR 209/ 6534 MOGADISHU ROAD, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2015
51	NDA/MAL/HDP/0 124	DAWA LIMITED	SUPER MEDIC LTD	AMPECIN	AMPICILLIN TRIHYDRATE	125MG/5ML	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2015

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52	NDA/MAL/HDP/0 125	DAWA LIMITED	SUPER MEDIC LTD	SULPHUR OINTMENT	SULPHUR	10%W/W	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE	01/07/2013
53	NDA/MAL/HDP/0 135	SHELYS PHARMACEUTICAL S LTD	BETA HEALTHCARE UGANDA LIMITED	HEMOVIT SYRUP	IRON + FOLIC ACID + PYRIDOXINE + CYANOCOBALAMI N + ZINC	200MG + 1.5MG + 0.5MG + 50 MCG + 2.33MG	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO LR 209/6534 MOGADISHU ROAD	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2013

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54	NDA/MAL/HDP/0 139	DAWA LIMITED-	SUPER MEDIC LTD	MOXAFORTE	FLUCLOXACILLIN SODIUM + AMOXICILLIN TRIHYDRATE	250MG + 250MG	DAWA PHARMACEUTICALS LIMITEDPLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2014
55	NDA/MAL/HDP/0 141	COSMOS LTD	ASTRA PHARMA (U) LIMITED	NYCOSTAT SUSPENSION	NYSTATIN	100,000 I.U./ML	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/1998

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56	NDA/MAL/HDP/0 157	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RECODIN	CODEINE PHOSPHATE + CHLORPHENIRAM INE MALEATE	10MG + 4MG /5ML	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2015
57	NDA/MAL/HDP/0 158	MEGA LIFSCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	KIPEL 10	MONTELUKAST SODIUM	10MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2015

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58	NDA/MAL/HDP/0 160	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	TIZIGESIC	TIZANIDINE HYDROCHLORIDE	2MG	UNICHEM LABORATORIES LIMITEDC-31,32 & D- 10, INDUSTRIAL AREA, MEERUT ROAD, GHAZIABAD, U.P.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
59	NDA/MAL/HDP/0 161	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	TRAMAREN	TRAMADOL HYDROCHLORIDE	50MG	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2014

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60	NDA/MAL/HDP/0 162	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	COSYP-D LINCTUS	DEXTROMETHOR PHAN HYDROBROMIDE + CHLORPHENAMIN E MALEATE	10MG +4MG /5ML	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2015
61	NDA/MAL/HDP/0 163	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	PHENAREN	PROMETHAZINE HYDROCHLORIDE	5MG/5ML	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2015

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62	NDA/MAL/HDP/0 164	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	RENPRESS	PROPRANOLOL	40MG	RENE INDUSTRIES LIMITED PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
63	NDA/MAL/HDP/0 165	TORRENT PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S LTD.	TOLANZ 5	OLANZAPINE ORODISPERSIBLE TABLETS	5MG	TORRENT PHARMACEUTICALS LTD .,AHMEDABAD- MEHSANA HIGHWAY, TALUKA- KADI, DIST. MEHSANA, INDRAD- 382721, GUJARAT	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013



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64	NDA/MAL/HDP/0166	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	X-PEL	MEBENDAZOLE	100MG/5ML	RENE INDUSTRIES LIMITED PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2015
65	NDA/MAL/HDP/0167	TORRENT PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	TOLANZ 10	OLANZAPINE ORODISPERSIBLE TABLETS	10MG	TORRENT PHARMACEUTICALS LTD., AHMEDABAD-MEHSANA HIGHWAY, TALUKA-KADI, DIST. MEHSANA, INDRAD-382721, GUJARAT	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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66	NDA/MAL/HDP/0 168	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S LIMITED	FEBUDAY	FEBUXOSTAT	80MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014
67	NDA/MAL/HDP/0 175	BAYER SCHERING PHARMA	SURGIPHARM (U) LIMITED	XARELTO 10MG	RIVAROXABAN	10MG	BAYER HEALTHCARE AG, D-51368, LEVERKUSEN	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2009

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68	NDA/MAL/HDP/0 178	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	COLD CAP DAYTIME AND NIGHT TIME CAPSULE	DAY TIME(PARACETA MOL +CAFFEINE ANHYDROUS+PSE UDOEPHEDRINE HCL) AND NIGHT TIME(PARACETA MOL +CHLORPHENIRA MINE MALEATE)	DAY TIME (500MG + 30MG + 30MG) AND NIGHT TIME (500MG +2MG)	REGAL PHARMACEUTICALS LIMITED PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X8.0 CAPSULE BLISTER	01/07/2013
69	NDA/MAL/HDP/0 182	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S LIMITED	FEBUDAY 40	FEBUXOSTAT	40MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014

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70	NDA/MAL/HDP/0 186	WIDE SPECTRUM ENTERPRISES (U) LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BBC SPRAY	BENZOCAINE+BE NZYDAMINE+CAT ALKONIUM CHLORIDE	1.5%W/V+0.15%W /V+0.0413%W/V	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	EGYPT	ORAL TOPICAL SPRAYS WITHOUT GAS	1.0X25.0 ML BOTTLE	01/07/2014
71	NDA/MAL/HDP/0 187	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	KAPRON TABLET	TRANEXAMIC ACID	500 MG	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2014

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72	NDA/MAL/HDP/0188	AMOUN PHARMACEUTICAL S LTD	BOOTS PHARMACEUTICAL S LIMITED	LEVOXIN	LEVOFLOXACIN	500MG	AMOUN PHARMACEUTICALS CO. S.A.E1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	EGYPT	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0 TABLET BLISTER	01/07/2014
73	NDA/MAL/HDP/0190	AMOUN PHARMACEUTICAL COMPANY	BOOTS PHARMACEUTICAL S LIMITED	ACNE FREE CREAM	TRETINOIN	50MG	AMOUN PHARMACEUTICALS CO. S.A.E1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	EGYPT	TOPICAL EXTERNAL CREAMS	, 1X30 G TUBE	01/07/2014

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74	NDA/MAL/HDP/0191	MEDOPHARM PRIVATE LIMITED	VITACARE LIMITED	CLEDOMOX 228.5	AMOXICILLIN + CLAVULANATE	200 MG + 28.5 MG	MEDOPHARM PVT LTD.NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X70.0 ML BOTTLE	01/07/2013
75	NDA/MAL/HDP/0193	MEDOPHARM, INDIA	VITACARE LIMITED	CLEDOMOX 625	AMOXICILLIN + CLAVULANIC ACID	500 MG + 125 MG	MEDOPHARM PVT LTD.NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER,1.0X2.0X10.0 TABLET STRIP	01/07/2013

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76	NDA/MAL/HDP/0196	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LAMIVUDINE AND ZIDOVUDINE TABLETS	LAMIVUDINE/ZIDOVUDINE	150MG/300MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED - PLOT 1-7 1ST RING ROAD, LUZIRA, KAMPALA	UGANDA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2013
77	NDA/MAL/HDP/0203	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	SERETIDE EVOHALER 250	SALMETEROL XINAFOATE + FLUTICASONE PROPIONATE	25MCG + 250MCG	GLAXO WELLCOME PRODUCTION ZONE INDUSTRIELLE NO. 2 23, RUE LAVOISIER 27000 EVREUX	FRANCE	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER	01/07/2015

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78	NDA/MAL/HDP/0 204	VIIV HEALTHCARE UK LTD-	UNITED HEALTHCARE DISTRIBUTORS LTD	TIVICAY	DOLUTEGRAVIR SODIUM	50MG	GLAXOSMITHKLINE PHARMACEUTICALS SAGRUNWALDZKA 189 STREET, 60-322 POZNANA GLAXO OPERATIONS UK LTDWARE SG120DJ UNITED KINGDOM	UNITED KINGDOM POLAND	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2015
79	NDA/MAL/HDP/0 205	MACLEODS PHARMACEUTICAL S LTDS LTD	VITACARE LIMITED	TENOFOVIR DISOPROXIL FUMARATE	TENOFOVIR DISOPROXIL FUMARATE	300MG	MACLEODS PHARMACEUTICALS LTD .PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2013



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80	NDA/MAL/HDP/0209	HETERO LABS LTD	AIVEEN (U) LIMITED	ABACAVIR SULPHATE ORAL SOLUTION	ABACAVIR SULPHATE	20MG/ML	HETERO LABS PRIVATE LIMITED UNIT IISURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) JEEDIMETLA, HYDERABAD-500 055, TELANGANA STATE	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1X240 ML BOTTLE	01/07/2013
81	NDA/MAL/HDP/0210	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	HEPATICUM	SILYMARIN	140MG	MEDICAL UNION PHARMACEUTICAL CO.PLANT: ABU-SULTAN, ISMAILIA, EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2011

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82	NDA/MAL/HDP/0 212	MEDICAL UNION PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	HEPATICUM	SILYMARIN	1G/100ML	MEDICAL UNION PHARMACEUTICAL CO.PLANT: ABU- SULTAN, ISMAILIA, EGYPT	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X120.0 ML BOTTLE	01/07/2012
83	NDA/MAL/HDP/0 221	DAWA LIMITED	SUPER MEDIC LTD	AMPICLO-DAWA	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	DAWA PHARMACEUTICALS LIMITEDPLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013

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84	NDA/MAL/HDP/0 222	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	AVIR-200	ACYCLOVIR	200MG	S KANT HEALTHCARE LIMITED1802 – 1805, G.I.D.C., PHASE III, VAPI -396195 GUJARAT, INDIA. LINCOLN PHARMACEUTICALS LTD .10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT KESAR PHARMA PVT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
85	NDA/MAL/HDP/0 226	AMOUM PHARMACEUTICAL S LTD	BOOTS PHARMACEUTICAL S LIMITED	ULTRASOLV SYRUP	OXOMEMAZINE HCL & CARBOCYSTEINE & GUAIFENESIN	2MG+125MG+100 MG/5ML	AMOUM PHARMACEUTICALS CO. S.A.E1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2014

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86	NDA/MAL/HDP/0 230	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	COMBIART	ARTHEMETHER + LUMEFANTRINE	20MG +120MG	UNIVERSAL CORPORATION LIMITED PLOT NO 13777, PO BOX 1748- 00902 KIKUYU CLUB RD STRIDES PHARMA SCIENCE LIMITED (STRIDES SHASUN)KRS GARDENS, PLOT 36/7 SURAGAJKKANAHALL I, INDLAWADI CROSS, ANKAL TALUK, BANGALORE SOUTH - 562106, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X6.0 TABLET BLISTER,1.0X1.0X6. 0 TABLET BLISTER,1.0X1.0X12 .0 TABLET BLISTER,1.0X1.0X18 .0 TABLET BLISTER,1.0X1.0X24 .0 TABLET BLISTER,1.0X24.0 TABLET BLISTER,1.0X30.0X1 8.0 TABLET BLISTER,1.0X30.0X2 4.0 TABLET BLISTER	01/07/2013
87	NDA/MAL/HDP/0 232	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	BRANTA	LOSARTAN POTASSIUM + AMLODIPINE BESILATE	50MG + 5MG	TORRENT PHARMACEUTICALS LTD .,AHMEDABAD- MEHSANA HIGHWAY, TALUKA- KADI, DIST. MEHSANA, INDRAD- 382721, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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88	NDA/MAL/HDP/0 233	MEDOCHÉMIE LTD	LABOREX UGANDA LIMITED	CEFIMED 400	CEFIXIME TRIHYDRATE	400MG	MEDOCHÉMIE LTD PHARMACEUTICAL INDUSTRY,FACTORY C-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIALAREA 4101 AGIOS ATHANASSIOS LIMASSOL CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0 TABLET BLISTER	01/07/2014
89	NDA/MAL/HDP/0 234	MEDOCHÉMIE LTD	LABOREX UGANDA LIMITED	CEFIMED 200	CEFIXIME TRIHYDRATE	200MG	MEDOCHÉMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X8.0 TABLET BLISTER,1.0X2.0X5. 0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2014

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90	NDA/MAL/HDP/0 235	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	AXETINE 500	CEFUROXIME AXETIL	500MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET STRIP	01/07/2014
91	NDA/MAL/HDP/0 239	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	KOMEFAN 140	ARTEMETHER + LUMEFANTRINE	20 MG+ 120 MG	MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0X3.0 TABLET BLISTER,1.0X18.0 TABLET BLISTER,1.0X24.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X2.0X6. 0 TABLET BLISTER	01/07/2014

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92	NDA/MAL/HDP/0 244	SAKAR HEALTHCARE PVT LTD	ROYAL PHARMA 2011 LIMITED	HYOCIN	HYOSCINE BUTYLBROMIDE	20MG/ML	SAKAR HEALTHCARE PVT LTDBLOCK NO. 10-13, NR. M.N DESAI PETRO PUMP, SARKHEJ-BAVLA ROAD, CHANGODAR, DIST: AHMEDABAD- 382213, GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE	01/07/2014
93	NDA/MAL/HDP/0 248	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	PANTONEX DR-40	PANTOPRAZOLE	40 MG	.IPCA LABORATORIES LTD PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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94	NDA/MAL/HDP/0 250	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	DIKON	DICLOFENAC	1%W/W	LINCOLN PHARMACEUTICALS LTD .10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT KESAR PHARMA PVT LTD PLOT SURVEY NO. 50/2. VILLAGE BILSHWARPURA CHHATRAL- -382729 TA. KALOL DIST	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G CONTAINER	01/07/2013
95	NDA/MAL/HDP/0 252	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	VAST-40	ATORVASTATIN	40MG	LINCOLN PHARMACEUTICALS LTD .10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014



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96	NDA/MAL/HDP/0 254	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CONCOR 5	BISOPROLOL HEMIFUMARATE	5MG	WINTHROP PHARMACEUTICALS( PTY) LTD,315 WATLOO ROAD,WATLOO,PRET ORIA,SOUTHAFRICA (FPP SECONDARY PACKAGING,FPP RELEASE/QC TESTING SITE) MERCK KGAA250 FRANKFRUTER STRASSE 250-64293 DARMSTADT	GERMANY SOUTH AFRICA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
97	NDA/MAL/HDP/0 255	BYANSI SERVICES LIMITED	AIVEEN (U) LIMITED	CAPETERO 150	CAPECITABINE	150MG	HETERO LABS (UNIT VI), INDIAAIIIC, FORMULATION SEZ, POLEPALLY (V),JEDCHERLA(M) MAHABOBNAGER DISTRICT ANDHRA PRADESH-509301, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X60 TABLET CONTAINER	01/07/2015

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98	NDA/MAL/HDP/0 256	HETERO LABS LTD	AIVEEN (U) LIMITED	CAPETERO 500	CAPECITABINE	500MG	HETERO LABS (UNIT VI), INDIAAPIIC, FORMULATION SEZ, POLEPALLY (V),JEDCHERLA(M) MAHABOBNAGER DISTRICT ANDHRA PRADESH-509301, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X120.0 TABLET CONTAINER	01/07/2015
99	NDA/MAL/HDP/0 266	ASTRA PHARMA (UK) LTD	ASTRA PHARMA (U) LIMITED	BENZATHINE PENICILLIN INJECTION	BENZATHINE PENICILLIN	2.400.000 IU	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTDNO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSH OP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0 VIAL CARTON	01/07/2001

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100	NDA/MAL/HDP/0 269	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	VOMISTAT-8	ONDANSETRON	8MG	LINCOLN PHARMACEUTICALS LIMITED 10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X1.0X10.0 TABLET BLISTER	01/07/2014
101	NDA/MAL/HDP/0 270	HETERO LABS LTD	AIVEEN (U) LIMITED	LEVIN 500MG	LEVOFLOXACIN HEMIHYDRATE	500MG	HETERO LABS LTD (UNIT- V)SY.NO.438,439,44 0 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	01/07/2013

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102	NDA/MAL/HDP/0 271	BIOLOGICAL E. LTD	GITTOES PHARMACEUTICAL S LIMITED	BETT	TETANUS VACCNE ADSORBED	40 I.U	BIOLOGICAL E LTD PLOT NO.1, S.P BIOTECHNOLOGY PARK, PHASE II KOLTHER (V), SHAMEERPET(M), RANGA REDDY(DIST), ANDHRA PRADESH, INDIA 500078	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X20.0X10.0 ML AMPOULE,1.0X24.0 X10.0 ML AMPOULE,1.0X5.0 ML VIAL (10 DOSES)	01/07/2015
103	NDA/MAL/HDP/0 272	HETERO LABS LTD	AIVEEN (U) LIMITED	LEVIN 250	LEVOFLOXACIN	250MG	HETERO LABS LTD. UNIT (V)439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2019

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104	NDA/MAL/HDP/0 275	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	ZENTEL	ALBENDAZOLE	400MG	GLAXOSMITHKLINE CONSUMER HEALTHCARE S.A (PTY) LIMITED39 HAWKINS AVENUE, EPPING INDUSTRIA 1, 7460, CAPE TOWN, SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0 TABLET BLISTER	01/07/2011
105	NDA/MAL/HDP/0 276	MICRO LABS LTD	LABOREX UGANDA LIMITED	MELANOV 80	GLICLAZIDE	80MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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106	NDA/MAL/HDP/0 278	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CHLORPROMAZIN E TABLETS B.P 100MG	CHLORPROMAZIN E HYDROCHLORIDE	100MG	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10 0.0 TABLET CONTAINER,10.0X1 0.0 TABLET BLISTER	01/07/1998
107	NDA/MAL/HDP/0 283	DAWA LIMITED	SUPER MEDIC LTD	AMPICLO-DAWA	AMPICILLIN + CLOXACILLIN	125 MG + 125 MG	DAWA PHARMACEUTICALS LIMITEDPLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2013

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108	NDA/MAL/HDP/0 290	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	NATOA	MEBENDAZOLE	100MG	LABORATORY & ALLIED LTD-PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X6.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1997
109	NDA/MAL/HDP/0 296	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PRAZITEL TABLETS	PRAZIQUANTEL	600MG	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	2.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/1998

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110	NDA/MAL/HDP/0 298	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	SEFIXI-50 DRY SYRUP	CEFIXIME	50MG	SAKAR HEALTH CARE PVT, LTDBLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ- BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X60.0 ML BOTTLE	01/07/2013
111	NDA/MAL/HDP/0 301	HETERO LABS LTD	AIVEEN (U) LIMITED	MONAST 10	MONTELUKAST SODIUM	10MG	HETERO LABS LTD. UNIT (V)S.NO.439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013



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112	NDA/MAL/HDP/0 303	HETERO LABS LTD	AIVEEN (U) LIMITED	ABACAVIR SULPHATE	ABACAVIR SULPHATE	300MG	HETERO DRUGS LTD, UNIT III 22-110, IDA, JEEEDIMETLA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2014
113	NDA/MAL/HDP/0 305	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	CEFAX-250 DRY SYRUP	CEFALEXIN	250MG/5ML	SAKAR HEALTH CARE PVT, LTDBLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ- BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X1.0X50.0 ML BOTTLE,1.0X1.0X10 0.0 ML BOTTLE	01/07/2013

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114	NDA/MAL/HDP/0 307	HETERO DRUGS LTD	AIVEEN (U) LIMITED	LAMIVUDINE ORAL SOLUTION	LAMIVUDINE	10MG/ML	HETERO DRUGS LTD, UNIT III 22-110, IDA, JEEEDIMETLA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X240.0 ML CONTAINER	01/07/2013
115	NDA/MAL/HDP/0 308	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	CEFAX-250	CEFALEXIN	250MG	SAKAR HEALTH CARE PVT, LTDBLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ- BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013

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116	NDA/MAL/HDP/0311	MARTINDALE PHARMACEUTICALS LTD	LABOREX UGANDA LIMITED	FENTANYL	FENTANYL CITRATE	50MCG/ML	MARTINDALE PHARMACEUTICAL LIMITED BAMPTON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2013
117	NDA/MAL/HDP/0312	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	CLOXISPA ORAL SOLUTION 125	CLOXACILLIN	125MG/5ML	SPARSH BIO-TECH LTD PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2013

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118	NDA/MAL/HDP/0314	MARTINDALE PHARMACEUTICALS LTD	LABOREX UGANDA LIMITED	SUXAMETHONIUM CHLORIDE SOLUTION FOR INJECTION	SUXAMETHONIUM CHLORIDE	50MG/ML	MARTINDALE PHARMA BAMPトン ROAD, HAROLD HILL,ROMFORD,RM3844	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2013
119	NDA/MAL/HDP/0317	YURIA PHARM LTD-UKRAINE	PHARMA VILLE LIMITED	CIPROFLOXACIN-UF	CIPROFLOXACIN	2MG/ML	YURIA-PHARM LLC MANUFACTURING SITE NO. 1108, KOBZARSKA STREET, CHERKASY, 18030	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X200.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2013

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120	NDA/MAL/HDP/0 318	DAWA LIMITED	SUPER MEDIC LTD	SABULIN	SALBUTAMOL	4MG	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
121	NDA/MAL/HDP/0 320	DAWA LIMITED	SUPER MEDIC LTD	DAZOLE	CLOTRIMAZOLE	1%W/W	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2013

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122	NDA/MAL/HDP/0 322	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	NEBILONG-5	NEBIVOLOL HCL	5MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2009
123	NDA/MAL/HDP/0 326	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	OSTEBON	CALCIUM + COLECALCIFEROL	250MG + 125 IU	ARISTO PHARMACEUTICALS PVT LIMITEDPLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP- 462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	01/07/2014

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124	NDA/MAL/HDP/0 333	KOPRAN LIMITED	TATA UGANDA LIMITED	CLAVAMYN-625	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500MG +125MG	KOPRAN LIMITEDVILLAGE- SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2014
125	NDA/MAL/HDP/0 335	GOOD DAY PHARMACY LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	NEOMYCIN SULPHATE CREAM USP	NEOMYCIN SULPHATE CREAM USP	0.5%WW	KREMOINT PHARMA PVT LTDB- 8,ADDITIONAL AMBERNATH MIDC, AMBERNATH (E),DIST: THANE 421506, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	01/07/2013

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126	NDA/MAL/HDP/0 337	IND-SWIFT	PLANET PHARMACEUTICAL S UGANDA LTD	SWAZI *500	AZITHROMYCIN	500MG	IND SWIFT LTDGLOBAL BUSINESS UNIT JAWAHARPUR OFF NH-21 DERABASSI DIST MOHALI PUNJAB 140507	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0 TABLET BLISTER, 1.0X10.0X1.0X3.0X 10.0 TABLET BLISTER	01/07/2014
127	NDA/MAL/HDP/0 339	IND-SWIFT	PLANET PHARMACEUTICAL S UGANDA LTD	SWAZI *250	AZITHROMYCIN	250MG	IND SWIFT LTDGLOBAL BUSINESS UNIT JAWAHARPUR OFF NH-21 DERABASSI DIST MOHALI PUNJAB 140507	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X6.0 TABLET BLISTER, 1.010.0X1.0X6.0 TABLET BLISTER	01/07/2014



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128	NDA/MAL/HDP/0341	IND SWIFT LTD	PLANET PHARMACEUTICALS UGANDA LTD	TELSWIFT- H 40	TELMISARTAN + HYDROCHLOROTHIAZIDE	40MG + 12.5MG	IND SWIFT LTDGLOBAL BUSINESS UNIT JAWAHARPUR OFF NH-21 DERABASSI DIST MOHALI PUNJAB 140507	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2014
129	NDA/MAL/HDP/0342	IND SWIFT LTD	PLANET PHARMACEUTICALS UGANDA LTD	TELSWIFT- H 80	TELMISARTAN + HYDROCHLOROTHIAZIDE	80MG + 12.5MG	IND SWIFT LTDGLOBAL BUSINESS UNIT JAWAHARPUR OFF NH-21 DERABASSI DIST MOHALI PUNJAB 140507	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER,3.0X10.0 TABLET BLISTER	01/07/2014

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130	NDA/MAL/HDP/0 348	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	XBETA	BETAMETHASONE SODIUM PHOSPHATE	0.1%W/V	ABACUS PARENTERAL DRUGS LIMITEDBLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL,1.0X5.0 ML VIAL	01/07/2015
131	NDA/MAL/HDP/0 349	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICAL S LIMITED	CLAXY 1.2 G	COAMOXICLAV	1.2G	SWISS PARENTERALS (UNIT-2), PLOT 402, 412-414, KERALA INDUSTRIAL ESTATE, G.I.D.C., NR. BAVLA, DIST. AHMEDABAD- 382 220, GUJARAT, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.2 G VIAL	01/07/2013

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132	NDA/MAL/HDP/0350	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	CETRIREN	CETIRIZINE HYDROCHLORIDE	10MG	RENE INDUSTRIES LIMITED PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2015
133	NDA/MAL/HDP/0351	MANKIND PHARM LTD	TATA UGANDA LIMITED	DEPREGDINA	LEVONORGESTREL	1.5MG	ACME FORMULATION PVT LTD. ROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0 TABLET BLISTER	01/07/2014

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134	NDA/MAL/HDP/0 354	KOPRAN LIMITED	TATA UGANDA LIMITED	LEVOKOP	LEVOFLOXACIN	500MG	KOPRAN LIMITEDVILLAGE- SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2013
135	NDA/MAL/HDP/0 355	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	BICO VITA	THIAMINE HCL + RIBOFLAVIN + PYRIDOXINE HCL + NICOTINAMIDE	10MG + 0.1MG + 1MG + 10MG	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2015

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136	NDA/MAL/HDP/0 356	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	LEVO DENK 500	LEVOFLOXACIN HEMIHYDRATE	500MG	ALLPHAMED PHARMBIL ARZNEIMITTEL GMBH HILDERBRAND, STR 12-37081, GOTTINGEN	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0 TABLET BLISTER,1.0X1.0X10 .0 TABLET BLISTER	01/07/2014
137	NDA/MAL/HDP/0 358	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	STREPTOCIN	STREPTOMYCIN SULPHATE	1GM	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY I M VIALS	1.0X1.0 G VIAL	01/07/2014

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138	NDA/MAL/HDP/0 360	ASTRA ZENECA AB	MACNAUGHTON LIMITED	NEXIUM 20MG	ESOMEPRAZOLE	20MG	ASTRA ZENECA AB, SODERTALJEGARTUN AYEGEN, SODERTALJE	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER,1.0X7.0 TABLET BLISTER,1.0X14.0 TABLET CARTON	01/07/2001
139	NDA/MAL/HDP/0 362	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	BUPI	BUPIVACAINE	5 MG/ML	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL	01/07/2015

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140	NDA/MAL/HDP/0 363	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	AGYCIN	AZITHROMYCIN	250MG	BLISS GVS PHARMA LIMITEDNO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X6.0 TABLET BLISTER	01/07/2014
141	NDA/MAL/HDP/0 366	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	AGYCIN 500	AZITHROMYCIN	500MG	BLISS GVS PHARMA LIMITEDNO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0 TABLET BLISTER	01/07/2014

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142	NDA/MAL/HDP/0370	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILONG-H	NEBIVOLOL + HYDROCHLOROTHIAZIDE	5MG + 12.5MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2010
143	NDA/MAL/HDP/0372	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	LEZYNCET	LEVOCETIRIZINE	5MG	UNICHEM LABORATORIES LIMITED UNICHEM LABORATORIES LIMITED. UNIT II, VILLAGE BHATAULI KALAN, BADDI, DIST. SOLAN PIN CODE 173 205, HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER, 5.0X2.0X10.0 TABLET BLISTER	01/07/2009



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144	NDA/MAL/HDP/0376	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ASOMEX-D	AMLODIPINE + HYDROCHLOROT HIAZIDE	2.5 MG + 12.5 MG	EMCURE PHARMACEUTICALS LTD LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014
145	NDA/MAL/HDP/0386	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	LOMOH-80	ENOXAPARIN SODIUM	80MG/ 0.8ML	EMCURE PHARMACEUTICALS LTD PLOT NO. P-1 ITBT PARK PHASE II MIDC HINJWADI PUNE 411057	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X1.0 ML PRE-FILLED SYRINGE	01/07/2014

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146	NDA/MAL/HDP/0 388	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	AZUCLOX	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE STRIP,1.0X250.0 CAPSULE CONTAINER,1.0X10 00.0 CAPSULE CONTAINER,1.0X50 0.0 CAPSULE CONTAINER,1.0X10 0.0X10.0 CAPSULE BLISTER	01/07/1997
147	NDA/MAL/HDP/0 389	PT SANBE FARMA	MEDVIN PHARMA LIMITED	SANMOL INFUSION IV	PARACETAMOL	1000MG/100ML	PT SANBE FARMA JI INDUSTRINO.8 KOMPLEKS INDUSTRI CIMAREME PADALARANG BANDUNG	INDONESIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2014

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148	NDA/MAL/HDP/0394	LEBEN LABORATORIES PVT.LTD	MALIX PHARMA (U) LIMITED	DOXYLEB	DOXYCYCLINE	100MG	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2014
149	NDA/MAL/HDP/0397	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ASOMEX-LT	AMLODIPINE + LOSARTAN POTASSIUM	2.5 MG + 50 MG	EMCURE PHARMACEUTICALS LTDLANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X3.0X10.0 TABLET BLISTER	01/07/2013

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150	NDA/MAL/HDP/0401	FOURRTS (INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	L MONTUS	LEVOCETIRIZINE HYDROCHLORIDE + MONTELUKAST SODIUM	5MG + 10MG	FOURRTS (INDIA) LABORATORIES (PVT) LTDFOURRTS AVENUE, VANDALUR ROAD	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET STRIP	01/07/2015
151	NDA/MAL/HDP/0403	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	SUPRIDOL	TRAMADOL HYDROCHLORIDE	50MG/ML	NEON LABORATORIES LTD - PLOT NO. 29, 30, 31, 32, 57 & 60, THE PALGHAR TALUKA - CO-OP ESTATE LTD., BOISAR ROAD, PALGHAR, DIST - THANE - 401404, MAHARASHTRA	INDIA	PARENTERAL ORDINARY I V AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE	01/07/2013

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152	NDA/MAL/HDP/0 405	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	CHEMLET	LETROZOLE	2.5MG	NEON LABORATORIES LTD PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
153	NDA/MAL/HDP/0 406	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	EVATOCIN	OXYTOCIN	10 I.U./ ML	NEON LABORATORIES LTD PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY I V AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE	01/07/2015

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154	NDA/MAL/HDP/0407	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	NEOROF	PROPOFOL	1%W/V	NEON LABORATORIES LTD - PLOT NO. 29, 30, 31, 32, 57 & 60, THE PALGHAR TALUKA - CO-OP ESTATE LTD., BOISAR ROAD, PALGHAR, DIST - THANE - 401404, MAHARASHTRA	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL	01/07/2013
155	NDA/MAL/HDP/0408	MSN LABORATORIES LTD	METRO PHARMACEUTICAL S LIMITED	ALGIC - P	ACECLOFENAC + PARACETAMOL	100 MG + 500 MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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156	NDA/MAL/HDP/0409	NEON LABORATORIES LTD.	NORVIK ENTERPRISES LIMITED	TYDE-S*	CHLORAMPHENICOL SODIUM SUCCINATE	1G/VIAL	NEON LABORATORIES LTD - PLOT NO. 29, 30, 31, 32, 57 & 60, THE PALGHAR TALUKA - CO-OP ESTATE LTD., BOISAR ROAD, PALGHAR, DIST - THANE - 401404, MAHARASHTRA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2013
157	NDA/MAL/HDP/0410	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LDNIL 20	ROSUVASTATIN CALCIUM	20MG	MSN LABORATORIES LTD PLOT NO.42, ANRICH INDUSTRIAL ESTATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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158	NDA/MAL/HDP/0 411	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	JADELLE SINE	LEVONORGESTRE L	150MG	BAYER OYPANSIONATE 47 20210 TURKU FINLAND	FINLAND	PARENTERAL RETARD IMPLANTS	1.0X10.0X1.0X2.0X 75.0 MG IMPLANT	01/07/2003
159	NDA/MAL/HDP/0 413	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	XSPAS	HYOSCINE BUTYLBROMIDE	20MG/ML	NEON LABORATORIES LTD - PLOT NO. 29, 30, 31, 32, 57 & 60, THE PALGHAR TALUKA - CO-OP ESTATE LTD., BOISAR ROAD, PALGHAR, DIST - THANE - 401404, MAHARASHTRA	INDIA	PARENTERAL ORDINARY I V AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE	01/07/2013



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160	NDA/MAL/HDP/0415	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	RELEX	DIPHENHYDRAMINE HYDROCHLORIDE +AMMONIUM CHLORIDE+SODIUM CITRATE+MENTHOL	14.03MG+138MG+57.03MG+0.90MG	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997
161	NDA/MAL/HDP/0418	ASTRA ZENECA	MACNAUGHTON LIMITED	KOMBIGLYZE XR 5MG/1000	SAXAGLIPTIN + METFORMIN	5MG + 1000MG	ASTRAZENECA PHARMACEUTICALS LP.4601 HIGHWAY 62 EAST MOUNT VERNON INDIANA 47620 USA	UNITED STATES	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE,1.0X4.0X7.0 TABLET BLISTER	01/07/2013

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162	NDA/MAL/HDP/0 419	ASTRAZENECA	MACNAUGHTON LIMITED	KOMBIGLYZE XR 2.5MG/1000MG	SAXAGLIPTIN + METFORMIN	2.5MG + 1000MG	ASTRAZENECA PHARMACEUTICALS LP.4601 HIGHWAY 62 EAST MOUNT VERNON INDIANA 47620 USA	UNITED STATES	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2013
163	NDA/MAL/HDP/0 421	MSN LABORATORIES PRIVATE LIMITED,	METRO PHARMACEUTICAL S LIMITED	PREGASAFE 150	PREGABALIN	150MG	MSN LABORATORIES LTD PLOT NO.42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2014

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164	NDA/MAL/HDP/0422	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	PARAFLAM	IBUPROFEN + PARACETAMOL	100MG + 162.5MG /5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2013
165	NDA/MAL/HDP/0423	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOTRAM	TRAMADOL	50MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0X10.0 CAPSULE BLISTER	01/07/2013

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166	NDA/MAL/HDP/0 424	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CHLORPROMAZIN E TABLETS B.P 25MG	CHLORPROMAZIN E	25MG	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X100.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER,10.0X1 0.0 TABLET BLISTER	01/07/1998
167	NDA/MAL/HDP/0 427	MICRO LABS LTD	LABOREX UGANDA LIMITED	AMLOZAAR -H	LOSARTAN POTASSIUM + AMLODIPINE BESILATE + HYDROCHLOROT HIAZIDE	50MG + 5MG + 12.5MG	MICRO LABS LTD ..57, SIPCOT INDUSTRIAL COMPLEX, HOSUR- 635126, TAMIL NADU	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2015

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168	NDA/MAL/HDP/0428	MICRO LABS LTD	LABOREX UGANDA LIMITED	MICROMOX-400	MOXIFLOXACIN	400MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X5.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	01/07/2013
169	NDA/MAL/HDP/0429	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	FLEXON MR	IBUPROFEN + PARACETAMOL + CHLORZOXAZONE	400MG + 325MG + 250MG	ARISTO PHARMACEUTICALS PVT. LIMITED PLOT NO. 208, NEW INDUSTRIAL AREA NO. II, MANDIDEEP-462046, DIST. - RAISEN, MADHYA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X1.0X10.0 TABLET BLISTER,1.0X10.0X1.0X10.0 TABLET BLISTER	01/07/2014

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170	NDA/MAL/HDP/0430	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO ACECLO PLUS	ACECLOFENAC+PARACETAMOL	100MG+500MG	ARISTO PHARMACEUTICALS PVT LIMITED PLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP-462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X15.0X10.0 TABLET BLISTER	01/07/2013
171	NDA/MAL/HDP/0432	FOURRTS (INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	K MAC ORAL SOLUTION	POTASSIUM CITRATE + MAGNESIUM CITRATE	22MG + 7.5MG	FOURRTS INDIA LABORATORIES PVT. LIMITED VANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X200.0 ML BOTTLE	01/07/2013

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172	NDA/MAL/HDP/0 433	PT SAMBE FARMA	MEDVIN PHARMA LIMITED	PROANES MCT/LCT	PROPOFOL	1%W/V	PT SANBE FARMA JI INDUSTRINO.8 KOMPLEKS INDUSTRI CIMAREME PADALARANG BANDUNG	INDONESIA	PARENTERAL ORDINARY I V AMPOULES	1.0X5.0X20.0 ML AMPOULE	01/07/2014
173	NDA/MAL/HDP/0 434	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	PROHIBIN	GASTRO- RESISTANT OMEPRAZOLE CAPSULES BP 20	20 MG	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X10.0X1 0.0 CAPSULE STRIP	01/07/2010

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174	NDA/MAL/HDP/0441	AGIO PHARMACEUTICALS LTD	ROYAL PHARMA 2011 LIMITED	AGISEC	SECNIDAZOLE	1GM	AGIO PHARMACEUTICALS LTD PLOT NO. T-81, 82 MIDC, BHOSARI, PUNE-26	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0 TABLET BLISTER	01/07/2015
175	NDA/MAL/HDP/0447	PT SANBE FARMA	MEDVIN PHARMA LIMITED	SANEXON®125	METHYLPREDNISOLONE SODIUM SUCCINATE	125MG/VIAL	PT SANBE FARMA UNIT 3.JL INDUSTRI CIMAREME NO.8 PADALARANG 40533 BANDUNG	INDONESIA	PARENTERAL ORDINARY DRY VIALS	1.0X125.0 MG VIAL + 1*2ML AMPOULE OF WFI	01/07/2014



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176	NDA/MAL/HDP/0449	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AMINO GUARD GRANULES	CYANOCOBALAMIN	5MCG	STEDMAN PHARMACEUTICALS PVT LIMITED NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL SOLID ORDINARY GRANULES	1.0X10.0X5.0 G SACHET	01/07/2013
177	NDA/MAL/HDP/0451	PT SANBE FARMA	MEDVIN PHARMA LIMITED	SANEXON®500	METHYLPREDNISOLONE SODIUM SUCCINATE	500MG/VIAL	PT SANBE FARMA UNIT 3.JL INDUSTRI CIMAREME NO.8 PADALARANG 40533 BANDUNG	INDONESIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL + 1*8ML AMPOULE OF WFI	01/07/2014

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178	NDA/MAL/HDP/0453	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AMINO GUARD LIQUID	AMINO ACIDS + MULTIVITAMINS	MULTI INGREDIENTS	STEDMAN PHARMACEUTICALS PVT LIMITED NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X200.0 ML BOTTLE	01/07/2013
179	NDA/MAL/HDP/0454	PT SANBE FARMA	MEDVIN PHARMA LIMITED	LEVOCIN INFUSION	LEVOFLOXACIN HEMIHYDRATE	500 MG	PT SANBE FARMA JI INDRAMATI 8 KOMPLEKS INDUSTRIAL CIMA RE ME PADALARANG BANDUNG	INDONESIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2014

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180	NDA/MAL/HDP/0456	LEBEN LABORATORIES PVT. LTD	MALIX PHARMA (U) LIMITED	METROLEB	METRONIDAZOLE	125MG/5ML	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2014
181	NDA/MAL/HDP/0460	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	AMBRODIL	AMBROXOL HYDROCHLORIDE	7.5MG/ML	ARISTO PHARMACEUTICALS PVT. LIMITED PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X15.0 ML BOTTLE	01/07/2009

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182	NDA/MAL/HDP/0 463	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	TOPHEN	PHENYTOIN	100MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0 CAPSULE CONTAINER,1.0X10 0.0X10.0 CAPSULE BLISTER	01/07/2011
183	NDA/MAL/HDP/0 467	DAWA PHARMACEUTICAL S LIMITED	SUPER MEDIC LTD	CURAMOL PLUS	PARACETAMOL/C AFFEINE	500MG/60MG	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	50.0X2.0 TABLET STRIP	01/07/1997

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184	NDA/MAL/HDP/0470	NOVO NORDISK PHARMA GULF FZ-LC	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NOVOMIX 30 FLEXPEN	INSULIN ASPART	100I.U/ML	NOVO NORDISK PRODUCTION SAS45 AVENUE D'ORLEANS, 28000 CHARTRES, FRANCE NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDAAV. "C", 1413, DISTRITO INDUSTRIAL - 390404 004 MONTES CLAROS, MINAS GERAIS - BRAZIL NOVO NORDISK A/S NOVO ALLE DK-2880 BAGSVAERD	DENMARK BRAZIL FRANCE	PARENTERAL ORDINARY DRY PRE-FILLED PENS	1.0X5.0X3.0 ML PREFILLED PEN	01/07/2014
185	NDA/MAL/HDP/0471	NOVO NORDISK PHARMA GULF FZ-LC	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NOVORAPID FLEXPEN	INSULIN ASPART	100 I.U/ML	NOVO NORDISK PRODUCTION SAS45 AVENUE D'ORLEANS, 28000 CHARTRES, FRANCE NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDAAV. "C", 1413, DISTRITO INDUSTRIAL - 390404 004 MONTES CLAROS, MINAS GERAIS - BRAZIL NOVO NORDISK A/S NOVO ALLE DK-2880 BAGSVAERD	DENMARK BRAZIL FRANCE	PARENTERAL ORDINARY PRE-FILLED PENS	1.0X5.0X3.0 ML PREFILLED PEN	01/07/2014

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186	NDA/MAL/HDP/0472	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	BCG VACCINE (FREEZE DRIED)	BCG VACCINE(FREEZE DRIED)	1.33*100000 C.F.U/0.1ML	SERUM INSTITUTE OF INDIA PRIVATE LIMITEDS/NO 105-110, MANJARI BUDRUK, TAL - HAVEIL, PUNE 412307 - INDIA SERUM INSTITUTE OF INDIA LTD212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 ML VIAL,1.0X0.5 ML VIAL	01/07/2015
187	NDA/MAL/HDP/0475	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	TINI-500	TINIDAZOLE	500MG	LINCOLN PHARMACEUTICALS LIMITED 10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X25.0X4.0 TABLET BLISTER	01/07/2015

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188	NDA/MAL/HDP/0477	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	VOMISTAT-4	ONDANSETRON	4MG	LINCOLN PHARMACEUTICALS LIMITED 10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X1.0X10.0 TABLET BLISTER	01/07/2014
189	NDA/MAL/HDP/0482	LEBEN LABORATORIES PVT. LTD	MALIX PHARMA (U) LIMITED	AZILEB-500	AZITHROMYCIN	500MG	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X20.0X3.0 TABLET BLISTER	01/07/2014

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190	NDA/MAL/HDP/0 489	LEBEN LABORATORIES PVT.LTD	MALIX PHARMA (U) LIMITED	CEBAY-200 DT	CEFIXIME	200MG	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0 TABLET BLISTER	01/07/2014
191	NDA/MAL/HDP/0 491	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABCHLOR EYE DROPS	CHLORAMPHENIC OL	0.5% W/V	ABACUS PARENTERAL DRUGS LTD PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE,  MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X5.0 ML VIAL,1.0X10.0 ML VIAL	01/07/2013



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192	NDA/MAL/HDP/0 493	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PRASUSAFE 10	PRASUGREL	10MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1X3X10 TABLET BLISTER	01/07/2013
193	NDA/MAL/HDP/0 496	ADCOCK INGRAM LIMITED	SURGIPHARM (U) LIMITED	MYPRODOL	PARACETAMOL + IBUPROFEN + CODEINE PHOSPHATE	250MG + 200MG + 10MG	ADCOCK INGRAM LIMITED 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE  560099, KARNATAKA STATE, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X20.0 CAPSULE BLISTER, 1.0X3.0X10 .0 CAPSULE BLISTER	01/07/2014

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194	NDA/MAL/HDP/0497	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	KEMOXYL DRY SUSPENSION	AMOXYCILLIN TRIHYDRATE	125MG/5ML	LABORATORY & ALLIED LTD PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997
195	NDA/MAL/HDP/0502	STEDMAN PHARMACEUTICALS LTD	VEERAM HEALTHCARE (U) LIMITED	DREZ GARGLE	IODINATED POVIDONE	2%W/V	STEDMAN PHARMACEUTICALS PVT LIMITED NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X50.0 ML BOTTLE, 1.0X100.0 ML BOTTLE	01/07/2013

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196	NDA/MAL/HDP/0507	FOURRTS (INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	FILDILOL 12.5	CARVEDILOL	12.5 MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDALUR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014
197	NDA/MAL/HDP/0509	FOURRTS (INDIA) LABORATORIES (PVT) LTD	DELMAW ENTERPRISES LIMITED	FILDILOL 25	CARVEDILOL	25MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDALUR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2015

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198	NDA/MAL/HDP/0510	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	LIZOLID-600	LINEZOLID	600MG	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X4.0 TABLET STRIP	01/07/2004
199	NDA/MAL/HDP/0512	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAN ENTERPRISES LIMITED	FILSTAT 10	ATORVASTATIN CALCIUM	10MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITED VANDALUR ROAD, KELAMBAKKA M-603 103, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014

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200	NDA/MAL/HDP/0515	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	FILSTAT 20	ATORVASTATIN	20MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDALUR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014
201	NDA/MAL/HDP/0518	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	CYCLOREN	ACICLOVIR	200MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2014

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202	NDA/MAL/HDP/0520	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	FILSTAT 40	ATORVASTATIN CALCIUM	40MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDALUR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2014
203	NDA/MAL/HDP/0521	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PAN 40	PANTOPRAZOLE SODIUM	40MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2014

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204	NDA/MAL/HDP/0 526	LEBEN LABORATORIES LTD	MALIX PHARMA (U) LIMITED	AMILEB- 25	AMITRIPTYLINE	25MG	LEBEN LABORATORIES PVT. LTD.PLOT NO. L-4, PHASE-III, MIDC, AKOLA- 444 104 (MS).	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X20.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2014
205	NDA/MAL/HDP/0 531	LEBEN LABORATORIES LTD	MALIX PHARMA (U) LIMITED	ENDERM-GM	CLOBETASOL PROPIONATE + GENTAMYCIN + MICONAZOLE NITRATE	0.05%W/W + 0.10%W/W + 2.0%W/W	LEBEN LABORATORIES PVT. LTD.PLOT NO. L-4, PHASE -III, M.I.D.C, AKOLA, 444104, MAHARASHTRA, INDIA.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE,1.0X15.0 G TUBE	01/07/2014

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206	NDA/MAL/HDP/0 538	MICRO LABS LTD	LABOREX UGANDA LIMITED	XONADINE 180	FEXOFENADINE HYDROCHLORIDE	180 MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X1.0X10 .0 TABLET BLISTER	01/07/2013
207	NDA/MAL/HDP/0 541	MICRO LABS LTD	LABOREX UGANDA LIMITED	XONADINE 120	FEXOFENADINE HYDROCHLORIDE	120MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013



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208	NDA/MAL/HDP/0 542	DAWA LIMITED	SUPER MEDIC LTD	PHENBITAL	PHENOBARBITAL	30MG	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
209	NDA/MAL/HDP/0 543	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	GLIMERYL 2	GLIMEPIRIDE	2MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTDP.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL- RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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210	NDA/MAL/HDP/0544	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	DOLOWIN PLUS	ACECLOFENAC + PARACETAMOL	100 MG + 500 MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
211	NDA/MAL/HDP/0547	NAARI LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	MISO-KARE	MISOPROSTOL	200MCG	NAARI PHARMA PRIVATE LIMITED PLOT NO. 14-16 & 55-57, SECTOR-5, IIE, PANTNAGAR, RUDRAPUR-263153, DIST. U.S. NAGAR, UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0 TABLET BLISTER (COMBIPACK), 1.0X3.0X4.0 TABLET BLISTER	01/07/2013

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212	NDA/MAL/HDP/0 548	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNICAST	MONTELUKAST	5MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD .-P.O BOX 69 AMMAM 11591 JORDAN NUZHAT SAHID AL- RAQEEM NEAR PUBLIC HOUSING SECURITY	JORDAN	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2012
213	NDA/MAL/HDP/0 550	DAWA LIMITED	SUPER MEDIC LTD	DA-ZEPAM	DIAZEPAM	5MG	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2014

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214	NDA/MAL/HDP/0551	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	REDAMOX	AMOXICILLIN + CLAVULANIC ACID	125 MG/ 5 ML + 31.25 MG/ 5 ML	SAKAR HEALTH CARE PVT, LTD (BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382-213,GUJARAT-INDIA)	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2014
215	NDA/MAL/HDP/0553	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	EQUIRAB	RABIES ANTISERUM	1000IU/ 5ML	BHARAT SERUMS AND VACCINES LIMITED,PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X5.0 ML VIAL (5 DOSE VIAL)	01/07/2013

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216	NDA/MAL/HDP/0 555	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	CARZEPIN	CARBAMAZEPINE	200MG	HOVID BHDLOT 56442,71/2 MILES JALAN IPOH,PERAK,MALAYS IA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
217	NDA/MAL/HDP/0 558	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABGENTA EYE DROPS	GENTAMICIN SULPHATE	0.3% W/V	ABACUS PARENTERAL DRUGS LIMITEDBLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE,1.0X5.0 ML VIAL	01/07/2014

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218	NDA/MAL/HDP/0 559	HOVID BHD	MEDICAL ACCESS (UGANDA) LIMITED	DIABETMIN RETARD	METFORMIN HYDROCHLORIDE	850MG	HOVID BHDLOT 56442,71/2 MILES JALAN IPOH,PERAK,MALAYS IA	MALAYSIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
219	NDA/MAL/HDP/0 563	IND SWIFT LTD	PLANET PHARMACEUTICAL S UGANDA LTD	EZO 40	ESOMEPRAZOLE MAGNESIUM	40MG	IND-SWIFT- LTD,GLOBAL BUSINESS UNIT, JAWAHARPUR, OFF NH-21 DERABASSI	INDIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013

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220	NDA/MAL/HDP/0 566	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	CEFROTIL SUSPENSION	CEFUROXIME AXETIL	125MG/5ML	SAKAR HEALTHCARE PVT. LTD PLOT 10/13 SAKHEJ-BAVLA ROAD, AHMEDABAD, GUJUR AT, INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X1.0X50.0 ML BOTTLE	01/07/2013
221	NDA/MAL/HDP/0 568	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	FLUOXIREN	FLUOXETINE	20MG	RENE INDUSTRIES LIMITED PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013

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222	NDA/MAL/HDP/0570	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	TETGLOB 250 I.U	HUMAN TETANUS IMMUNOGLOBULIN	250IU	BHARAT SERUMS AND VACCINES LIMITED,PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERAL ORDINARY I M VIALS	1.0X1.0X2.0 ML VIAL (1 DOSE VIAL)	01/07/2013
223	NDA/MAL/HDP/0572	NORVATIS PHARMA AG-SWITZERLAND	LABOREX UGANDA LIMITED	AZARGA	BRINZOLAMIDE + TIMOLOL	10MG/ML + 5MG/ML	ALCON COUVREUR NVRIJKSWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML VIAL	01/07/2010



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224	NDA/MAL/HDP/0573	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL PARACETAMOL-250	PARACETAMOL	250MG/5ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2014
225	NDA/MAL/HDP/0574	IPCA LABORATOIES LTD	MEDVIN PHARMA LIMITED	ARTESUNATE AND AMODIAQUINE TABLETS 100/270	ARTESUNATE AND AMODIAQUINE	100MG+270MG	IPCA LABORATORIES LIMITED -SEJAVTA VILLAGE, DIST. RATLAM (M.P) 457002 INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER,1.0X1.0X6.0 TABLET BLISTER	01/07/2013

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226	NDA/MAL/HDP/0 576	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	DUODART	DUTASTERIDE + TAMSULOSIN	0.5MG + 0.4MG	CATALENT GERMANY SCHONDORF GMBH STEINBEISSTRASSE 1- 2, 73614 SCHORNDORF, GERMANY	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X30.0 CAPSULE CONTAINER	01/07/2015
227	NDA/MAL/HDP/0 580	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLUCAP	MULTINGREDIENT	MULTINGREDIENT	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1997

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228	NDA/MAL/HDP/0582	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ACECLO SERA	ACECLOFENAC+PARACETAMOL+SERRATIOPEPTIDASE	100MG + 500MG + 15MG	ARISTO PHARMACEUTICALS PVT LTD VILLAGE: MAKHNUMAJRA P.O. BHUD BADDI DISTRIC: SOLAN (H.P) 173205	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X10.0X10.0 TABLET BLISTER	01/07/2015
229	NDA/MAL/HDP/0584	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	TRIGLIMIPREX 1	GLIMEPIRIDE+PIOGlitazone+METFORMIN HYDROCHLORIDE	1MG+15MG+500MG	ARISTO PHARMACEUTICALS PVT LTD--VILLAGE MAKHNUMAJRA P.O BHUD BADDI DISTRICT SOLAN (H.P) 173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER, 1.0X10.0X10.0 TABLET BLISTER	01/07/2014

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230	NDA/MAL/HDP/0587	CADILA PHARMACEUTICALS LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	CADIGREL	CLOPIDOGREL	75MG	CADILA PHARMACEUTICALS LIMITED 1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
231	NDA/MAL/HDP/0588	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROFORT	PREDNISOLONE ACETATE	1%W/V	AUROLABNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA	INDIA	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML BOTTLE	01/07/2013

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232	NDA/MAL/HDP/0589	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	TRIGLIMIPREX 2	GLIMEPIRIDE+PIOGlitazone+Metformin Hydrochloride	2MG+15MG+500MG	ARISTO PHARMACEUTICALS PVT LTD--VILLAGE MAKHNUMAJRA P.O BHUD BADDI DISTRICT SOLAN (H.P) 173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/2014
233	NDA/MAL/HDP/0592	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROCHROME	CROMOLYN SODIUM	2%W/V	AUROLABNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA	INDIA	OPHTHALMIC LIQUIDS	1.0X10.0 ML CONTAINER	01/07/2013

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234	NDA/MAL/HDP/0593	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	PANTOP-D	PANTOPRAZOLE SODIUM SESQUIHYDRATE + DOMPERIDONE CAPSULES	20MG+10MG	ARISTO PHARMACEUTICALS PVT LTD .MAKHNUMAJRA P.O BHUD BADDI DISTRICT SOLAN HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED CAPSULES	1.0X10.0X10.0 CAPSULE STRIP,1.0X3.0X10.0 CAPSULE STRIP	01/07/2014
235	NDA/MAL/HDP/0595	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ORNOF	ORNIDAZOLE + OFLOXACIN	500MG + 200MG	ARISTO PHARMACEUTICALS PVT LTD--VILLAGE MAKHNUMAJRA P.O BHUD BADDI DISTRICT SOLAN (H.P) 173205	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2015

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236	NDA/MAL/HDP/0596	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ARBITEL-H	TELMISARTAN/HYDROCHLOROTHIAZIDE	40MG/12.5MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2011
237	NDA/MAL/HDP/0598	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LIPICURE-20	ATORVASTATIN	20MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2003

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238	NDA/MAL/HDP/0 599	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	GRAMOCEF-O- 400	CEFIXIME	400MG	MICROLABS LIMITED PLOT NO. 121-124, KIADB, BOMMASANDRA, - JIGNI LINK ROAD, ANEKUL TALUK, BANGALORE, KARNATAKA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER, 1.0X10.0 TABLET BLISTER	01/07/2013
239	NDA/MAL/HDP/0 600	DENK PHARM GMBH & CO. KG	BENLE CONSULT LIMITED	CARVEDI-DENK 6.25	CARVEDILOL	6.25MG	ARTESAN PHARMA GMBH & CO. KG WENDLANDSTRABE 1,29439 LUCHOW, GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2015



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240	NDA/MAL/HDP/0603	MEDLEY PHARMACEUTICALS LTD	EUROPA HEALTHCARE (U) LTD	GROMIN SYRUP	MULTI-INGREDIENT	MULTI-INGREDIENT	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE, 1.0X200.0 ML BOTTLE	01/07/1999
241	NDA/MAL/HDP/0605	DENK PHARM GMBH&CO.KG	BENLE CONSULT LIMITED	CARVEDI-DENK 25	CARVEDILOL	25MG	ARTESAN PHARMA GMBH & CO. KG WENDLANDSTRABE 1,29439 LUCHOW,GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2015

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242	NDA/MAL/HDP/0609	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	CLOPI-DENK 75	CLOPIDOGREL BESYLATE	75MG	ARTESAN PHARMA GMBH & CO. KG WENDLANDSTRABE 1,29439 LUCHOW,GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2015
243	NDA/MAL/HDP/0610	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	PYLOR KIT	LANSOPRAZOLE DELAYED RELEASE + CLARITHROMYCIN + TINIDAZOLE	30MG + 250MG + 500MG	LINCOLN PHARMACEUTICALS LTD .10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X7.0X1.0X6.0 TABLET BLISTER (BLISTER CONTAINS 2 CAPSULES AND 4 TABLETS)	01/07/2016

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244	NDA/MAL/HDP/0611	GALPHAR LABORATORIES LTD	DAWASANA PHARMACEUTICALS LTD	GALCIPRO 500	CIPROFLOXACIN HYDROCHLORIDE	500MG	GALPHA LABORATORIES LIMITED VILLAGE "A" THANA BADDI, TEHSIL BADDI SOLAN HIMACHAL PRADESH-173 205 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2015
245	NDA/MAL/HDP/0614	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	CLAVULIN	AMOXICILLIN + CLAVULANIC ACID	125MG/5ML + 31.25MG/5ML	SMITHKLINE BEECHAM PHARMACEUTICALS, CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X70.0 ML BOTTLE, 1.0X100.0 ML BOTTLE	01/07/1998

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246	NDA/MAL/HDP/0 617	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	SILVEX	SILVER SULFADIAZINE + CHLORHEXIDINE	1%W/W + 0.2%W/W	LINCOLN PHARMACEUTICALS LTD .10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2014
247	NDA/MAL/HDP/0 619	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	D10	GLUCOSE	10%W/V	ABACUS PARENTERAL DRUGS LTD PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE,  MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE, 1.0X250.0 ML BOTTLE	01/07/2013

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248	NDA/MAL/HDP/0 623	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	GELCID	MAGNESIUM SULPHATE	50%W/V	LINCOLN PHARMACEUTICALS LTD-11 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ- 382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X5.0X10.0 ML AMPOULE,1.0X10.0 X5.0X5.0 ML AMPOULE IN BLISTER PACK,1.0X5.0 ML AMPOULE IN BLISTER PACK	01/07/2015
249	NDA/MAL/HDP/0 626	KPI INDUSTRIES(1996) LTED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	CARDIPAC-10	AMLODIPINE BESILATE	10MG	KPI INDUSTRIES (1996) LTD PLOT NO.M444B STRETCHER RD, NTINDA, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0X10.0 TABLET BLISTER	01/07/2015

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250	NDA/MAL/HDP/0 627	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	AMOXIKID	AMOXICILLIN TRIHYDRATE	125MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD PLOT M 444B STRETCHER ROAD NTINDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP,1.0X2.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2015
251	NDA/MAL/HDP/0 633	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	CIPROCIIN	CIPROFLOXACIN	0.3%W/V	ABACUS PARENTERAL DRUGS LTD PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE,  MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL,1.0X5.0 ML VIAL	01/07/2013

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252	NDA/MAL/HDP/0634	MEDLEY PHARMACEUTICALS	EUROPA HEALTHCARE (U) LTD	TRISOLIV	ANDROGRAPHOLIDES/TRICHLINOCITRATE	50MCG+50MG/ML	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2014
253	NDA/MAL/HDP/0635	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGO-AMIN	AMINOPHYLLINE	100MG	AGOG PHARMA LTD PLOT NO.33, SECTOR II, VASAI, TALUKA INDL CO-OP ESTATE LTD, GAURAI PADA, VASAI(E) DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X1000.0 TABLET CONTAINER, 1.0X100.0X10.0 TABLET BLISTER	01/07/2009

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254	NDA/MAL/HDP/0636	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	REVOKE-1.5	LEVONORGESTREL	1.5MG	MYLAN LABORATORIES LIMITED..PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, AHMEDABAD, GUJARAT, INDIA 382213 MYLAN LABORATORIES LIMITED.-PLOT NO. 1606.1609	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0 TABLET BLISTER	01/07/2014
255	NDA/MAL/HDP/0637	NABIQASIM INDUSTRIES (PVT) LIMITED	JEET PHARMACEUTICALS LIMITED	ZUDICORT	FUSIDIC ACID + BETAMETHASONE VALERATE	20MG + 1MG/G	NABIQASIM INDUSTRIES (PVT) LIMITED17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2014



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256	NDA/MAL/HDP/0 638	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABLOL-5 EYE DROPS	TIMOLOL MALEATE	0.5% W/V	ABACUS PARENTERAL DRUGS LTD PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE,  MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL	01/07/2013
257	NDA/MAL/HDP/0 639	NEM LABORATORIES (PVT) LTD	RENE PHARMACY LTD	RHEUMATIC CREAM	MULTI- INGREDIENT	MULTI- INGREDIENT	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997

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258	NDA/MAL/HDP/0 654	NVS KENYA LTD	SURGIPHARM (U) LIMITED	GALVUS MET	VILDAGLIPTIN / METFORMIN	50MG/500MG	NORVATIS PHARMA PRODUCTIONS GMBH, WEHRGERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2013
259	NDA/MAL/HDP/0 657	NVS KENYA LTD	SURGIPHARM (U) LIMITED	GALVUS MET	VILDAGLIPTIN / METFORMIN	50MG / 850MG	NORVATIS PHARMA PRODUCTIONS GMBH, WEHRGERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X6.0X10 .0 TABLET BLISTER	01/07/2013

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260	NDA/MAL/HDP/0 658	NVS KENYA LTD	SURGIPHARM (U) LIMITED	GALVUS MET	VILDAGLIPTIN/ METFORMIN	50MG/1000MG	NORVATIS PHARMA PRODUCTIONS GMBH, WEHRGERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X6.0X10 .0 TABLET BLISTER	01/07/2013
261	NDA/MAL/HDP/0 665	HETERO LABS LTD	AIVEEN (U) LIMITED	IRBIS 150	IRBESARTAN	150MG	HETERO LABS LTD (UNIT- V)SY.NO.438,439,44 0 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOONNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2013

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262	NDA/MAL/HDP/0 666	HETERO LABS LTD	AIVEEN (U) LIMITED	IRBIS-H 300	IRBESARTAN	300MG	HETERO LABS LTD (UNIT- V)SY.NO.438,439,44 0 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOONNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER	01/07/2013
263	NDA/MAL/HDP/0 667	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXEL MICONAZOLE	MICONAZOLE NITRATE	2%W/W	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE,1.0X15.0 G TUBE	01/07/2013

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264	NDA/MAL/HDP/0668	CADILA PHARMACEUTICALS LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	TELI 40	TELMISARTAN	40MG	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
265	NDA/MAL/HDP/0669	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXEL FUNGICORT CREAM	MICONAZOLE NITRATE + HYDROCORTISON E	2% W/W + 1% W/W	KOTRA PHARMA SDN BDN-1, 2, &3, JALANTTC12 CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE,1.0X15.0 G TUBE	01/07/2013

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266	NDA/MAL/HDP/0670	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	FLUNAZ-200	FLUCONAZOLE	200MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0 CAPSULE BLISTER, 1.0X5.0X4.0 CAPSULE BLISTER	01/07/2014
267	NDA/MAL/HDP/0672	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGONOR TABLETS	NORFLOXACIN	400MG	AGOG PHARMA LTD PLOT NO.33, SECTOR II, VASAI, TALUKA INDL CO-OP ESTATE LTD, GAURAI PADA, VASAI(E) DIST. T HANE INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X100.0X10.0 TABLET BLISTER	01/07/2013

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268	NDA/MAL/HDP/0674	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGODAPS-100	DAPSONE	100MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER	01/07/2013
269	NDA/MAL/HDP/0675	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (A) LTD.	AXCEL METRONIDAZOLE 400	METRONIDAZOLE	400MG	KOTRA PHARMA-BHD 1, JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA, MALAYSIAKESAR PHARMA PVT LTD PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIAMALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2015

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270	NDA/MAL/HDP/0677	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	DOPAMET	METHYLDOPA	250MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
271	NDA/MAL/HDP/0678	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL HYDROCORTISONE CREAM	HYDROCORTISONE	1%W/W	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE, 1.0X5.0 G TUBE	01/07/2014



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272	NDA/MAL/HDP/0679	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	MEFENA-250 CAPSULES	MEFENAMIC ACID	250MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0X10.0 CAPSULE BLISTER	01/07/2013
273	NDA/MAL/HDP/0681	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ELAXIM 40	TENECTEPLASE (RECOMBINANT TISSUE PLASMINOGEN ACTIVATOR)	40MG/VIAL	GENNOVA BIOPHARMACEUTICALS LIMITED BLOCK 1, PLOT NO. P-1 AND P-2, ITBT PARK, PHASE II, MIDC, HINJAWADI, PUNE - 411057	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X40.0 MG VIAL , 1*8 ML VIAL OF WFI	01/07/2013

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274	NDA/MAL/HDP/0 685	FERRER INTERNACIONAL S.A	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	SOMAZINA	CITICOLINE	1000MG	FERRER INTERNATIONAL, S.A.C/JOAN BUSCALLA, 1- 9.08173 SANT CUGAT DEL VALLES, BARCELONA	SPAIN	PARENTERAL RETARD I M AMPOULES	1.0X5.0X4.0 ML AMPOULE	01/07/2015
275	NDA/MAL/HDP/0 687	FERRER INTERNACIONAL S.A	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	SOMAZINA	CITICOLINE	1000MG	FERRER INTERNATIONAL, S.A.C/JOAN BUSCALLA, 1- 9.08173 SANT CUGAT DEL VALLES, BARCELONA	SPAIN	ORAL LIQUID ORDINARY LIQUIDS	1.0X6.0X10.0 ML SACHET	01/07/2015

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276	NDA/MAL/HDP/0 688	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	HBB	HYOSCINE BUTYLBROMIDE	10MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
277	NDA/MAL/HDP/0 689	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGONAL	NALIDIXIC ACID	500MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013

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278	NDA/MAL/HDP/0690	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	HEALTHEASE CREAM	BECLOMETHASON E DIPROPIONATE + PHENYLEPHRINE HCL + LIGNOCAINE HCL + CHLOROCRESOL	0.025%W/W + 0.1%W/W + 2.5%W/W + 0.1%W/W	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	01/07/2014
279	NDA/MAL/HDP/0691	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	OLMAT-20	OLMESARTAN MEDOXOMIL	20 MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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280	NDA/MAL/HDP/0 692	DAWA LIMITED	SUPER MEDIC LTD	DAWACLOX -250	CLOXACILLIN SODIUM	250MG	DAWA LIMITED BABA DOGO RWARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/2015
281	NDA/MAL/HDP/0 693	DAWA LIMITED	SUPER MEDIC LTD	MOXACIL -250	AMOXYCILLIN TRIHYDRATE	250MG	DAWA PHARMACEUTICALS LIMITEDPLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/2014

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282	NDA/MAL/HDP/0694	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	DT ZINC-20 TABLETS	ZINC SULPHATE	20MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0 TABLET BLISTER, 1.0X10.0X10.0 TABLET CARTON	01/07/2013
283	NDA/MAL/HDP/0696	BYANSI SERVICES LIMITED	AIVEEN (U) LIMITED	RITONAVIR	RITONAVIR	100MG	HETERO LABS LTD 22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2014

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284	NDA/MAL/HDP/0700	ZYDUS LIFESCIENCES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	VAXIRAB N	INACTIVATED RABIES VIRUS(PITMAN MOORE STRAIN)	>2.5 I.U	ZYDUS LIFESCIENCES LIMITED -PLOT 417,419,420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL: SANAND DISTRICT AHMEDABAD 382210	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL + 1ML AMPOULE OF WFI(1 DOSE VIAL)	01/07/2015
285	NDA/MAL/HDP/0702	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	SEPTOCIN	STREPTOMYCIN SULPHATE	1GM	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X1.0 G VIAL,1.0X100.0X1.0 G VIAL,1.0X10.0X1.0 G VIAL	01/07/2014

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286	NDA/MAL/HDP/0703	GOOD DAY PHARMACY LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	DICLODAY GEL	DICLOFENAC DIETHYLAMINE+ LINSEED OIL+ METHYL SALICYLATE +MENTHOL	11.6MG + 30MG + 100MG + 50MG	KREMOINT PHARMA PVT LTD--B-8 ADDITIONAL AMBERNATH MIDC OPP. ANAND NAGAR POLICE CHECK POST AMBERNATH (E) DIST THANE 421 506	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/2013
287	NDA/MAL/HDP/0704	HETERO LABS LTD UNIT IX	AIVEEN (U) LIMITED	M-FLOX	MOXIFLOXACIN HYDROCHLORIDE	400MG	HETERO LABS LTDUNIT II & III BADDI THE NALAGARH DIST SOLAN H.P HETERO LABS LTD (UNIT-V)SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,10.0X1.0X5.0 TABLET BLISTER	01/07/2013



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288	NDA/MAL/HDP/0705	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	ACICLOVIR	ACICLOVIR	5%W/W	LINCOLN PHARMACEUTICAL LIMITED TRIMAL ESTATE KHATRAJ KOLOL, GUJARAT INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE	01/07/2011
289	NDA/MAL/HDP/0706	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	ROVAS 5	ROSUVASTATIN	5MG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI-248197, DEHRADUN UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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290	NDA/MAL/HDP/0707	HETERO LABS LTD	AIVEEN (U) LIMITED	PENVIR 500	FAMCICLOVIR	500MG	HETERO LABS LTD(UNIT V).JADCHERLA (M),MAHABOBNAGAR DIST, ANDHRA PRADESH,INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	01/07/2013
291	NDA/MAL/HDP/0710	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	ROVAS 20	ROSUVASTATIN	20MG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI-248197,DEHRADUN UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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292	NDA/MAL/HDP/0 712	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	ZENTEL	ALBENDAZOLE	100MG/5ML	ASPEN BAD OLDESLOE GMBH, INDUSTRIESTRASSEI INDUSTRIESTRASSE 32-36, 23843 BAD OLDESLOE	FRANCE	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X20.0 ML BOTTLE	01/07/1997
293	NDA/MAL/HDP/0 713	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	PANTO-DENK 20	PANTOPRAZOLE SODIUM SESQUIHYDRATE	20MG	ALLPHAMED PHARMBIL ARZNEIMITTEL GMBH HILDERBRAND, STR 12-37081, GOTTINGEN	GERMANY	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2015

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294	NDA/MAL/HDP/0715	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	PANTO-DENK 40	PANTOPRAZOLE SODIUM SESQUIHYDRATE	40MG	ALLPHAMED PHARMBIL ARZNEIMITTEL GMBHHILDERBRAND , STR 12-37081, GOTTINGEN	GERMANY	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2015
295	NDA/MAL/HDP/0718	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	GLYMET-2	GLIMEPIRIDE+METFORMIN HYDROCHLORIDE	2MG + 500MG	LINCOLN PHARMACEUTICALS L.T.DTRIMUL ESTATE KHATRAJ 382721 GHANDINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X5.0X10.0 TABLET BLISTER	01/07/2014

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296	NDA/MAL/HDP/0719	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	WEPOX 4000	RECOMBINANT HUMAN ERYTHROPOIETIN	4000 I.U	WOCKHARDT LIMITED - WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X0.4 ML PRE-FILLED SYRINGE	01/07/2011
297	NDA/MAL/HDP/0720	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	JUSDEE 400 DROPS	COLECALCIFEROL	400 I.U/ML	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X15.0 ML BOTTLE	01/07/2013

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298	NDA/MAL/HDP/0722	FDC LTD	AIVEEN (U) LIMITED	IOTIM 0.5%	TIMOLOL MALEATE	0.5% W/V	FDC LIMITED B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.☐	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2014
299	NDA/MAL/HDP/0726	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	T DOL RAPID	TRAMADOL HYDROCHLORIDE	50MG	TROIKAA PHARMACEUTICALS LTD SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2014

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300	NDA/MAL/HDP/0727	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	STOMACH FIT SYRUP	BISMUTH AMMONIUM CITRATE+BELLADONA DRY EXTRACT+THYMO L+MENTHOL	140MG+9MG+0.15 MG+0.2/5ML	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X225.0 ML BOTTLE	01/07/2013
301	NDA/MAL/HDP/0728	IPCA LABORATOIES LTD	MEDVIN PHARMA LIMITED	ARTESUNATE AND AMODIAQUINE 25/67.5	ARTESUNATE+AMODIAQUINE	25MG+67.5MG	IPCA LABORATORIES LIMITED -SEJAVTA VILLAGE, DIST. RATLAM (M.P) 457002 INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER	01/07/2013

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302	NDA/MAL/HDP/0 731	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	ARTESUNATE AND AMODIAQUINE 50/135	ARTESUNATE + AMODIAQUINE	50/135MG	IPCA LABORATORIES LIMITED -SEJAVTA VILLAGE, DIST. RATLAM (M.P) 457002 INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER	01/07/2013
303	NDA/MAL/HDP/0 732	AIVEEN (U) LIMITED	AIVEEN (U) LIMITED	VOLTAMED-100	DICLOFENAC	100 MG	MEDICO REMEDIES PVT LIMITED8 & 9 DEWAN & SONS, UDYOG NAGAR PALGAR, DISTRICT THANE MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2015



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304	NDA/MAL/HDP/0734	AIVEEN (U) LIMITED	AIVEEN (U) LIMITED	OMMED -20	OMEPRAZOLE	20MG	MEDICO REMEDIES PVT LIMITED8 & 9 DEWAN & SONS, UDYOG NAGAR PALGAR, DISTRICT THANE MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	01/07/2015
305	NDA/MAL/HDP/0736	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MABRON 50	TRAMADOL HYDROCHLORIDE	50MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013

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306	NDA/MAL/HDP/0 740	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	COTRIM	CO-TRIMOXAZOLE	960MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X17.0X6.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2013
307	NDA/MAL/HDP/0 741	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MEDOCIPRIN	CIPROFLOXACIN	500MG	MEDOCHEMIE LTD (FACTORY AZ)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS, INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL, CYPRUS	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2013

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308	NDA/MAL/HDP/0 742	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	BROT	METFORMIN HYDROCHLORIDE	500MG	MEDOCHEMIE (FACTORY AZ).-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
309	NDA/MAL/HDP/0 746	COSMOS LTD	ASTRA PHARMA (U) LIMITED	DTS-Z KIT	TABLET-ZINC, SACHET-NACL + KCL + TRISODIUM CITRATE + ANHYDROUS GLUCOSE	TABLET-54.89MG , SACHET 1.3G + 0.75G + 1.45G + 6.75G	COSMOS LIMITED, KENYARANGWE ROAD, OFF LUNGA ROAD, INDUSTRIAL AREA NAIROBI - KENYA	KENYA	ORAL LIQUID ORDINARY UNIT DOSE POWDERS	1.0X4.0X10.3 G SACHET + 1.0X10.0 TABLET BLISTER	01/07/2013

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310	NDA/MAL/HDP/0 748	BAYER PHARMA	SURGIPHARM (U) LIMITED	XARELTO 15MG	RIVAROXABAN	15MG	BAYER PHARMA AG 51368 LEVERKUSENBAYER PHARMA AG 51368 LEVERKUSEN	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X14.0 TABLET BLISTER	01/07/2013
311	NDA/MAL/HDP/0 749	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	MEROGRAM 1000	MEROPENEM	1000MG	AURONEXT PHARMA PVT LTD.A- 1128 RIICO INDUSTRIAL AREA, PHASE III, DISTALWAR, BHIWADI	INDIA	PARENTERAL ORDINARY DRY VIALS	1X1 G VIAL	01/07/2014

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312	NDA/MAL/HDP/0 750	BAYER PHARMA	SURGIPHARM (U) LIMITED	XARELTO 20MG	RIVAROXABAN	20MG	BAYER PHARMA AG 51368 LEVERKUSENBAYER PHARMA AG 51368 LEVERKUSEN	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X14.0 TABLET BLISTER	01/07/2013
313	NDA/MAL/HDP/0 751	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	DOLOWIN	ACECLOFENAC	100MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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314	NDA/MAL/HDP/0754	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	TORAS DENK 10	TORASEMIDE	10MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2015
315	NDA/MAL/HDP/0759	MICRO LABS LTD	LABOREX UGANDA LIMITED	COTRIMOXAZOLE	COTRIMOXAZOLE	960MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2011

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316	NDA/MAL/HDP/0764	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	CORVADIL 5	AMLODIPINE	5MG	UNICHEM LABORATORIES LIMITED UNIT IIVILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2011
317	NDA/MAL/HDP/0765	SHANGHAI DAHUA PHARMACEUTICAL CO., LTD.	UNITED HEALTHCARE DISTRIBUTORS LTD	LEVOPLANT	LEVONORGESTREL	75MG	SHANGHAI DAHUA PHARMACEUTICAL CO. LTDCHANG ZENG FARM, CHONGMING COUNTY, SHANGHAI	CHINA	PARENTERAL RETARD IMPLANTS	1.0X10.0X2.0 ROD IMPLANT	01/07/2010

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318	NDA/MAL/HDP/0768	FDC LTD	AIVEEN (U) LIMITED	PYRIMON EYE DROP	DEXAMETHASON E/CHLORAMPHENICOL	1%W/V + 0.1%W/V	FDC LIMITED B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.☒	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/1999
319	NDA/MAL/HDP/0770	BEIJING HOLLEY COTEC PHARMA CHINA	SUPER PHARMACEUTICALS LIMITED	AMPIL-500	AMPICILLIN	500MG	CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHANG) CO. LTD WORKSHOP NO. 88 YANGZI ROAD, SHIJIAZHANG CITY, HEBEI PROVINCE, CHINA WORKSHOP 406 AND 407	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X500.0 MG VIAL	01/07/2013



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320	NDA/MAL/HDP/0772	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	LIGABA - 150	PREGABALIN	150MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2014
321	NDA/MAL/HDP/0775	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	LIGABA - 75	PREGABALIN	75MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2014

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322	NDA/MAL/HDP/0776	FREDUN PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	FREMOL TABLETS	PARACETAMOL TABLETS	500MG	FREDUN PHARMACEUTICALS LTD14,15,16 ZORBIAN INDUSTRIAL COMPLEX VEOR PALGHAR EAST INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1999
323	NDA/MAL/HDP/0781	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	TRICOLD	PARACETAMOL/P HENYLEPHRINE HYDROCHLORIDE/CAFFEINE ANHYDROUS/CHLORPHENIRAMINE	500MG/10MG/30MG/2MG	TRIVENI FORMULATIONS LIMITED -PLOT NO 52-54,62-64 ALEAP INDUSTRIAL ESTATE SURAMPALLI (V) VIJAYAWADA A.P	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X50.0X4.0 TABLET BLISTER	01/07/2013

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324	NDA/MAL/HDP/0 784	COSMOS LTD	ASTRA PHARMA (U) LIMITED	HEMOSAN	FERROUS FUMERATE	300MG	COSMOS LIMITED, KENYARANGWE ROAD, OFF LUNGA ROAD, INDUSTRIAL AREA NAIROBI - KENYA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2013
325	NDA/MAL/HDP/0 792	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	AS-V	PHENOXYMETHYL PENICILLIN	250MG	ASTRA LIFE CARE (INDIA) PVT.LTD PLOT NO. 57/P, SARKHEJ- BAVLA HIGHWAY, POST RAJODA- 382220, TALUKA BAVLA, AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET STRIP	01/07/2010

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326	NDA/MAL/HDP/0794	REMINGTON PHARMACEUTICAL INDUSTRIES PVT LTD	HEALTHCARE LTD.	AMYGYDEX	TOBRAMYCIN/DEXAMETHASONE	3MG+1MG/ML	REMINGTON PHARMACEUTICALS (PVT) LTD18KM, MULTAN ROAD, LAHORE 53800, PAKISTAN	PAKISTAN	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2014
327	NDA/MAL/HDP/0795	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPEN-250	PHENOXYMETHYL PENICILLIN POTASSIUM	250MG	MILAN LABORATORIES (INDIA) PVT LTD .PLOTS 63,67,87,35,36,64,65 , JAWAHAR CO-OP IND. ESTATE LTD, KAMOTHE, PANVEL (NAVI MUMBAI)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER	01/07/2013

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328	NDA/MAL/HDP/0 802	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	EXFORGE HCT 5MG/ 160MG/12.5MG	AMLODIPINE + VALSARTAN + HYDROCHLOROT HIAZIDE	5MG+ 160MG+ 12.5MG	NOVARTIS PHARMA STEIN AGSCHAFFHARVSERT RASSE CH-4332 STEIN SWITZERLAND.	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER	01/07/2015
329	NDA/MAL/HDP/0 811	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	DOLOWIN -SR	ACECLOFENAC	200MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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330	NDA/MAL/HDP/0 816	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	GLIMEPIRIDE DENK 2	GLIMEPIRIDE	2MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2012
331	NDA/MAL/HDP/0 821	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	GLIMEPIRIDE DENK 3	GLIMEPIRIDE	3MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2012

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332	NDA/MAL/HDP/0 822	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	CLOXCIN-500	CLOXACILLIN SODIUM	500MG	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X0.5 G VIAL,1.0X100.0X0.5 G VIAL,1.0X10.0X0.5 G VIAL	01/07/2014
333	NDA/MAL/HDP/0 824	I CARE PHARMA LIMITED	VITACARE LTD	CLOXACILLIN	CLOXACILLIN	250MG	MEDICO REMEDIES PVT LTD,-8 & 9 DEWAN AND SONS, UDYOG NAGAR, PALGHAR, DIST. THANE-401404, MAHARSHITRA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/2013

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334	NDA/MAL/HDP/0 826	I CARE PHARMA LIMITED	VITACARE LTD	AMOXYCILLIN	AMOXYCILLIN	250MG	MEDICO REMEDIES PVT LTD,-8 & 9 DEWAN AND SONS, UDYOG NAGAR, PALGHAR, DIST. THANE-401404, MAHARSHITRA AMN LIFE SCIENCE PVT LTD-67/P-1, MALAV, AREA- BHILAD, VALSAD- 396105, GUJARAT	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/2013
335	NDA/MAL/HDP/0 827	GALPHA LABORATORIES LTD	DAWASANA PHARMACEUTICAL S LTD	CLANOXY 1.2	AMOXICILLIN + CLAVUNATE POTASSIUM	1000MG/200MG	GALPHA LABORATORIES LTDAT: ALKEM LABORATORIES LTD PLOT 167/2 MAHATMA UDYOG NAGAR AMALIYA DAMAN 396210	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.2 G VIAL + 1*20ML VIAL OF WFI	01/07/2015



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336	NDA/MAL/HDP/0830	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	EUTHYROX 25 MCG	LEVOTHYROXINE SODIUM	25 MCG	MERCK KGAA - FRANKFRUTER STRASSE 250, D-64293,DARMSTADT-GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X30.0 TABLET BLISTER,1.0X4.0X25.0 TABLET BLISTER	01/07/2015
337	NDA/MAL/HDP/0831	I CARE PHARMA LIMITED	VITACARE LTD	AMPICILLIN CAPSULES	AMPICILLIN	250MG	MEDICO REMEDIES PVT LTD,-8 & 9 DEWAN AND SONS, UDYOG NAGAR, PALGHAR, DIST. THANE-401404, MAHARSHITRA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/2013

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338	NDA/MAL/HDP/0832	MERCK	UNITED HEALTHCARE DISTRIBUTORS LTD	EUTHYROX 100MCG	LEVOTHYROXINE	100MCG	MERCK KGAA - FRANKFRUTER STRASSE 250, D-64293,DARMSTADT-GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X4.0X25.0 TABLET BLISTER,1.0X1.0X30.0 TABLET BLISTER	01/07/2015
339	NDA/MAL/HDP/0834	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	VOMI-6	DOXYLAMINE SUCCINATE & PYRIDOXINE HYDROCHLORIDE	10MG + 10MG	LINCOLN PHARMACEUTICALS LIMITED.TRIMUL ESTATE NEAR KHATRAJ CHOKADI KHATRAJ 382721 GHANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER	01/07/2013

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340	NDA/MAL/HDP/0835	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOBIS	BISACODYL	5MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2013
341	NDA/MAL/HDP/0836	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	CALBONE-500	CALCIUM CARBONATE + COLECALCIFEROL	1250MG + 250 I.U	LINCOLN PHARMACEUTICALS LIMITED 10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X1.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/2012

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342	NDA/MAL/HDP/0 842	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	SAC	SECNIDAZOLE	1000MG	LINCOLN PHARMACEUTICALS LIMITED 10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X2.0 TABLET BLISTER	01/07/2013
343	NDA/MAL/HDP/0 843	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	COXERIN	CYCLOSERINE	250MG	MACLEODS PHARMACEUTICALS LTD .PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	01/07/2013

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344	NDA/MAL/HDP/0 845	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICAL S LIMITED	OLEVO-500	LEVOFLOXACIN	500 MG	LINCOLN PHARMACEUTICALS LIMITED 10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER,1.0X5.0X1. 0X10.0 TABLET BLISTER	01/07/2013
345	NDA/MAL/HDP/0 846	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	MOXIMAC	MOXIFLOXACIN	400MG	MACLEODS PHARMACEUTICALS LTD-PLOT 25-27 SURVEY NO. 366 PREMIER INDUSTRIAL ESTATE KACHIGAM DAMAN	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0 TABLET BLISTER	01/07/2014

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346	NDA/MAL/HDP/0848	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	MACROZIDE 500	PYRAZINAMIDE	500MG	MACLEODS PHARMACEUTICALS LTD--PLOT NO 25-27 SURVEY PREMEIRE INDUSTRIAL ESTATE KACHIGAM DAMAN (U.T) 396401	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER	01/07/2014
347	NDA/MAL/HDP/0850	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	LCT KIT	LANSOPRAZOLE + CLARITHROMYCIN + TINIDAZOLE	30MG + 250MG + 500MG	LINCOLN PHARMACEUTICALS LIMITED 10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X7.0X1.0X6.0 TABLET BLISTER (BLISTER CONTAINS 2 CAPSULES AND 4 TABLETS)	01/07/2012

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348	NDA/MAL/HDP/0 853	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICAL S LTD	BRUSTAN GEL	IBUPROFEN + LEVOMENTHOL	5% W/W+ 3%W/W	SUN PHARMACEUTICAL IND. LTD PLOT NO. B- 2, MADKAI INDUSTRIAL ESTATE, PONDA- GOA, INDIA- 403404	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X50.0 G CONTAINER	01/07/2012
349	NDA/MAL/HDP/0 855	HETERO LABS LTD	AIVEEN (U) LIMITED	LAZINE	LEVOCETIRIZINE DIHYDROCHLORID E	5MG	HETERO LABS LTD22- 110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	01/07/2013

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350	NDA/MAL/HDP/0 857	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	CANDID-V6 VAGINAL TABLETS	CLOTRIMAZOLE	100MG	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	VAGINAL TABLETS	1.0X6.0 PESSARY STRIP	01/07/2000
351	NDA/MAL/HDP/0 858	ASTRA ZENECA	MACNAUGHTON LIMITED	PLENDIL	FELODIPINE	5MG	ASTRAZENECA SWEDEN OPERATIONSASTRAZ ENECA SWEDEN OPERATIONS SE-151 85 SODERTALJE ASTRAZENECA PHARMACEUTICAL CO LTD.NO. 2 HUANGSHAN ROAD, WUXI, 214028, JIANGSU	CHINA SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2001



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352	NDA/MAL/HDP/0 861	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	PROZINE	PROMETHAZINE	25MG/ML	SAKAR HEALTHCARE PVT. LTD PLOT 10/13 SAKHEJ-BAVLA ROAD, AHMEDABAD, GUJUR AT, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	2.0X5.0X2.0 ML AMPOULE	01/07/2013
353	NDA/MAL/HDP/0 864	HETERO LABS LTD UNIT IX	AIVEEN (U) LIMITED	PANTIN-40	PANTOPRAZOLE SODIUM	40 MG	HETERO LABS LIMITED UNIT VAPIC PHARMA SEZ, S. NO. 439, 440, 441 & 458 MOLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOBNAGAR (DISTRICT). PIN 509301	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X3.0X10 .0 TABLET BLISTER	01/07/2013

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

354	NDA/MAL/HDP/0 866	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	LIZOLID	LINEZOLID	2MG/ML	AMANTA HEALTHCARE LIMITEDPLOT NO. 876 N.H. NO. 8 VILLAGE-HIRIYALA TALUKA, MATAR, DIST KHEDA-387 411, GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X300.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2013
355	NDA/MAL/HDP/0 868	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	VARMIKA-500	AMIKACIN	500MG	SAKAR HEALTH CARE PVT, LTDBLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ- BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X2.0X6.0X2.0 ML VIAL	01/07/2013

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356	NDA/MAL/HDP/0870	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TROY-K	PHYTOMENADIONE	10MG/ML	TROIKAA PHARMACEUTICALS LIMITED THOL, DIST. MEHSANA-382728, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2010
357	NDA/MAL/HDP/0871	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	DEXA	DEXAMETHASONE SODIUM	4MG/ML	SAKAR HEALTH CARE PVT, LTDBLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382-213,GUJARAT-INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1X2X6X2 ML VIAL	01/07/2013

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358	NDA/MAL/HDP/0873	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	OXYTOCIN INJECTION	OXYTOCIN	10I.U/ML	SAKAR HEALTH CARE PVT LTD10/13 CHONGODAR SARKHEJ BAVLA ROAD DIST AHMABAD 382213 GUJARATI	CHINA INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2009
359	NDA/MAL/HDP/0874	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	LEBASMA-4	SALBUTAMOL	4MG	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X20.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/2014

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360	NDA/MAL/HDP/0 877	LEBEN LABORATORIES LTD	MALIX PHARMA (U) LIMITED	ANTAGIT DS GEL MINT FLAVOUR	DRIED ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE	400MG + 400MG + 50MG	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X170.0 ML BOTTLE	01/07/2007
361	NDA/MAL/HDP/0 879	COSMOS LTD.	ASTRA PHARMA (U) LIMITED	TRIBEES FORTE FILM COATED TABLETS	THIAMINE + PYRIDOXINE + CYANOCOBALAMI N	200MG + 50MG +1000MCG	COSMOS LIMITED, KENYARANGWE ROAD, OFF LUNGA ROAD, INDUSTRIAL AREA NAIROBI - KENYA	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2012

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362	NDA/MAL/HDP/0882	MERCK	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOVANCE 500MG/2.5MG	METFORMIN + GLIBENCLAMIDE	500MG + 2.5MG	MERCK SANTE S.A.SCENTRE DE PRODUCTION DE SEMOY 2 RUE DU PRESSIOR VERT 45400 SEMOY	FRANCE	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER,1.0X4.0X15.0 TABLET BLISTER	01/07/2012
363	NDA/MAL/HDP/0883	MERCK	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOVANCE 500MG/5MG	METFORMIN + GLIBENCLAMIDE	500MG + 5MG	MERCK SANTE S.A.SCENTRE DE PRODUCTION DE SEMOY 2 RUE DU PRESSIOR VERT 45400 SEMOY	FRANCE	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER,1.0X4.0X15.0 TABLET BLISTER	01/07/2012

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364	NDA/MAL/HDP/0 889	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	DNS	SODIUM CHLORIDE + GLUCOSE	0.9%W/V + 5% W/V	ABACUS PARENTERAL DRUGS LIMITEDBLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X250.0 ML BOTTLE,1.0X500.0 ML BOTTLE	01/07/2012
365	NDA/MAL/HDP/0 895	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	HYORTH	SODIUM HYALURONATE	10MG/1ML	VIRCHOW BIOTECH PVT, LTDSURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DIST	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X2.0 ML PRE- FILLED SYRINGE	01/07/2015

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366	NDA/MAL/HDP/0 897	VIRCHOW HEALTHCARE PVT LTD	LEGIT MEDEQ 2007 LIMITED	DEBRIDACE	PAPAIN + UREA	521700UNITS+100 MG/G	VIRCHOW BIOTECH PVT, SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DISTRICT TELANGANA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/2015
367	NDA/MAL/HDP/0 899	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	VIRIAXONE	CEFTRIAXONE	1G	INJECTCARE PARENTERALS PVT. LTD.PLOT130 SILVASSA ROAD GIDC VAPI 396195 GUJARAT	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 10 ML VIAL WFI	01/07/2013



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368	NDA/MAL/HDP/0902	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPINE SR	NIFEDIPINE	20MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID RETARD FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
369	NDA/MAL/HDP/0906	VIRCHOW HEALTHCARE PVT LTD	LEGIT MEDEQ 2007 LIMITED	IONSIL	SILVER NITRATE	0.2%W/W	VIRCHOW BIOTECH PVT, SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DISTRICT TELANGANA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X15.0 G TUBE	01/07/2015

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370	NDA/MAL/HDP/0 911	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	HEALACE	RECOMBINANT HUMAN PLATELET DERIVED GROWTH FACTOR -B	100MCG/G	VIRCHOW BIOTECH PVT, LTDSURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DIST	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X15.0 G TUBE	01/07/2015
371	NDA/MAL/HDP/0 914	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	OSTEOTIDE	TERIPARATIDE [RECOMBINANT HUMAN PARATHYROID HORMONE (1-34)] INJECTION	250MCG/ML	VIRCHOW BIOTECH PVT LTD SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DISTRICT ANDHRA PRADESH	INDIA	PARENTERAL ORDINARY VIALS	1.0X3.0 ML VIAL,1.0X3.0 ML PREFILLED PEN	01/07/2015

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372	NDA/MAL/HDP/0920	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BUPITROY HEAVY	BUPIVACAINE HYDROCHLORIDE	5MG/ML	TROIKAA PHARMACEUTICALS LTD .SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0X4.0 ML VIAL	01/07/2012
373	NDA/MAL/HDP/0926	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	BACTOCLAV-375	AMOXICILLIN +CLAVULANATE POTASSIUM	250MG + 125MG	MICRO LABS LIMITED.PLOT 16, VEERASANDRA IND. AREA,ANEKAL TALUK, BANGALORE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET STRIP,1.0X2.0X10.0 TABLET STRIP	01/07/2004

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374	NDA/MAL/HDP/0 928	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	INSTACLOP 75	CLOPIDOGREL	75MG	AJANTA PHARMA LIMITEDPLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT- 392130 AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013
375	NDA/MAL/HDP/0 929	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	DUOQUIN	DIHYDROARTEMI SININ + PIPERAQUINE PHOSPHATE	40MG +320MG	IPCA LABORATORIES LTD PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X1.0X9.0 TABLET BLISTER,10.0X1.0X8 .0 TABLET BLISTER	01/07/2012

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376	NDA/MAL/HDP/0 938	FEROZSONS LABORATORIES LTD	HEALTHCARE LTD.	ESOMEGA 20MG	ESOMEPRAZOLE AS MAGNESSIUM TRIHYDRATE PELLETS	20MG	FEROZSONS LABORATORIES LTDAMANGARH- NOWSHERA, (KHYBER ☒ PAKHTOONKHWA), PAKISTAN	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER	01/07/2013
377	NDA/MAL/HDP/0 940	FEROZSONS LABORATORIES LTD	HEALTHCARE LTD.	ESOMEGA 40MG	ESOMEPRAZOLE AS MAGNESSIUM TRIHYDRATE PELLETS	40MG	FEROZSONS LABORATORIES LTDAMANGARH- NOWSHERA, (KHYBER ☒ PAKHTOONKHWA), PAKISTAN	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER	01/07/2013

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378	NDA/MAL/HDP/0 941	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ZAHA	AZITHROMYCIN	200MG/5ML	AJANTA PHARMA LIMITED31-0 MIDC INDUSTRIAL AREA CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA STATE	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X15.0 ML BOTTLE	01/07/2013
379	NDA/MAL/HDP/0 948	COSMOS LTD	ASTRA PHARMA (U) LIMITED	LORHISTINA SYRUP 5MG/5ML	LORATADINE	5MG/5ML	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL LIQUID ORDINARY LIQUIDS	1.0X60.0 ML BOTTLE	01/07/2013

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380	NDA/MAL/HDP/0 951	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	NORAD	STERILE NORADRENALINE CONCENTRATE	2MG/2ML	NEON LABORATORIES LTD PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY S C AMPOULES	1.0X5.0X2.0 ML AMPOULE	01/07/2013
381	NDA/MAL/HDP/0 952	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	EFFECTAL	CEFTRIAXONE	1G	NEON LABORATORIES LTD PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2013

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382	NDA/MAL/HDP/0 953	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	CIZCAN	CISPLATIN	10MG/10ML	NEON LABORATORIES LTD PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	01/07/2013
383	NDA/MAL/HDP/0 954	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	ANAWIN	BUPIVACAINE	50MG/20ML	NEON LABORATORIES LTD PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL RETARD OTHER VIALS	1.0X20.0 ML VIAL	01/07/2013



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384	NDA/MAL/HDP/0 957	MACK BROWN PHARMACEUTICAL S PVT LIMITED	SHURIK LTD	LYRED SYRUP	VITAMINE A + VITAMINE E ACETATE + ASCORBIC ACID + SELENIUM + ZINC	2500 IU + 10 IU + 50MG + 35MCG + 3MG	TORQUE PHARMACEUTICALS PVT LTDISAAPUR P.O DAPPAR 140056 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2012
385	NDA/MAL/HDP/0 959	AJANTA PHARMA LTD 31-0	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN DISPERSIBLE 20/120	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	AJANTA PHARMA LIMITEDPLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT- 392130 AJANTA PHARMA LIMITED PAITHANMANUFACT URING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X12.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X30.0X6 .0 TABLET BLISTER,1.0X30.0X1 2.0 TABLET BLISTER	01/07/2013

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386	NDA/MAL/HDP/0 969	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	ASOMEX-2.5	AMLODIPINE BESILATE	2.5MG	EMCURE PHARMACEUTICALS LTD LANE NO.3 PHASE II,SIDCO INDUSTRIAL COMPLEX,BARI- BRAHMANA JAMMU 181 133, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2005
387	NDA/MAL/HDP/0 974	SQUARE CEPHALOSPORINS LTD	GAMA PHARMACEUTICAL S (U) LIMITED	CEF-3	CEFIXIME	100MG/5ML	SQUARE CEPHALOSPORINS LTDKALIAKOIR, GAZIPUR – 1750, BANGLADESH	BANGLADESH	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X50.0 ML BOTTLE	01/07/2015

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388	NDA/MAL/HDP/0978	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	AMBROX 75 SR CAPSULE	AMBROXOL	75MG	SQUARE PHARMACEUTICALS LIMITED KALI AKOIR GAZIPUR - 1750, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2012
389	NDA/MAL/HDP/0981	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	CLOFENAC SR TABLETS	DICLOFENAC SODIUM	100MG	HOVID BERHAD (CHEMOR SITE)-LOT 56442, 71/2, JALAN IPOH/CHEMOR 31200, PERAK. MALAYSIA	MALAYSIA	ORAL SOLID RETARD FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008

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390	NDA/MAL/HDP/0 986	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CONVENTIN	GABAPENTIN	100MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2013
391	NDA/MAL/HDP/0 988	CADILA PHARMACEUTICAL S LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	CADITOR 20	ATORVASTATIN	20MG	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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392	NDA/MAL/HDP/0990	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FUSIDERM CREAM	FUSIDIC ACID	2%W/W	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2013
393	NDA/MAL/HDP/0995	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	FLUCOMOL	PARACETAMOL + PHENYLEPHRINE HCL + DEXTROMETHORPHAN HBR + CHLORPHENIRAMINE MALEATE	250MG + 5MG + 10MG + 2MG	LINCOLN PHARMACEUTICALS LTD-TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2014

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394	NDA/MAL/HDP/0997	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	GENUPHIL	GLUCOSAMINE SULPHATE SODIUM CHLORIDE+METH YLSULPHONYLMETHANE+CHONDROITIN SULPHATE	375MG+375MG+300MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
395	NDA/MAL/HDP/0999	EVA PHARMA	UNITED HEALTHCARE DISTRIBUTORS LTD	THIOEVA	THIOTIC ACID	600MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2014

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396	NDA/MAL/HDP/1000	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TROYCURIUM	ATRACURIUM	10MG/ML	TROIKAA PHARMACEUTICALS LIMITED THOL, DIST. MEHSANA-382728, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.5 ML AMPOULE	01/07/2012
397	NDA/MAL/HDP/1001	EVA PHARMA	UNITED HEALTHCARE DISTRIBUTORS LTD	THIOEVA	THIOTIC ACID	300MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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398	NDA/MAL/HDP/1002	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	CIPROKEN 750	CIPROFLOXACIN	750MG	SQUARE PHARMACEUTICALS LIMITED KALIAKOIR GAZIPUR – 1750, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2013
399	NDA/MAL/HDP/10030	SAKAR HEALTHCARE LIMITED -	TATA UGANDA LIMITED	NISTAN	NYSTATIN	100,000IU	SAKAR HEALTHCARE PVT LTDBLOCK NO. 10-13, NR. M.N DESAI PETRO PUMP, SARKHEJ-BAVLA ROAD, CHANGODAR, DIST: AHMEDABAD-382213, GUJARAT	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1X30 ML BOTTLE	17/05/2022



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400	NDA/MAL/HDP/1 0033	MEDOPHARM	PLANET PHARMACEUTICAL S UGANDA LTD	EMCAR	CARBAMAZEPINE	200 MG	MEDOPHARMNO. 34B, INDUSTRIAL AREA, MALUR- 563160, KARNATAKA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER,1.0X50.0X1 0.0 TABLET BLISTER,1.0X100.0X 1.0X10.0 TABLET BLISTER	14/07/2022
401	NDA/MAL/HDP/1 0034	AUROLAB	SWASTIK PHARMACEUTICAL LTD	M-FLOX	MOXIFLOXACIN HYDROCHLORIDE	0.5 %W/V	AUROLAB LIMITEDNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI " 625 020 TAMIL NADU INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	14/07/2022

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402	NDA/MAL/HDP/1 0036	MEDOPHARM	PLANET PHARMACEUTICAL S UGANDA LTD	MEDOMOL	PARACETAMOL	500 MG	MEDOPHARMNO. 34B, INDUSTRIAL AREA, MALUR- 563160, KARNATAKA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER,1.0X50.0X1 0.0 TABLET BLISTER,1.0X100.0X 1.0X10.0 TABLET BLISTER	14/07/2022
403	NDA/MAL/HDP/1 0037	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BORINI-K	LANSOPRAZOLE + TINIDAZOLE + CLARITHROMYCIN	30 MG + 500 MG + 250 MG	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X7.0X1.0X6.0 TABLET STRIP	14/07/2022

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404	NDA/MAL/HDP/1 0038	MEDOPHARM PRIVATE LIMITED	VITACARE LIMITED	CLEDOMOX 312.5 MG/5 ML	AMOXILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	312.5 MG/5 ML	MEDOPHARM PVT LIMITED NO. 50 KAYARAMBEDU VILLAGE, GUDUVANCHERY- 603202	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X100.0 ML CONTAINER	14/07/2022
405	NDA/MAL/HDP/1 0039	LEGIT MEDEQ 2007 LIMITED	LEGIT MEDEQ 2007 LIMITED	ZENMIC	TRANEXAMIC ACID	500MG/5 ML	ZEN PHARMA PVT LTD 75/1, GIDC. VAPI- 396 195 GUJARAT,	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0 ML AMPOULE, 1.0X1.0X10.0X5.0 ML AMPOULE	14/07/2022

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406	NDA/MAL/HDP/1 0041	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	PUMPINOX	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	20MG	PHARMA INTERNATIONAL CO. LTD AL QASTAL AIRPORT ROAD, P.O. BOX 334 AL JUBAIHA 11941, AMAAN	JORDAN	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X1.0X14.0 TABLET CONTAINER	06/07/2022
407	NDA/MAL/HDP/1 0042	GLOBELA PHARMA PVT. LTD.	SHREEJI CARE LIMITED	BACIPRO	CIPROFLOXACIN HYDROCHLORIDE	500 MG	GLOBELA PHARMA PVT.LTD.357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	19/07/2022

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

408	NDA/MAL/HDP/1 0043	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROYO- ADRENALINE	ADRENALINE ACID TARTRATE	1 MG/ML	SANJAR PHARMACEUTICALS LIMITEDSURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1X1X10X1 ML AMPOULE,	19/07/2022
409	NDA/MAL/HDP/1 0044	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	TERBI RO 250	TERBINAFINEHYD ROCHLORIDE	250 MG	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	19/07/2022

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

410	NDA/MAL/HDP/1 0045	PHARMACTIV FZCO	HEALTHCARE LTD.	SURGITEC	CEFOTAXIME SODIUM	1 G/VIAL	SURGE LABORATORIES (PVT) LTD.,,10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN.	PAKISTAN	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 1*5ML, WFI IN A CLEAR GLASS AMPOULE	19/07/2022
411	NDA/MAL/HDP/1 0046	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ARTEMETHER INJECTION 80 MG/ML	ARTEMETHER	80 MG/ ML	SCOTT-EDIL PHARMACIA LTD (UNIT I)56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X6.0X1.0 ML AMPOULE	19/07/2022

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

412	NDA/MAL/HDP/1 0048	JOSHPA AFRICA LTD	AAFIYA (A) LIMITED	AAFISUNATE 60 MG	ARTESUNATE	60 MG/VIAL	SANJAR PHARMACEUTICALS LIMITEDSURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1X60 MG VIAL	19/07/2022
413	NDA/MAL/HDP/1 0049	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ERYTHROMYCIN ESTOLATE ORAL SUSPENSION USP 125 MG/5ML	ERYTHROMYCIN ESTOLATE	125 MG/5ML	SCOTT-EDIL PHARMACIA LTD (UNIT I)56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	19/07/2022

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414	NDA/MAL/HDP/10052	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HI DEE 5000 IU	CHOLECALCIFEROL	5,000IU	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY OTHER CAPSULES	1X1X30 CAPSULE CONTAINER	19/07/2022
415	NDA/MAL/HDP/10054	LEGIT MEDEQ 2007 LIMITED	LEGIT MEDEQ 2007 LIMITED	HEMCROZ	IRON SUCROSE COMPLEX	20 MG/ML	ZEN PHARMA PVT LTD75/1, GIDC. VAPI-396 195 GUJARAT,	INDIA	PARENTERAL ORDINARY I V AMPOULES	1.0X1.0X5.0X5.0 ML AMPOULE	19/07/2022



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416	NDA/MAL/HDP/1 0055	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	FIMABUTE-400	CEFIXIME TRIHYDRATE	400MG	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	19/07/2022
417	NDA/MAL/HDP/1 0056	MEGA LIFSCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	AVARIN	SIMETHICONE+ ALVERINE CITRATE	300 MG + 60 MG	MEGA LIFSCIENCES PUBLIC CO. LTDPLANT 1; 384 MOO 4, SOI 6, BANGPOO INDUSTRIAL ESTATE, PATTANA 3 ROAD, PHRAEKSA, MUEANG, SAMUTPRAKARN 10280 THAILAND	THAILAND	ORAL SOLID ORDINARY OTHER CAPSULES	1X5X1X10 CAPSULE BLISTER	19/07/2022

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418	NDA/MAL/HDP/10059	SAGA LIFESCIENCES LTD	ABACUS PHARMA (AFRICA) LIMITED	FULCOVER	ITRACONAZOLE	100 MG	SAGA LABORATORIES .198/2 & 198/3, CHACHRAWADI, VASNA NO. CLARIS LIFE SCIENCE, TA SANAND, DIST. DIST: AHMEDABAD	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X1.0X4.0 CAPSULE STRIP	19/07/2022
419	NDA/MAL/HDP/1006	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TRIPRIDE-2	GLIMEPIRIDE + PIOGLITAZONE+ METFORMIN	2MG+15MG+500MG	MICRO LABS LTD 92 SIPCOT 92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2012

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420	NDA/MAL/HDP/1 0061	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	INSTACLOP PLUS	CLOPIDOGREL + ASPIRIN	75 MG + 75 MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	19/07/2022
421	NDA/MAL/HDP/1 0062	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BRUCLOX-500	CLOXACILLIN SODIUM	500MG	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	19/07/2022

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422	NDA/MAL/HDP/1 0063	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	CARDIONE 25	SPIRONOLACTON E	25MG	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	19/07/2022
423	NDA/MAL/HDP/1 0065	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	EFAVIRENZ, LAMIVUDINE AND TENOFIVIR DISOPROXIL FUMARATE TABLETS 600 MG/ 300 MG/ 300 MG	EFAVIRENZ + LAMIVUDINE + TENOFIVIR DISOPROXIL FUMARATE	600 MG + 300 MG + 300 MG	LAURUS LABS LTD (UNIT 2)PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X90.0 TABLET BOTTLE,1.0X30.0 TABLET BOTTLE	19/07/2022

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424	NDA/MAL/HDP/1 0066	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	FEMPRO	LETROZOLE	2.5MG	CIPLA LTDUNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X3X10 TABLET BLISTER	19/07/2022
425	NDA/MAL/HDP/1 0067	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	TRITINI	TINIDAZOLE	500MG	TRIVENI FORMULATIONS LTD PLOT NO. 52,53,54,63,62,64 ALEAP INDUSTRIUAL ESTATE SARAMPALLI VIJAYWADA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X25.0X4.0 TABLET BLISTER	19/07/2022

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426	NDA/MAL/HDP/1 0068	LEGIT MEDEQ 2007 LIMITED	LEGIT MEDEQ 2007 LIMITED	Z- ENOX	ENOXAPARIN SODIUM	10 MG/0.1 ML	ZEN PHARMA PVT LTD75/1, GIDC. VAPI- 396 195 GUJARAT,	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X0.6.0 ML PRE- FILLED SYRINGE, 1.0X0.4.0 ML PRE- FILLED SYRINGE	14/07/2022
427	NDA/MAL/HDP/1 0069	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	OPELAN ODT 5	OLANZAPINE	5 MG	MICRO LABS LIMITED .,92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X3.0X10.0 TABLET BLISTER	14/07/2022

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428	NDA/MAL/HDP/1007	COSMOS LTD	ASTRA PHARMA (U) LIMITED	ZINCOS DISPERSIBLE TABLETS 20MG	ZINC SULPHATE	20MG	COSMOS LIMITED, KENYARANGWE ROAD, OFF LUNGA ROAD, INDUSTRIAL AREA NAIROBI - KENYA	KENYA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
429	NDA/MAL/HDP/10074	TAURUS CHEMICALS (P) LTD.	HEALTHCARE LTD.	MAGACID SUSPENSION	ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE	(215 MG + 80 MG + 25 MG)/5ML	AL FAZAL PHARMA INDUSTRIES (PVT) LTD-PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X120.0 ML BOTTLE, 1.0X1.0X20.0 ML BOTTLE	14/07/2022

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430	NDA/MAL/HDP/1 0075	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	TELPER 80	TELMISARTAN	80 MG	GLOBELA PHARMA PVT.LTD.357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	14/07/2022
431	NDA/MAL/HDP/1 0076	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	RO-CID INJ	OMEPRAZOLE SODIUM	40MG	SANJAR PHARMA LLPSURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 MG VIAL + 10 ML WATER FOR INJECTION AMPOULE	14/07/2022



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432	NDA/MAL/HDP/1 0080	COMED CHEMICALS LTD.	LEGIT MEDEQ 2007 LIMITED	LYSER-D	DICLOFENAC SODIUM + SERRATIOPEPTID ASE	50 MG + 10 MG	COMED CHEMICALS LTD (UNIT-III)VILL: DASSOMATRA BADDI, NALAGARGH ROAD DISTRICT: SOLAN, PIN.173205 HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	14/07/2022
433	NDA/MAL/HDP/1 0081	INDIANA OPHTHALMICS	SWASTIK PHARMACEUTICAL LTD	IO-NEPA	NEPAFENAC	0.1%W/V	INDIANA OPHTHALMICS (135, 136, 137, GIDC ESTATE, WADHWAN- 363035)	INDIA	OPHTHALMIC SUSPENSIONS	1.0X1.0X5.0 ML Bottle	14/07/2022

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434	NDA/MAL/HDP/1 0083	THE SEARLE COMPANY LIMITED	SURGIPHARM (U) LIMITED	MORCET	ESCITALOPRAM OXALATE	20 MG	SEARLE PAKISTAN LTD..F-319, S.I.T.E., OPP. KESC POWER STATION, KARACHI	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X14.0 TABLET BLISTER	14/07/2022
435	NDA/MAL/HDP/1 0084	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	SEDAFOL	PROPOFOL	10 MG/ ML	ASPIRO PHARMA LIMITEDSY. NO. 321, BIOTECH PARK, PHASE-III, KARKAPATLA, MARKOOK MANDAL, SIDDIPET DISTRICT- 502 281, TELANGANA, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X20.0 ML VIAL	14/07/2022

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436	NDA/MAL/HDP/10087	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	AZUNATE	ARTESUNATE	60 MG/VIAL	MACLEODS PHARMACEUTICALS LTD. ..UNIT I/UNIT II, PLOT 25-27, SR. NO. 366, PREMIER IND. ESTATE, KACHIGAM, DAMAN (U.T)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X60.0 MG VIAL + 1* 1ML CLEAR GLASS AMPOULE OF 5%W/V SODIUM BICARBONATE + 1*5ML CLEAR GLASS AMPOULE OF 0.9%W/V SODIUM CHLORIDE	14/07/2022
437	NDA/MAL/HDP/10089	NABIQASIM INDUSTRIES (PVT) LIMITED	HEALTHCARE LTD.	CEFEXOL DS SUSPENSION	CEFIXIME TRIHYDRATE	200 MG/5 ML	NABIQASIM INDUSTRIES (PVT) LTD .17/24 KORANGI INDUSTRIAL AREA KORANGI KARACHI	PAKISTAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1X1X30 ML BOTTLE	14/07/2022

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438	NDA/MAL/HDP/1009	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BUPITROY 0.5%	BUPIVACAINE	5MG/ML	TROIKAA PHARMACEUTICALS LTD .SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL	01/07/2012
439	NDA/MAL/HDP/10090	NABIQASIM INDUSTRIES (PVT) LIMITED	HEALTHCARE LTD.	CEFEXOL SUSPENSION	CEFIXIME TRIHYDRATE	100 MG/5 ML	NABIQASIM INDUSTRIES (PVT) LTD .17/24 KORANGI INDUSTRIAL AREA KORANGI KARACHI	PAKISTAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1X1X30 ML BOTTLE	14/07/2022

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440	NDA/MAL/HDP/10091	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	PG-150	PREGABALIN	150 MG	ZOTA HEALTHCARE LIMITED PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY STATION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY CAPSULES	1X3X10 CAPSULE BLISTER,	14/07/2022
441	NDA/MAL/HDP/10092	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROTHISTRONE 5	NORETHISTERONE	5 MG	SYNOKEM PHARMACEUTICALS LTD-PLOT NO.- 35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	14/07/2022

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442	NDA/MAL/HDP/1 0093	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MUCOSIL BR	SALBUTAMOL + BROMHEXINE HYDROCHLORIDE + GUAIFENESIN + MENTHOL	2.0 MG + 4.0 MG + 100 MG + 1.0 MG	RAVIAN LIFE SCIENCE PVT LTD PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1X1X100 ML BOTTLE	18/07/2022
443	NDA/MAL/HDP/1 0095	COMED CHEMICALS LTD.	LEGIT MEDEQ 2007 LIMITED	RAPCO -20	RABEPRAZOLE SODIUM	20 MG	COMED CHEMICALS LTD (UNIT-III)VILL: DASSOMATRA BADDI, NALAGARGH ROAD DISTRICT: SOLAN, PIN.173205 HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	18/07/2022

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444	NDA/MAL/HDP/1 0096	COMED CHEMICALS LTD.	LEGIT MEDEQ 2007 LIMITED	ZACY- SR	ACECLOFENAC	200 MG	COMED CHEMICALS LTD (UNIT-III)VILL: DASSOMATRA BADDI, NALAGARGH ROAD DISTRICT: SOLAN, PIN.173205 HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	18/07/2022
445	NDA/MAL/HDP/1 0097	ALKEM LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	NULOC 20	ESOMEPRAZOLE MAGNESIUM	20 MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1X3X10 TABLET BLISTER	18/07/2022

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446	NDA/MAL/HDP/1 0098	ALKEM LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	NULOC 40	ESOMEPRAZOLE MANESIUM	40 MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1X3X10 TABLET BLISTER	18/07/2022
447	NDA/MAL/HDP/1 0099	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	GLYFERON 1000	METFORMIN HYDROCHLORIDE	1000 MG	BILIM ILAC SAN.VE TIC.A.SGEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X3X10 TABLET BLISTER	18/07/2022



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448	NDA/MAL/HDP/1 0100	HETERO LABS LTD	AIVEEN (U) LIMITED	PANTIN	PANTOPRAZOLE SODIUM SESQUIHYDRATE	40 MG/VIAL	ASPIRO PHARMA LIMITEDSY. NO. 321, BIOTECH PARK, PHASE-III, KARKAPATLA, MARKOOK MANDAL, SIDDIPET DISTRICT- 502 281, TELANGANA, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X40.0 MG VIAL	18/07/2022
449	NDA/MAL/HDP/1 0101	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	VILDARIL 50	VILDAGLIPTIN	50 MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	18/07/2022

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450	NDA/MAL/HDP/1 0102	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	VILDARIL 100	VILDAGLIPTIN	100 MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	18/07/2022
451	NDA/MAL/HDP/1 0103	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	COLDPIL	PARACETAMOL +PHENYLEPHRINE HYDROCHLORIDE + CHLORPEHNAMIN E MALEATE	650 MG + 5 MG + 2 MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1X10X10 TABLET BLISTER	18/07/2022

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452	NDA/MAL/HDP/1 0104	IND-SWIFT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	TELSWIFT 40	TELMISARTAN	40 MG	IND-SWIFT LIMITED /VILL-JAWAHARPUR, OFF NH21, DERABASSI DIST: MOHALI, PUNJAB	INDIA	TABLETS (COATED)	1.0X3.0X10.0 TABLET BLISTER	06/07/2022
453	NDA/MAL/HDP/1 0105	IND-SWIFT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	TELSWIFT 80	TELMISARTAN	80 MG	IND-SWIFT LIMITED /VILL-JAWAHARPUR, OFF NH21, DERABASSI DIST: MOHALI, PUNJAB	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER	06/07/2022

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454	NDA/MAL/HDP/1 0106	VEERAM HEALTHCARE (U) LIMITED	VEERAM HEALTHCARE (U) LIMITED	SERAFEN	DICLOFENAC POTASSIUM + SERRATIOPEPTID ASE	50 MG + 10 MG	KESAR PHARMA PVT LTD PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER, 1.0X2.0X10.0 TABLET BLISTER	14/07/2022
455	NDA/MAL/HDP/1 0107	VEERAM HEALTHCARE (U) LIMITED	VEERAM HEALTHCARE (U) LIMITED	EXPECT	AMBROXOL HYDROCHLORIDE + TERBUTALINE SULPHATE + GUAIFENESIN	(15 MG + 1.25 MG + 50 MG)/ 5 ML	KESAR PHARMA PVT LTD PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE, 1.0X1.0X30.0 ML BOTTLE	14/07/2022

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456	NDA/MAL/HDP/1 0108	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	PIRO 20	PIROXICAM	20 MG	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL SOLID ORDINARY CAPSULES	1X10X10 CAPSULE BLISTER	14/07/2022
457	NDA/MAL/HDP/1 0109	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	RO MIFEN 500	MEFENAMIC ACID	500 MG	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	14/07/2022

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458	NDA/MAL/HDP/1 0110	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	RO TAMIC 500	TRANEXAMIC ACID	500 MG	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X10X10 TABLET BLISTER	14/07/2022
459	NDA/MAL/HDP/1 0112	KESAR PHARMA	ABACUS PHARMA (AFRICA) LIMITED	KESKETO	KETOCONAZOLE	2 % W/W	KESAR PHARMA PVT LTD PLOT SURVEY NO. 50/2. VILLAGE BILSHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	14/07/2022

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460	NDA/MAL/HDP/10113	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	RO-PERICEM	PIROXICAM	20 MG	SCOTT-EDIL PHARMACIA LTD (UNIT I)56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1X10X10 CAPSULE BLISTER	14/07/2022
461	NDA/MAL/HDP/10114	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS 300/300 MG	LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE	300 MG + 300 MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED (CIPLAQCIL)PLOT 1-7, 1ST RING ROAD, LUZIRA INDUSTRIAL PARK	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	06/07/2022

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462	NDA/MAL/HDP/1 0115	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ASPIRIN DELAYED RELEASE TABLETS USP 75MG	ASPIRIN	75 MG	SCOTT-EDIL PHARMACIA LTD (UNIT I)-56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	14/07/2022
463	NDA/MAL/HDP/1 0117	FAES FARMA S.A	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	VENOSMIL	HIDROSMIN	200 MG	FAES FARMA SAMAXIMO AGUIRRE 14. 48940 LEIOA – SPAIN	SPAIN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	06/07/2022



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464	NDA/MAL/HDP/1 012	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	LOX 2%	LIDOCAINE	2% W/V	NEON LABORATORIES LTD PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY OTHER VIALS	1.0X50.0 ML VIAL,1.0X20.0 ML VIAL	01/07/2013
465	NDA/MAL/HDP/1 0129	HETERO LABS LTD	AIVEEN (U) LIMITED	DARUNAVIR AND RITONAVIR TABLETS 400 MG/50 MG	DARUNAVIR ETHANOLATE + RITONAVIR	400 MG + 50 MG	HETERO LABS PRIVATE LIMITED UNIT IIISURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) JEEDIMETLA, HYDERABAD-500 055, TELANGANA STATE,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	18/07/2022

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466	NDA/MAL/HDP/1 013	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	THIOSOL	THIOPENTAL SODIUM	500MG	NEON LABORATORIES LTD PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X20.0 ML VIAL	01/07/2013
467	NDA/MAL/HDP/1 0134	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	ISONIAZID/ RIFAPENTINE COATED TABLETS 300 MG + 300 MG	ISONIAZID + RIFAPENTINE	300MG +300MG	OXALIS LABS LIMITED VILLAGE THEDA, P.O LODHIMAJRA, TEHSIL, BADDI, DIST. SOLAN, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X12.0 TABLET STRIP	18/07/2022

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468	NDA/MAL/HDP/1 0135	RAPTAKOS, BRETT & CO. LTD.	EUROPA HEALTHCARE (U) LTD	ZEVAC SYRUP	ZINC ACETATE (AS DIHYDRATE)	20MG/5ML	RAPTAKOS BRETT & CO.LTD1ST POKHRAN ROAD,THANE 400 606	INDIA	ORAL LIQUID ORDINARY SYRUPS	1X1X60 ML BOTTLE	18/07/2022
469	NDA/MAL/HDP/1 0138	NABIQASIM INDUSTRIES (PVT) LIMITED	HEALTHCARE LTD.	CLARITHRO TABLETS	CLARITHROMYCIN	500MG	NABIQASIM INDUSTRIES (PVT) LTD .17/24 KORANGI INDUSTRIAL AREA KORANGI KARACHI	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1X1X10 TABLET BLISTER	18/07/2022

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470	NDA/MAL/HDP/1 014	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	TIDAZOL TABLETS	TINIDAZOLE	500MG	ELYS CHEMICAL INDUSTRIES LIMITED- ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X20.0X4.0 TABLET BLISTER	01/07/2015
471	NDA/MAL/HDP/1 0140	UNICHEM LABORATORIES LIMITEDV	EUROPA HEALTHCARE (U) LTD	ALDROL 5	DONEPEZIL HYDROCHLORIDE	5MG	UNICHEM LABORATORIES BADI- UNIT IIVILLAGE BHATAULI, BADDI HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	06/07/2022

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472	NDA/MAL/HDP/1 0141	UNICHEM LABORATORIES LIMITEDV	EUROPA HEALTHCARE (U) LTD	ALDROL 10	DONEPEZIL HYDROCHLORIDE	10MG	UNICHEM LABORATORIES BADI- UNIT IIVILLAGE BHATAULI, BADDI HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	06/07/2022
473	NDA/MAL/HDP/1 0144	VIRCHOW BIOTECH PVT LTD,	SURGIPHARM (U) LIMITED	CLASIPRO	BACILLUS CLAUSII SPORES	2 X 10 <sup>9</sup> SPORES/ 5 ML	VIRCHOW BIOTECH PRIVATE LIMITEDSURVEY NO. 172 PART, GAGILLAPUR, QUTHBULLPUR, RR DISTRICT, TELANGANA-500043	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X5.0 ML AMPOULE	06/07/2022

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474	NDA/MAL/HDP/1 0145	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	I-PILL	LEVONORGESTRE L	1.5MG	CIPLA LTD-UNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X1.0 TABLET BLISTER	12/13/2023
475	NDA/MAL/HDP/1 0146	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	UMBILICA GEL	CHLORHEXIDINE GLUCONATE	4%W/W	ATCO LABS LTD,B-18, S.I.T.E, KARACHI	PAKISTAN	TOPICAL EXTERNAL GELS AND SOLS	1X10 G TUBE	18/07/2022

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476	NDA/MAL/HDP/1 0148	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	RALEF 60	ETORICOXIB	60MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X7.0 TABLET BLISTER	18/07/2022
477	NDA/MAL/HDP/1 0149	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	RALEF 90	ETORICOXIB	90MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X7.0 TABLET BLISTER	18/07/2022

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478	NDA/MAL/HDP/1 015	DAWA LIMITED	SUPER MEDIC LTD	ORACEF	CEFALEXIN	250MG	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1X10X10 CAPSULE STRIP	01/07/2013
479	NDA/MAL/HDP/1 0150	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	RALEF 120	ETORICOXIB	120MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X7.0 TABLET BLISTER	18/07/2022



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480	NDA/MAL/HDP/1 0151	S KANT HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	FUNGARIN	MICONAZOLE	2%W/W	S KANT HEALTHCARE LIMITED1802 – 1805, G.I.D.C., PHASE III, VAPI -396195 GUJARAT, INDIA.	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X1.0X30.0 G TUBE	06/07/2022
481	NDA/MAL/HDP/1 0152	BIOFARMA PLASMA LIMITED LIABILITY COMPANY	ONCOPHARM (U) LTD	ALBUMIN- BIOPHARMA	HUMAN ALBUMIN	20G/100ML	BIOPHARMA PLASMA LIMITED LIABILITY COMPANY37-V KYIVSKA ST., BILA TSERKVA, KYIV REGION, 09100 - UKRAINE	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1X1X100 ML VIAL	18/07/2022

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482	NDA/MAL/HDP/1 0155	MEDIPAK LIMITED	HEALTHCARE LTD.	MEDISOL NS	SODIUM CHLORIDE	0.9%W/V	MEDIPAK LTD132/2/ INDUSTRIAL ESTATE KOT LAKHPAT, LAHORE	PAKISTAN	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	02/09/2022
483	NDA/MAL/HDP/1 0156	MEDIPAK LIMITED	HEALTHCARE LTD.	MEDISOL 5%	DEXTROSE	5%W/V	MEDIPAK LTD132/2/ INDUSTRIAL ESTATE KOT LAKHPAT, LAHORE	PAKISTAN	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	02/09/2022

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484	NDA/MAL/HDP/1 0164	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ASPIRIN TABLETS	ACETYLSALICYCLI C ACID	300MG	ELYS CHEMICAL INDUSTRIES LIMITED,-OFF ENTERPRISE ROAD, OPP HILLOCK-INN ROAD B, INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET STRIP,1.0X200.0 TABLET TIN,1.0X1000.0 TABLET TIN	02/09/2022
485	NDA/MAL/HDP/1 0168	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	LYFE	ORAL REHYDRATION SALT	N/A	ELYS CHEMICAL INDUSTRIES LIMITED,-OFF ENTERPRISE ROAD, OPP HILLOCK-INN ROAD B, INDUSTRIAL AREA	KENYA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X14.0 G SACHET,1.0X28.0 G SACHET	02/09/2022

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486	NDA/MAL/HDP/1 0169	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ORODAR	SULFADOXINE+PY RIMETHAMINE	500MG+25MG	ELYS CHEMICAL INDUSTRIES LIMITED,-OFF ENTERPRISE ROAD, OPP HILLOCK-INN ROAD B, INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X30.0X3.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	02/09/2022
487	NDA/MAL/HDP/1 017	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYCLOX	AMPICILLIN/CLOX ACILLIN	125MG/125MG	ELYS CHEMICAL INDUSTRIES LIMITEDROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2015

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488	NDA/MAL/HDP/1 0170	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	PREDNISOLONE TABLETS	PREDNISOLONE	5MG	ELYS CHEMICAL INDUSTRIES LIMITED,-OFF ENTERPRISE ROAD, OPP HILLOCK-INN ROAD B, INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	02/09/2022
489	NDA/MAL/HDP/1 0172	SURGE LABORATORIES (PVT.) LTD.	HEALTHCARE LTD.	SURGICOMB INJECTION 2G	CEFOPRAZONE SODIUM + SULBACTUM SODIUM	(1G + 1G)/VIAL	SURGE LABORATORIES (PVT) LTD.,,10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN.	PAKISTAN	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X2.0 G VIAL + 10ML WFI CLEAR GLASS AMPOULE	09/09/2022

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490	NDA/MAL/HDP/10173	APAROZA PHARMA LTD	APAROZA PHARMA LIMITED	ESCAPELLE	LEVONORGESTREL	1.5MG	GEDEON RICHTER PLC (H-1103 BUDAPEST, GYOMROI UT 19-21 HUNGARY)	HUNGARY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X1.0 TABLET BLISTER	29/09/2022
491	NDA/MAL/HDP/10177	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	METOCLOPRAMIDE TABLETS BP 10 MG	METOCLOPRAMIDE HYDROCHLORIDE	10 MG	CIRON DRUGS PHARMACEUTICALS PRIVATE LIMITED PLOT NO. 35-37, 43-45, CFC-B, DEWAN UDHYOG NAGAR, ALIYALI, PALGHAR – 401404, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	09/09/2022

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492	NDA/MAL/HDP/1018	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM CHLOR	CHLORAMPHENIC OL	250MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	100.0 CAPSULE CONTAINER,1000.0 CAPSULE CONTAINER,250.0 CAPSULE CONTAINER,500.0 CAPSULE CONTAINER,1.0X10.0 CAPSULE CONTAINER	01/07/1997
493	NDA/MAL/HDP/10183	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	TEXAKIND	TRANEXAMIC ACID	500MG/5ML	MANKIND PHARMA LIMITEDUNIT - II, VILLAGE KISHANPURA, P.O. JAMNIWALA, TEHSIL PAONTA SAHIB, DISTRICT SIRMOUR - 173025, HIMACHAL PRADESH - INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X4.0X5.0 ML AMPOULE	09/09/2022

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494	NDA/MAL/HDP/1 0185	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TURBOVAS-10	ROSUVASTATIN CALCIUM	10MG	MICRO LABS LIMITED, HOSURNO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0X10.0 TABLET BLISTER	09/09/2022
495	NDA/MAL/HDP/1 0186	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICALS LIMITED	AARLOFLOX OZ	OFLOXACIN + ORNIDAZOLE	200 MG + 500 MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X20.0X10.0 TABLET BLISTER	09/09/2022



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496	NDA/MAL/HDP/1 0187	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICAL S LIMITED	AARCET 5	CETIRIZINE HYDROCHLORIDE	5 MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	09/09/2022
497	NDA/MAL/HDP/1 0188	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICAL S LIMITED	AARLEFLOX 750	LEVOFLOXACIN HEMIHYDRATE	750 MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	09/09/2022

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498	NDA/MAL/HDP/1 0189	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICAL S LIMITED	ETRICOX 120	ETORICOXIB	120 MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022
499	NDA/MAL/HDP/1 0192	INFUGEN PHARMA PVT. LTD.	TATA UGANDA LIMITED	INFUTAXIM 1 GM	CEFOTAXIME SODIUM	1 G/ VIAL	ZEISS PHARMACEUTICALS PRIVATE LIMITEDPLOT NO. 72 EPIP-PHASE-1 JHARMAJRI BADDI DISTRICT SOLAN (H.P.)INNOVA CAPTAB LIMITED 1281/1, HILLTOP INDUSTRIAL ESTATE, NEAR EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN [H.P] - INDIA	INDIA	PARENTERAL RETARD DRY VIALS	1.0X1.0X1.0 G VIAL	09/09/2022

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500	NDA/MAL/HDP/1 0193	UNITED PHARMACEUTICAL S MANUFACTURING LIMITED COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VIVAZAC PLUS	IRBESARTAN + HYDROCHLOROT HIAZIDE	300 MG + 12.5 MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022
501	NDA/MAL/HDP/1 0196	CONCEPT PHARMACEUTICAL LTD	JEET PHARMACEUTICAL S LIMITED	PANTEC-DSR	PANTOPRAZOLE SODIUM SESQUIHYDRATE + DOMPERIDONE	40 MG + 30 MG	CONCEPT PHARMACEUTICALS LIMITEDKISHANPUR JAMALPUR ROORKEE DIST HARIDWAR - 247667 UTTARAKHAND, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	29/09/2022

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502	NDA/MAL/HDP/10197	CENTURION LABORATORIES PVT. LTD.	SHREEJI PHARMACEUTICALS LIMITED	LEVOZINE	LEVOCETIRIZINE DIHYDROCHLORIDE	5 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIOTECH PARK, MANJUSAR, TALSAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	09/09/2022
503	NDA/MAL/HDP/10199	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	GOFEN 200	IBUPROFEN	200 MG	MEGA LIFESCIENCES PUBLIC CO. LTD PLANT 1; 384 MOO 4, SOI 6, BANGPOO INDUSTRIAL ESTATE, PATTANA 3 ROAD, PHRAEKSA, MUEANG, SAMUTPRAKARN 10280 THAILAND	THAILAND	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X6.0X1.0X1.0X1.0 CAPSULE BLISTER	09/09/2022

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504	NDA/MAL/HDP/1020	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	PA-12	PARACETAMOL SUSTAINED RELEASE	1000MG	LINCOLN PHARMACEUTICALS LIMITED TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT - INDIA	INDIA	ORAL SOLID RETARD LAYERED TABLETS	1.0X10.0X1.0X12.0 TABLET BLISTER	01/07/2012
505	NDA/MAL/HDP/10200	UNITED PHARMACEUTICALS MANUFACTURING LIMITED COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SENERGY PLUS 5/160/12.5 MG	AMLODIPINE BESYLATE + VALSARTAN + HYDROCHLOROTHIAZIDE	5 MG + 160 MG + 12.5 MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/09/2022

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506	NDA/MAL/HDP/1 0201	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICAL S LIMITED	ETRICOX 60	ETORICOXIB	60 MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022
507	NDA/MAL/HDP/1 0207	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	TACROTAS-1	TACROLIMUS MONOHYDRARE	1 MG	INTAS PHARMACEUTICALS LTD.PLOT NO. 457, 458, & 191/218P,VILLAGE: MATODA, TAL. SANAND, AHMEDABAD, GUJARAT, 382210 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER,1.0X30.0 CAPSULE CONTAINER	09/09/2022

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508	NDA/MAL/HDP/1 0209	FERRER INTERNATIONAL, S.A.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TRAMAPA FORT 75MG/650MG	TRAMADOL HYDROCHLORIDE + PARACETAMOL	75 MG + 650 MG	FERRER INTERNATIONAL, S.AC/ JOAN BUSCALLA, 1-9 08173 SANT CUGAT DEL VALLES,	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	09/09/2022
509	NDA/MAL/HDP/1 0210	FDC LTD	AIVEEN (U) LIMITED	IOPROST EYE DROPS	LATANOPROST	0.005%W/V	FDC LIMITED, WALUJ .PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD	INDIA	OPHTHALMIC LIQUIDS	1.0X1.0X5.0 ML BOTTLE	29/09/2022

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510	NDA/MAL/HDP/1 0211	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICAL S LIMITED	SPAZNOL	DICLOFENAC SODIUM + PARACETAMOL + CHLORZOXAZON	50 MG + 325 MG + 250 MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	09/09/2022
511	NDA/MAL/HDP/1 0212	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICAL S LIMITED	SPASNIL P	MEFENAMIC ACID + PARACETAMOL	500 MG + 325 MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022



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512	NDA/MAL/HDP/1 0213	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	PANTAKIND-40	PANTOPRAZOLE SODIUM	40 MG	MANKIND PHARMA LIMITED UNIT - II, VILLAGE KISHANPURA, P.O. JAMNIWALA, TEHSIL PAONTA SAHIB, DISTRICT SIRMOUR - 173025, HIMACHAL PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X6.0X10.0 TABLET BLISTER	09/09/2022
513	NDA/MAL/HDP/1 0214	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ILAXTEN 20 MG TABLETS	BILASTINE	20MG	A. MENARINI MANUFACTURING LOGISTICS AND SERVICES SRL-VIA CAMPO DI PILE 67100 L'AQUILA (AQ)	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER, 1.0X1.0X4. 0 TABLET BLISTER	09/09/2022

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514	NDA/MAL/HDP/1 0215	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	PARACETAMOL INTRAVENOUS INFUSION	PARACETAMOL	10 MG/ML	ABARIS HEALTHCARE PVT. LTDSURVEY NO. 1407/11, VILLAGE RAJPUR, TAL KADI DIST. MEHSANA, GUJARAT-382740	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML CONTAINER	09/09/2022
515	NDA/MAL/HDP/1 0216	KLM LABORATORIES PVT. LTD.	REDDYS PHARMA LIMITED	LULIZOL CREAM	LULICONAZOLE	1%W/W	CURETECH SKINCAREPLOT NO. 33 & 34, PHASE IV, BHATOLI KALAN, BADDI DISTT. SOLAN (HP) 173205	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	29/09/2022

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516	NDA/MAL/HDP/1 0218	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	COMIT-100	SILDENAFIL CITRATE	100 MG	BLISS GVS PHARMA LIMITED10,11 & 12,DEWAN UDYOG NAGAR,ALIYALI,PALG HAR,MAHARASHTRA 401404,INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	09/09/2022
517	NDA/MAL/HDP/1 0219	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	COMIT-50	SILDENAFIL CITRATE	50 MG	BLISS GVS PHARMA LIMITED10,11 & 12,DEWAN UDYOG NAGAR,ALIYALI,PALG HAR,MAHARASHTRA 401404,INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	09/09/2022

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518	NDA/MAL/HDP/1022	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES -	UNITED HEALTHCARE DISTRIBUTORS LTD	CONVENTIN	GABAPENTIN	300MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2013
519	NDA/MAL/HDP/10225	LUKAS LAB LTD	PLUTO PHARMACEUTICALS LIMITED	LUSNAT 60	ARTESUNATE	60 MG	BLISS INDAS LIFESCIENCE P. LTD..PLOT 73-76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X60.0 MG VIAL + 1ML OF 5.0%W/V SODIUM BICARBONATE VIAL + 5ML OF 0.9%W/V SODIUM CHLORIDE VIAL	09/09/2022

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520	NDA/MAL/HDP/1 0226	LUKAS LAB LTD	PLUTO PHARMACEUTICAL S LIMITED	LUSNAT 120	ARTESUNATE	120 MG	BLISS INDAS LIFESCIENCE P. LTD..PLOT 73-76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X120.0 MG VIAL + 2ML OF 5.0%W/V SODIUM BICARBONATE VIAL + 10ML OF 0.9%W/V SODIUM CHLORIDE VIAL	09/09/2022
521	NDA/MAL/HDP/1 0228	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	SEPTOPRIM 960	TRIMETHOPRIM + SULFAMETHOXAZ OLE	160 MG + 800 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	09/09/2022

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522	NDA/MAL/HDP/10229	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	SEPTOPRIM - S	TRIMETHOPRIM + SULFAMETHOXAZOLE	(40 MG + 200 MG)/5 ML	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIOTECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	09/09/2022
523	NDA/MAL/HDP/1023	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ZINNIA P	LEVONORGESTREL + ETHINYLESTRADIOL	150MCG + 30MCG	MYLAN LABORATORIES LIMITED..PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, AHMEDABAD, GUJARAT, INDIA 382213 MYLAN LABORATORIES LIMITED.-PLOT NO. 1606-1608	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X28.0 TABLET BLISTER, 3.0X28.0 TABLET BLISTER	01/07/2013

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524	NDA/MAL/HDP/1 0230	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	MBEN	MEBENDAZOLE	100 MG/5 ML	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X30.0 ML BOTTLE	09/09/2022
525	NDA/MAL/HDP/1 0231	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	MBEN 100	MEBENDAZOLE	100 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X20.0X6.0 TABLET BLISTER	09/09/2022

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526	NDA/MAL/HDP/1 0232	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	TOPGYL	METRONIDAZOLE BENZOATE	125 MG/5 ML	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	09/09/2022
527	NDA/MAL/HDP/1 0233	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	PAINFORCE 400	IBUPROFEN	400 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	09/09/2022



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528	NDA/MAL/HDP/1 0234	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	TERBINA FORCE 250	TERBINAFINEHYD ROCHLORIDE	250 MG	MANKIND PHARMA LIMITED UNIT - II, VILLAGE KISHANPURA, P.O. JAMNIWALA, TEHSIL PAONTA SAHIB, DISTRICT SIRMOUR - 173025, HIMACHAL PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022
529	NDA/MAL/HDP/1 0235	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	LOFNAC GEL	LINSEED OIL + DICLOFENAC DIETHYLAMINE + METHYL SALICYLATE + MENTHOL	3.00%W/W + 1.16% W/W + 10.00%W/W + 5.00%W/W	KREMOINT PHARMA PVT LTD PLANT IIB-8, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST) DIST. THANE 421506	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X1.0X30.0 G TUBE	09/09/2022

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530	NDA/MAL/HDP/1 0239	B&O PHARM	TRIDEM PHARMA UGANDA LIMITED	ZITMYC	AZITHROMYCIN	500MG	CSPC OUYI PHARMACEUTICAL CO. LTD.WORKSHOPS 112,113 AND 117 PLOT NO. 88 YANGZI ROAD,ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA	CHINA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	09/09/2022
531	NDA/MAL/HDP/1 0240	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	OLMESAR 40	OLMESARTAN MEDOXOMIL	40MG	MACLEODS PHARMACEUTICALS LIMITED, UNIT VIVILLAGE THEDA, KHARUNI LODHI MAJRA RD, TEHSIL BADDI N2, DISTRICT SOLAN, HIMACHAL PRADESH-174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	09/09/2022

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532	NDA/MAL/HDP/10241	S K AGE EXPORTS	DAVIMED PHARMA LIMITED	LARIACT FORTE	ARTEMETHER + LUMEFANTRINE	80 MG + 480 MG	S KANT HEALTHCARE LIMITED1802 – 1805, G.I.D.C., PHASE III, VAPI -396195 GUJARAT, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X6.0 TABLET BLISTER	09/09/2022
533	NDA/MAL/HDP/10242	EMCURE PHARMACEUTICALS LTD -	HARLEYS UGANDA LIMITED	INSTGRA	DOLUTEGRAVIR SODIUM	50MG	EMCURE PHARMACEUTICALS LIMITEDPLOT NO. P-2. ITBT PARK, PHASE II, MIDC, HINJWADI PUNE 411057, MHARASHTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE	09/09/2022

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534	NDA/MAL/HDP/1 0246	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICAL S LTD	GLENDES	DESLORATADINE	5MG	GLENMARK PHARMACEUTICALS LIMITED PLOT NO. S - 7, COLVALE, INDUSTRIAL ESTATE COLVALE, BARDEZ 403513, GOA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	19/09/2022
535	NDA/MAL/HDP/1 0247	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	MOXIKIND-CV 228.5	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	200MG/5ML + 28.5MG/5ML	COPMED PHARMACEUTICALS PVT LTD-UNIT II. ,PLOT 50, GONDPUR INDUSTRIAL AREA, PAONTA, SAHIB, SIRMOUR, HIMACHAL PRADESH- 173025, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X100.0 ML BOTTLE	09/09/2022

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536	NDA/MAL/HDP/1 0249	FDC LTD	AIVEEN (U) LIMITED	IOPROST – T	LATANOPROST + TIMOLOL MALEATE	(50 MCG + 5 MG)/ML	FDC LIMITED, WALUJ .PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD	INDIA	OPHTHALMIC DROPS	1.0X1.0X2.5 ML BOTTLE	09/09/2022
537	NDA/MAL/HDP/1 0250	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	SINUTAB SINUS PAIN EXTRA STRENGTH	CODEINE PHOSPHATE +CHLORPHENIRA MINE MALEATE +PSEUDOEPHEDRI NE HYDROCHLORIDE + PARACETAMOL	10 MG + 2 MG + 30 MG + 500 MG	JOHNSON & JOHNSON (PTY) LTD241 MAIN ROAD, RETREAT, 7945, CAPE TOWN	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X12.0 TABLET BLISTER	09/09/2022

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538	NDA/MAL/HDP/1 0251	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CITADONE	BETAMETHASONE	0.6 MG/5 ML	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE	09/09/2022
539	NDA/MAL/HDP/1 0254	CENTURION LABORATORIES PVT. LTD.	SHREEJI PHARMACEUTICAL S LIMITED	AZICEN 500	AZITHROMYCIN	500MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	09/09/2022

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540	NDA/MAL/HDP/1 0258	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SENERGY PLUS 5/160 25 MG	AMLODIPINE BESYLATE + VALSARTAN + HYDROCHLOROT HIAZIDE	5 MG + 160 MG + 25 MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022
541	NDA/MAL/HDP/1 0259	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SENERGY PLUS 10/160 12.5 MG	AMLODIPINE BESYLATE + VALSARTAN + HYDROCHLOROT HIAZIDE	10 MG + 160 MG + 12.5 MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022

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542	NDA/MAL/HDP/1 0261	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	NTCLOT-C75	CLOPIDOGREL BILSULFATE	75 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	09/09/2022
543	NDA/MAL/HDP/1 0262	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROFLOX	OFLOXACIN	0.3%W/V	AUROLAB LIMITED NO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI - 625 020 TAMIL NADU INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	19/09/2022



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544	NDA/MAL/HDP/1 0263	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	WORMAID ORAL SUSPENSION	ALBENDAZOLE	200 MG/5ML	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X10.0 ML BOTTLE	09/09/2022
545	NDA/MAL/HDP/1 0267	SAGA LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	PROTOZOX-500	NITAZOXANIDE	500MG	SAGA LIFESCIENCES LIMITED SURVEY NO. 198/2 & 198/3, CHACHRAWADI VASNA, TA-SANAND, DIST. AHMEDABAD - 382210, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	09/09/2022

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546	NDA/MAL/HDP/1 0268	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	WORMAID TABLET	ALBENDAZOLE	400 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X1.0 TABLET BLISTER	09/09/2022
547	NDA/MAL/HDP/1 0269	NATIONAL PHARMACEUTICAL INDUSTRIES CO.	MEDVIN PHARMA LIMITED	DIOCLAV 625 MG	AMOXICILLIN + CLAVULANATE POTASSIUM	500 MG + 125 MG	NATIONAL PHARMACEUTICAL INDUSTRIES COMPANY OMANP.O.BOX 120, RUSAYL, POSTAL CODE-124, SULTANATE OF OMAN	OMAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET STRIP	09/09/2022

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

548	NDA/MAL/HDP/1 0280	INDCHEMIE HEALTH SPECIALITIES PVT. LTD.	NUMED STORES SMC LIMITED	ZENOXIM 500	CEFUROXIME AXETIL	500 MG	INDCHEMIE HEALTH SPECIALITIES PVT. LTDVILLAGE-THANA, BADDI, DIST. SOLAN, HIMACHAL PRADESH- 173 205.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	09/09/2022
549	NDA/MAL/HDP/1 0281	PLANET PHARMACEUTICAL S UGANDA LTD	PLANET PHARMACEUTICAL S UGANDA LTD	H- CURE ES	ESOMEPRAZOLE MAGNESIUM + CLARITHROMYCIN + TINIDAZOLE	40MG + 500MG + 500MG	FREDUN PHARMACEUTICALS LIMITED,14,15,16 - ZORABIAN INDUSTRIAL COMPLEX, VEOOR, PALGHAR (E), THANE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X7.0X1.0X6.0 TABLET BLISTER	09/09/2022

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

550	NDA/MAL/HDP/1 0282	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	MUPIWAYS	MUPIROCIN	2.0 W/W	NEXT WAVERAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X10.0 G TUBE	09/09/2022
551	NDA/MAL/HDP/1 0283	DAWA LIMITED-	SUPER MEDIC LTD	DAZOLE	CLOTRIMAZOLE	100MG	DAWA LIMITEDPLOT NO. 7879/8 BABADOGO ROAD, RUARAKA P. O. BOX 16633-00620 NAIROBI, KENYA	KENYA	VAGINAL TABLETS	1.0X1.0X6.0 PESSARY BLISTER	09/09/2022

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

552	NDA/MAL/HDP/1 0284	NATIONAL PHARMACEUTICAL INDUSTRIES CO.	MEDVIN PHARMA LIMITED	MACROMAX 500	AZITHROMYCIN	500MG	NATIONAL PHARMACEUTICAL INDUSTRIES COMPANY OMANP.O.BOX 120, RUSAYL, POSTAL CODE-124, SULTANATE OF OMAN	OMAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	09/09/2022
553	NDA/MAL/HDP/1 0285	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	DOLUTEGRAVIR SODIUM TABLET FOR ORAL SUSPENSION (DISPERSIBLE TABLETS) 10MG	DOLUTEGRAVIR SODIUM	10 MG	MACLEODS PHARMACEUTICALS LTD ,.PHASE I & II, PLOT NO. 25-27 SURVEY NO. 366, PREMIERE INDUSTRIAL ESTATE, KACHIGAN, DAMAN- 396210	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X90.0 TABLET CONTAINER	09/09/2022

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554	NDA/MAL/HDP/1 0286	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	PERLEX 250	CEFALEXIN MONOHYDRATE	250 MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	09/09/2022
555	NDA/MAL/HDP/1 0287	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	VILDA DENK 50 MG	VILDAGLIPTIN	50 MG	DENK PHARMA GMBH & CO. KGGOLLSTR. 1, 84529, TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER	09/09/2022

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556	NDA/MAL/HDP/1 0292	SAGA LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	SPASMOTRIT	DICYCLOMINE HYDROCHLORIDE + PARACETAMOL	20MG + 500MG	SAGA LIFESCIENCES LIMITEDSURVEY NO. 198/2 & 198/3, CHACHRAWADI VASNA, TA-SANAND, DIST. AHMEDABAD - 382210, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	09/09/2022
557	NDA/MAL/HDP/1 0294	ALTHEA PHARMA PVT LTD.	JOINT MEDICAL STORE (UPMB - UCMB)	ALTCIP	CIPROFLOXACIN	200MG	ALTHEA PHARMA PRIVATE LIMITEDWORKS: PLOT NO. 374, SHED NO. 'E', ALPHA INDL. PARK, ATHIAWAD, DABHEL, NANI DAMAN - 396210 (U.T.), INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	09/09/2022

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558	NDA/MAL/HDP/1 0296	LUPIN LIMITED-	AIVEEN (U) LIMITED	RIFAMPIN, ISONIAZID, PYRAZINAMIDE, ETHAMBUTOL HYDROCHLORIDE TABLETS USP150/75/400/2 75MG	RIFAMPIN + ISONIAZID + PYRAZINAMIDE + ETHAMBUTOL HYDROCHLORIDE	150MG + 75MG + 400MG + 275MG	LUPIN LTDA-28/1, M.I.D.C., CHIKALTHANA, AURANGABAD- 431210, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X24.0X14.0 TABLET BLISTER	09/09/2022
559	NDA/MAL/HDP/1 0297	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	ACECLAV 1000	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	875 MG + 125 MG	MEDICEF PHARMA- NO. 28, PHASE 1, EPIP, JHARRMAJRI, BADDI, DIST SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	09/09/2022



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560	NDA/MAL/HDP/1 0298	ZOTA HEALTHCARE LTD	HARLEYS UGANDA LIMITED	COXZOTA 90	ETORICOXIB	90 MG	ZOTA HEALTHCARE LIMITEDPLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY SATTION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022
561	NDA/MAL/HDP/1 0299	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	ACECLAV 625	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500 MG + 125 MG	MEDICEF PHARMA- NO. 28, PHASE 1, EPIP, JHARRMAJRI, BADDI, DIST SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	09/09/2022

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562	NDA/MAL/HDP/1030	LABORATORIOS SALVAT SA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MALACUR	DIHYDROARTEMISININ + PIPERAQUINE PHOSPHATE	40MG + 320MG	CIRON DRUGS PHARMACEUTICALS PRIVATE LTD,35-37, 43-45, CFC-B DEWAN UDYOG NAGAR, ALIYALI, DIST - PALGHAR 401 404, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X12.0 TABLET BLISTER,1.0X1.0X9.0 TABLET BLISTER	01/07/2014
563	NDA/MAL/HDP/10300	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	ACECLAV 375	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	250 MG + 125 MG	MEDICEF PHARMA- NO. 28, PHASE 1, EPIP, JHARRMAJRI, BADDI, DIST SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	09/09/2022

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564	NDA/MAL/HDP/1 0303	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DAPZIN-5	DAPAGLIFLOZIN	5 MG	MICRO LABS LIMITED, HOSURNO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022
565	NDA/MAL/HDP/1 0304	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DAPZIN-10	DAPAGLIFLOZIN	10 MG	MICRO LABS LIMITED, HOSURNO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022

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566	NDA/MAL/HDP/1 0305	SAGA LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	SPASCOLIC	DICYCLOMINE HYDROCHLORIDE + MEFENAMIC ACID	10 MG + 250 MG	SAGA LIFESCIENCES LIMITEDSURVEY NO. 198/2 & 198/3, CHACHRAWADI VASNA, TA-SANAND, DIST. AHMEDABAD - 382210, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	09/09/2022
567	NDA/MAL/HDP/1 0307	ZOTA HEALTHCARE LTD	HARLEYS UGANDA LIMITED	DESLOZED-5	DESLORATADINE	5 MG	ZOTA HEALTHCARE LIMITEDPLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY SATTION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	09/09/2022

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568	NDA/MAL/HDP/1 031	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MOXIFLOX	MOXIFLOXACIN	400MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X1.0X5.0 TABLET BLISTER	01/07/2013
569	NDA/MAL/HDP/1 0310	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ZINRO INFUSION	ORNIDAZOLE	500MG/100ML	ABACUS PARENTERAL DRUGS LIMITEDPLOT 114, BLOCK 191, KINGA	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	09/09/2022

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570	NDA/MAL/HDP/1 0311	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	LOPINAVIR AND RITONAVIR TABLETS USP	LOPINAVIR + RITONAVIR	200MG + 50MG	LAURUS LABS LTD (UNIT 2)PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X120.0 TABLET BOTTLE	09/09/2022
571	NDA/MAL/HDP/1 0313	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	LOPINAVIR AND RITONAVIR TABLETS USP	LOPINAVIR + RITONAVIR	100MG + 25MG	LAURUS LABS LTD (UNIT 2)PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET BOTTLE	09/09/2022

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572	NDA/MAL/HDP/1 0315	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	INDOMETHACIN	INDOMETHACIN	25MG	M/S SCOTT-EDIL PHARMACIA LIMITED-56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE TIN,1.0X500.0 CAPSULE TIN,1.0X10.0X10.0 CAPSULE BLISTER	01/07/2008
573	NDA/MAL/HDP/1 0317	Y.S.P. INDUSTRIES (M) SDN. BHD.	ROYAL PHARMA 2011 LIMITED	VOREN SUPPOSITORY 100 MG	DICLOFENAC SODIUM	100MG	Y.S.P INDUSTRIES (M) SDN BHN.LOT 3, 5 & 7, JALAN P/7, SECTION 13, KAWASAN PENDUSTRIAN BANDAR BARU BANGI, 43000, KAJANG, SELANGOR, MALAYSIA	MALAYSIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY STRIP	09/09/2022

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574	NDA/MAL/HDP/1 032	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ARTHFREE 20	LEFLUNOMIDE	20MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2013
575	NDA/MAL/HDP/1 0320	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	METROSCOT 125MG/5ML	METRONIDAZOLE BENZOATE	125MG/5ML	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	09/09/2022



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576	NDA/MAL/HDP/1 0323	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	XELTIN	TOFACITINIB CITRATE	5MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022
577	NDA/MAL/HDP/1 0324	APEX LABORATORIES PRIVATE LIMITED	NORVIK ENTERPRISES LIMITED	ZINCOVIT TABLETS	VITAMIN A (AS ACETATE) + VITAMIN D3 (CHOLECALCIFER OL) + VITAMIN E (AS DL- TOCOPHERYL ACETATE) + THIAMINE NITRATE + RIBOFLAVIN + PYRIDOXINE HYDROCHLORIDE + CYANOCOBALAMI N+	5000IU + 400IU + 15MG +10MG + 10MG + 2MG + 7.5MCG + 50MG + 10MG + 75 MG + 30MG + 2.8MG + 2MG + 63MG +70MCG	APEX LABORATORIES PRIVATE LIMITED- PLANT 1-B-23, SIDCO PHARMACEUTICAL COMPLEX ALATHUR, KANCHEEPURAM DISTRICT 603 110	INDIA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER	09/09/2022

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578	NDA/MAL/HDP/1 0325	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	ONCET	CETIRIZINE DIHYDROCHLORID E	5MG/5ML	MEDLEY PHARMACEUTICALS LTD PLOT 18 & 19 SURVEY NO. 378/7&8, 379/2&3 ZARI CAUSEWAY ROAD, KACHIGAM DAMAN-396210, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE	09/09/2022
579	NDA/MAL/HDP/1 0326	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	RISEOL 50	TRAMADOL HYDROCHLORIDE	50MG	SUNRISE INTERNATIONAL LABS LTD PLOT NO. 100, LANE-5, SECTOR II, PHASE-II, IDA, CHERLAPALLY INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	19/09/2022

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580	NDA/MAL/HDP/1 033	FAES FARMA S.A	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DYNAMOGEN	GLUTODINE (CYPROHEPTADIN E ALPHA- KETOGLUTARATE) + ARGININE ASPARTATE	3MG +1G	FAES FARMA, S.A MAXIMO AGUIRRE, 14, LEJONA 48940 VIZCAYA	SPAIN	ORAL LIQUID ORDINARY LIQUIDS	1.0X20.0X10.0 ML SACHET	01/07/2015
581	NDA/MAL/HDP/1 0332	MIDDLE EAST PHARMACEUTICAL INDUSTRIES CO. LTD. (AVALON PHARMA)	GAMA PHARMACEUTICAL S (U) LIMITED	AVOCOM	MOMETASONE FUROATE	0.05%W/W	MIDDLE EAST PHARMACEUTICAL INDUSTRIES COMPANY LIMITED (AVALON PHARMA)P.O. BOX 4180, RIYADH 11491, 2ND INDUSTRIAL CITY, RIYADH, SAUDI ARABIA	SAUDI ARABIA	NASAL TOPICAL PRESSURISED AEROSOLS	1.0X1.0X120.0 METERED DOSE BOTTLE	19/09/2022

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582	NDA/MAL/HDP/1 0335	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	PRIDOCAINE	LIDOCAINE + PRILOCAINE	2.5% W/W + 2.5%W/W	GLOBAL NAPI PHARMACEUTICALS- 2ND INDUSTRIAL ZONE, ST 18, 6TH OCTOBER CITY	EGYPT	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	09/09/2022
583	NDA/MAL/HDP/1 0338	NEOMI PHARMACEUTICAL S PVT LTD -	ROYAL PHARMA 2011 LIMITED	ROART 20/120	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X24.0 TABLET BLISTER	09/09/2022

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584	NDA/MAL/HDP/1 034	VOGEN LABORATORIES LTD	BUFFALO HEALTH CARE LTD	DURAMOX	AMOXICILLIN	250MG/5ML	VOGEN LABORATORIES LTD70, M.HERACLEOUS STR. AYIOS ATHANASIOS INDUSTRIAL AREA, LIMASSOL, CYPRUS	CYPRUS	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2007
585	NDA/MAL/HDP/1 0340	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	KERELLA	BETAMETHASONE DIPROPIONATE + SALICYLIC ACID	(0.5 MG+ 220 MG)/G	GLOBAL NAPI PHARMACEUTICALS- 2ND INDUSTRIAL ZONE, ST 18, 6TH OCTOBER CITY	EGYPT	TOPICAL EXTERNAL LOTIONS	1.0X1.0X30.0 ML BOTTLE	09/09/2022

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586	NDA/MAL/HDP/1 0343	DAWA LIMITED-	SUPER MEDIC LTD	KENAZOLE	KETOCONAZOLE	2%W/W	DAWA LIMITEDPLOT NO. 7879/8 BABADOGO ROAD, RUARAKA P. O. BOX 16633-00620 NAIROBI, KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	09/09/2022
587	NDA/MAL/HDP/1 0346	EAST AFRICAN (INDIA) OVERSEAS	ROYAL PHARMA 2011 LIMITED	LACTORIV	LACTULOSE	10 G/15 ML	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X120.0 ML BOTTLE	09/09/2022

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588	NDA/MAL/HDP/1 0349	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	GLUMAC	ARTEMETHER + LUMEFANTRINE	80MG + 480MG	GUILIN PHARMACEUTICAL CO LTD .NO. 43, QULIDIAN ROAD, GUILIN 541004	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X6.0 TABLET BLISTER,30.0X6.0 TABLET BLISTER	09/09/2022
589	NDA/MAL/HDP/1 0353	BIOMATRIX HEALTHCARE PVT LTD.-	MEDIWORLD PHARMA AFRICA LTD	PAINAID	PARACETAMOL + IBUPROFEN + CAFFEINE	400 MG + 325 MG + 40 MG	BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD – 382 220, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	09/09/2022

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590	NDA/MAL/HDP/1 0355	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	RIVATAS 15	RIVAROXABAN	15 MG	INTAS PHARMACEUTICALS LTD.PLOT NO. 457, 458, & 191/218P,VILLAGE: MATODA, TAL. SANAND, AHMEDABAD, GUJARAT, 382210 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022
591	NDA/MAL/HDP/1 0356	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	RIVATAS 20	RIVAROXABAN	20MG	INTAS PHARMACEUTICALS LTD.PLOT NO. 457, 458, & 191/218P,VILLAGE: MATODA, TAL. SANAND, AHMEDABAD, GUJARAT, 382210 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X0.01 TABLET BLISTER	09/09/2022



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592	NDA/MAL/HDP/1 0358	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	VOLDIC - K	DICLOFENAC POTASSIUM	50MG	PHARMA INTERNATIONAL CO. LTD AL QASTAL AIRPORT ROAD, P.O. BOX 334 AL JUBAIHA 11941, AMAAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	09/09/2022
593	NDA/MAL/HDP/1 0361	AFRICURE PHARMACEUTICAL S (INDIA) PVT. LTD	AFRICURE PHARMACEUTICAL S U LIMITED	AFRICAL	CALCIUM LACTATE	300 MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9- 12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1X10X10 TABLET BLISTER	19/09/2022

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594	NDA/MAL/HDP/1 0363	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	RO - AMIKACIN	AMIKACIN SULFATE	500 MG/2 ML	SANJAR PHARMA LLPSURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X2.0 ML VIAL	19/09/2022
595	NDA/MAL/HDP/1 0365	MYLAN LABORATORIES LIMITED-	KIMSY MEDS LTD	MYLTEGA DT	DOLUTEGRAVIR SODIUM	10MG	MYLAN LABORATORIES LTD PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR - 454775; DIST; DHAR; MADHYA PRADESH;	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X90.0 TABLET BOTTLE	09/09/2022

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596	NDA/MAL/HDP/1 0369	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SITAPRIL 50	SITAGLIPTIN PHOSPHATE MONOHYDRATE	50MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022
597	NDA/MAL/HDP/1 0370	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SITAPRIL 100	SITAGLIPTIN PHOSPHATE MONOHYDRATE	100MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022

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598	NDA/MAL/HDP/1 0371	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROLEXIN 250	CEFALEXIN MONOHYDRATE	250MG	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	19/09/2022
599	NDA/MAL/HDP/1 0376	SURGE LABORATORIES (PVT.) LTD.	HEALTHCARE LTD.	SURGICOMB 1G INJECTION	CEFOPRAZONE SODIUM + SULBACTUM SODIUM	0.5G + 0.5G	SURGE LABORATORIES (PVT) LTD.,,10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN.	PAKISTAN	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL + 1*5ML AMPOULE OF WFI	09/09/2022

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600	NDA/MAL/HDP/1 0378	CENTURION LABORATORIES PVT. LTD.	SHREEJI PHARMACEUTICAL S LIMITED	ESOMIZAP	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	09/09/2022
601	NDA/MAL/HDP/1 0379	ACINO PHARMA (PTY) LTD	LABOREX UGANDA LIMITED	ORATANE® 10 MG	ISOTRETINOIN	10MG	DOUGLAS MANUFACTURING LIMITED CORNER TE PAI PLACE AND CENTRAL PARK DRIVE, LINCOLN, AUCKLAND 0610 - NEW ZEALAND SWISS CAPS AG HUSENSTRASSE 35, CH-9533 KIRCHBERG (SG) - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X4.0X15.0 CAPSULE BLISTER	19/09/2022

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602	NDA/MAL/HDP/1 038	SQUARE CEPHALOSPORINS LTD	GAMA PHARMACEUTICAL S (U) LIMITED	CEF-3	CEFIXIME TRIHYDRATE	200MG	SQUARE CEPHALOSPORINS LTDKALIAKOIR, GAZIPUR – 1750, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X6.0 CAPSULE BLISTER	01/07/2014
603	NDA/MAL/HDP/1 0380	ACINO PHARMA (PTY) LTD	LABOREX UGANDA LIMITED	ORATANE® 20 MG	ISOTRETINOIN	20MG	DOUGLAS MANUFACTURING LIMITEDCORNER TE PAI PLACE AND CENTRAL PARK DRIVE, LINCOLN, AUCKLAND 0610 - NEW ZEALAND SWISS CAPS AG HUSENSTRASSE 35, CH-9533 KIRCHBERG (SG) - SWITZERLAND	NEW ZEALAND SWITZERLAND	ORAL SOLID ORDINARY OTHER CAPSULES	1X4X15 CAPSULE BLISTER	19/09/2022

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604	NDA/MAL/HDP/1 0381	ACINO PHARMA (PTY) LTD	LABOREX UGANDA LIMITED	ORATANEÂ® 40 MG	ISOTRETINOIN	40MG	DOUGLAS MANUFACTURING LIMITEDCORNER TE PAI PLACE AND CENTRAL PARK DRIVE, LINCOLN, AUCKLAND 0610 - NEW ZEALAND SWISS CAPS AG HUSENSTRASSE 35, CH-9533 KIRCHBERG (SG) - SWITZERLAND	NEW ZEALAND	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X15.0 CAPSULE BLISTER	19/09/2022
605	NDA/MAL/HDP/1 0382	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICAL S LIMITED	PINN-TRYPTILLIN	AMITRIPTYLINE HYDROCHLORIDE	25MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	09/09/2022

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606	NDA/MAL/HDP/1 0385	XL LABORATORIES PRIVATE LIMITED-	ROYAL PHARMA 2011 LIMITED	SOFKOF	DEXTROMETHOR PHAN HYDROBROMIDE + PHENYLEPHRINE HYDROCHLORIDE + CHORPHENIRAMI NE MALEATE	10MG + 5MG + 2MG	XL LABORATORIES PRIVATE LIMITEDA- 141, EPIP INDUSTRIAL AREA, NEEMRANA, DIST. ALWAR, RAJASTHAN - 301705 (INDIA)	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	19/09/2022
607	NDA/MAL/HDP/1 0386	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	OLMAC 5	OLANZAPINE	5MG	MACLEODS PHARMACEUTICALS LIMITED, UNIT VIVILLAGE THEDA, KHARUNI LODHI MAJRA RD, TEHSIL BADDI N2, DISTRICT SOLAN, HIMACHAL PRADESH-174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022



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608	NDA/MAL/HDP/1 0387	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	OLMAC 10	OLANZAPINE	10MG	MACLEODS PHARMACEUTICALS LIMITED, UNIT VIVILLAGE THEDA, KHARUNI LODHI MAJRA RD, TEHSIL BADDI N2, DISTRICT SOLAN, HIMACHAL PRADESH-174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022
609	NDA/MAL/HDP/1 0389	EAST AFRICAN (INDIA) OVERSEAS	ROYAL PHARMA 2011 LIMITED	VIREXIM INJECTION	CEFTRIAXONE SODIUM	1G	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 1*10ML AMPOULE OF WFI	09/09/2022

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610	NDA/MAL/HDP/1 0390	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN DT 40/240	ARTEMETHER + LUMEFANTRINE	40MG + 240MG	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X6.0 TABLET BLISTER	09/09/2022
611	NDA/MAL/HDP/1 0391	SANDOZ GMBH .	SURGIPHARM (U) LIMITED	HYDROXYUREA 100MG	HYDROXYCARBA MIDE	100MG	HAUPT PHARMA AMAREG GMBH- DONAUSTAUFER STRASSE 378, 93055 REGENSBURG	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X60.0 TABLET BOTTLE,1.0X1.0X90 .0 TABLET BOTTLE,1.0X1.0X12 0.0 TABLET BOTTLE,1.0X200.0 TABLET BOTTLE	09/09/2022

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612	NDA/MAL/HDP/10392	SANDOZ GMBH .	SURGIPHARM (U) LIMITED	HYDROXYUREA 1000MG	HYDROXYCARBAMIDE	1000MG	HAUPT PHARMA AMAREG GMBH- DONAUSTAUFER STRASSE 378, 93055 REGENSBURG	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE	09/09/2022
613	NDA/MAL/HDP/1040	SQUARE CEPHALOSPORINS LTD	GAMA PHARMACEUTICALS (U) LIMITED	CEF-3 DS	CEFIXIME TRIHYDRATE	400MG	SQUARE CEPHALOSPORINS LTDKALIAKOIR, GAZIPUR – 1750, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X6.0 CAPSULE BLISTER	01/07/2014

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614	NDA/MAL/HDP/1 0418	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	KAMAGRA CT 100	SILDENAFIL CITRATE	100 MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X4.0 TABLET BLISTER	08/02/2023
615	NDA/MAL/HDP/1 0419	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	SITAPRIL M 50/1000	SITAGLIPTIN PHOSPHATE MONOHYDRATE + METFORMIN HYDROCHLORIDE	50 MG + 1000 MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023

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616	NDA/MAL/HDP/1042	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO TELVAS-H 80/12.5	TELMISARTAN +HYDROCHLOROTHIAZIDE	80MG +12.5 MG	ARISTO PHARMACEUTICALS PVT. LIMITED PLOT NO. 208, NEW INDUSTRIAL AREA NO. II, MANDIDEEP-462046, DIST. - RAISEN, MADHYA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP, 1.0X3.0X10.0 TABLET STRIP	01/07/2013
617	NDA/MAL/HDP/10420	AJANTA PHARMALTD	ABACUS PHARMA (AFRICA) LIMITED	SITAPRIL M 50/500	SITAGLIPTIN PHOSPHATE MONOHYDRATE + METFORMIN HYDROCHLORIDE	50 MG + 500 MG	AJANTA PHARMA LIMITED AJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023

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618	NDA/MAL/HDP/1 0421	MEGA LIFSCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	MIOPOLOL ER 50	METOPROLOL SUCCINATE	50MG	INVENTIA HEALTHCARE PVT LTD F1-F1/1 ADDITIONAL MIDC AMBERNATH (E) DIST. THANE	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023
619	NDA/MAL/HDP/1 0422	MEGA LIFSCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	MIOPOLOL ER 25	METOPROLOL SUCCINATE	25MG	INVENTIA HEALTHCARE PVT LTD F1-F1/1 ADDITIONAL MIDC AMBERNATH (E) DIST. THANE	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023

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620	NDA/MAL/HDP/1 0427	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	CELMAC 400	CELECOXIB	40 MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	08/02/2023
621	NDA/MAL/HDP/1 0428	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	AMOXI-DENK 1000	AMOXICILLIN TRIHYDRATE	1000 MG	PENCEF PHARMA GMBHBREITENBACH STRABE 13-14, 13509 BERLIN - GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	08/02/2023

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622	NDA/MAL/HDP/1 0429	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	AMOXI-DENK 500	AMOXICILLIN TRIHYDRATE	500 MG	PENCEF PHARMA GMBHBREITENBACH STRABE 13-14, 13509 BERLIN - GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	08/02/2023
623	NDA/MAL/HDP/1 0430	CIPLA LIMITED.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	QUADRIMUNE	ABACAVIR + LAMIVUDINE + LOPINAVIR + RITONAVIR	30 MG + 15 MG + 40 MG +10 MG	CIPLA LIMITED, GOA (UNIT X)PLOT NO. S- 103 TO S-105, S-107 TO S-112, L-147, L- 147/1 TO L-147/3, L- 138 AND L-147/A, VERNA INDUSTRIAL ESTATE, VERNA, SALCETTE, GOA. PIN: 403722	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X120.0 CAPSULE CONTAINER	08/02/2023



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624	NDA/MAL/HDP/10433	BIOLOGICAL E. LIMITED	GITTOES PHARMACEUTICALS LIMITED	TETANUS ANTITOXIN 1500 IU/ML BP	TETANUS ANTITOXIN	1500 IU/ML	BIOLOGICAL E. LIMITED 18/1 & 3, AZAMABAD, HYDERABAD, TELANGANA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X20.0 ML VIAL	08/02/2023
625	NDA/MAL/HDP/10435	PROFARMA SH.A	JOINT MEDICAL STORE (UPMB - UCMB)	A FEBRIL 5 MG/2.5ML	DIAZEPAM	5MG/2.5ML	PROFARMA SH.A MYSLYM KETA, TIRANA	ALBANIA	RECTAL SYSTEMIC OTHER SUPPOSITORIES	1.0X5.0X1.0 ML AMPOULE, 1.0X2.5 ML AMPOULE, 1.0X5.0X1.0X2.5 ML VIAL	08/02/2023

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626	NDA/MAL/HDP/10436	YICHANGHUMANWELL PHARMACEUTICAL CO., LTD.	KAIYUANTANG (U) LIMITED	PETHIDINE HYDROCHLORIDE INJECTION	PETHIDINE HYDROCHLORIDE	50 MG/ML	YICHANG HUMANWELL PHARMACEUTICAL COMPANY LIMITED (NO. 19, DALIAN ROAD, YICHANG DEVELOPING ZONE, YICHANG, HUBEI, CHINA)	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	10/02/2023
627	NDA/MAL/HDP/1044	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ANGINET 80MG	VALSARTAN	80MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTDP.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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628	NDA/MAL/HDP/1 0441	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	PREDNOVA 5	PREDNISOLONE	5MG	BIOMATRIX HEALTHCARE PRIVATE LIMITEDSURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/02/2023
629	NDA/MAL/HDP/1 0447	PT SANBE FARMA	MEDVIN PHARMA LIMITED	TRADOSIK	TRAMADOL HYDROCHLORIDE	50 MG/ML	PT. SANBE FARMA STERILE PREPARATION PLANT - (UNIT 3)JALAN INDUSTRI CIMAREME NO. 8 DESA CIMAREME, KECAMATAN PADALARANG, KABUPATEN BANDUNG BARAT 40553 - INDONESIA	INDONESIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X1.0X5.0X2. 0 ML AMPOULE	08/02/2023

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630	NDA/MAL/HDP/1 0448	PT SANBE FARMA	MEDVIN PHARMA LIMITED	DOLONES	LIDOCAINE + PRILOCAINE	(25 MG + 25 MG)/G	PT CAPRIFARMINDO LABORATORIES ,JALAN INDUSTRI CIMAREME NO. 8 DESA CIMAREME, KECAMATAN PADALARANG, KABUPATEN BANDUNG BARAT 40553 - INDONESIA	INDONESIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X5.0 G TUBE	08/02/2023
631	NDA/MAL/HDP/1 045	SQUARE PHARMACEUTICAL S LTD	GAMA PHARMACEUTICAL S (U) LIMITED	ZIMAX 500	AZITHROMYCIN	500MG	SQUARE CEPHALOSPORINS LTDKALIAKOIR, GAZIPUR – 1750, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	01/07/2013

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632	NDA/MAL/HDP/1 0450	PT SANBE FARMA	MEDVIN PHARMA LIMITED	MEFINAL 500	MEFENAMIC ACID	500 MG	PT CAPRIFARMINDO LABORATORIES ,JALAN INDUSTRI CIMAREME NO. 8 DESA CIMAREME, KECAMATAN PADALARANG, KABUPATEN BANDUNG BARAT 40553 - INDONESIA	INDONESIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	08/02/2023
633	NDA/MAL/HDP/1 0451	GUANGZHOU WONDFO BIOTECH CO. LTD	METRO PHARMACEUTICAL S LIMITED	WAXFREE	SODIUM BICARBONATE	5%W/V	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	NASAL TOPICAL LIQUIDS	1.0X1.0X10.0 ML BOTTLE	08/02/2023

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634	NDA/MAL/HDP/1 0452	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	OPTIPRED	PREDNISOLONE ACETATE	1.0% W/V	JAMJOOM PHARMACEUTICALS COMPANY - PLOT NO: ME1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 - KINGDOM OF SAUDI ARABIA	SAUDI ARABIA	OPHTHALMIC SUSPENSIONS	1.0X1.0X5.0 ML BOTTLE	08/02/2023
635	NDA/MAL/HDP/1 0453	SANJAR PHARMA LLP.	NILKANTH PHARMACY LIMITED	ARTICURE 60MG	ARTESUNATE	60MG	SANJAR PHARMA LLP (SURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0x60.0 MG Vial + 10ML OF 0.9% SODIUM CHLORIDE SOLUTION, LDPE AMPOULE + 1ML OF 5.0% SODIUM BICARBONATE SOLUTION, GLASS AMOULE	10/02/2023

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636	NDA/MAL/HDP/1 0455	UNIMED LABORATORIES	OMAB UGANDA LIMITED	ENOXAMED 2000 IU ANTI-XA /0.2 ML	ENOXAPARIN SODIUM	2000 IU ANTI-XA /0.2 ML (EQUIVALENT TO 20 MG PER 0.2 ML)	UNIMED LABORATORIESP.O. BOX 38 - I.Z. KALAA KEBIRA - 4060 KALAA KEBIRA - TUNISIA	TUNISIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0X2.0X0.2 ML PRE- FILLED SYRINGE	08/02/2023
637	NDA/MAL/HDP/1 0456	UNIMED LABORATORIES	OMAB UGANDA LIMITED	ENOXAMED 4000 IU ANTI-XA /0.4 ML	ENOXAPARIN SODIUM	4000 IU ANTI-XA /0.4 ML (EQUIVALENT TO 40 MG PER 0.4 ML)	UNIMED LABORATORIESP.O. BOX 38 - I.Z. KALAA KEBIRA - 4060 KALAA KEBIRA - TUNISIA	TUNISIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0X2.0X0.4 ML PRE- FILLED SYRINGE	08/02/2023

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638	NDA/MAL/HDP/1 0457	UNIMED LABORATORIES	OMAB UGANDA LIMITED	ENOXAMED 6000 IU ANTI-XA /0.6 ML	ENOXAPARIN SODIUM	6000 IU ANTI-XA /0.6 ML (EQUIVALENT TO 60 MG PER 0.6 ML)	UNIMED LABORATORIESP.O. BOX 38 - I.Z. KALAA KEBIRA - 4060 KALAA KEBIRA - TUNISIA	TUNISIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0X2.0X0.4 ML PRE- FILLED SYRINGE	08/02/2023
639	NDA/MAL/HDP/1 0458	UNIMED LABORATORIES	OMAB UGANDA LIMITED	ENOXAMED 8000 IU ANTI-XA /0.8 ML	ENOXAPARIN SODIUM	8000 IU ANTI-XA /0.8 ML (EQUIVALENT TO 80 MG PER 0.8 ML)	UNIMED LABORATORIESP.O. BOX 38 - I.Z. KALAA KEBIRA - 4060 KALAA KEBIRA - TUNISIA	TUNISIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0X2.0X0.4 ML PRE- FILLED SYRINGE	08/02/2023



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640	NDA/MAL/HDP/1 0459	UNIMED LABORATORIES	OMAB UGANDA LIMITED	PARAMED	PARACETAMOL	1G/100ML	UNIMED LABORATORIES P.O. BOX 38 - I.Z. KALAA KEBIRA - 4060 KALAA KEBIRA - TUNISIA	TUNISIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X6.0X1.0X100.0 ML BAG	08/02/2023
641	NDA/MAL/HDP/1 0460	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	AERIALLERG 5MG	DESLORATIDINE	5 MG	PHARMA INTERNATIONAL CO. LTD AL QASTAL AIRPORT ROAD, P.O. BOX 334 AL JUBAIHA 11941, AMAAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023

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642	NDA/MAL/HDP/1 0461	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	AERIALLERG 0.5MG/ML	DESLORATIDINE	0.5MG/ML	PHARMA INTERNATIONAL CO. LTD AL QASTAL AIRPORT ROAD, P.O. BOX 334 AL JUBAIHA 11941, AMAAN	JORDAN	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X125.0 ML BOTTLE	08/02/2023
643	NDA/MAL/HDP/1 0462	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TOR - LOOP 10	ANHYDROUS TORSEMIDE	10 MG	AUROBINDO PHARMA LIMITED, UNIT III SURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELENGANA (STATE)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023

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644	NDA/MAL/HDP/1 0463	FAES FARMA S.A	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DISFOR	METHOCARBAMO L	500 MG	FAES FARMA SAMAXIMO AGUIRRE 14. 48940 LEIOA – SPAIN	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	08/02/2023
645	NDA/MAL/HDP/1 0464	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	BENYLIN 4 FLU TABLETS	DIPHENHYDRAMINE + PARACETAMOL + PSEUDOEPHEDRINE	12.5MG + 500MG + 22.5MG	SPECGX LLC100 LOUIS LATZER DRIVE, GREENVILLE, ILLINOIS, 62246 - UNITED STATES OF AMERICA JOHNSON & JOHNSON (PTY) LTD241 MAIN ROAD, RETREAT, 7945, CAPE TOWN	UNITED STATES SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X12.0 TABLET BLISTER	08/02/2023



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648	NDA/MAL/HDP/1 0468	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CORTIRIV-100	HYDROCORTISON E SODIUM SUCCINATE	100 MG/VIAL	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X100.0 MG VIAL, 1.0X50.0X100.0 MG VIAL	08/02/2023
649	NDA/MAL/HDP/1 047	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EXOFEN 180MG	FEXOFENADINE	180MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTDP.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL- RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X15.0 TABLET BLISTER	01/07/2013

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650	NDA/MAL/HDP/1 0472	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	TRAMADOL HYDROCHLORIDE INJECTION 100 MG/2ML	TRAMADOL HYDROCHLORIDE	100 MG/2 ML	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0X2.0 ML AMPOULE	08/02/2023
651	NDA/MAL/HDP/1 0473	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	POLYMOL SUSPENSION 125MG/5ML.	PARACETAMOL	125MG/5ML.	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE, 1.0X60.0ML BOTTLE	08/02/2023

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652	NDA/MAL/HDP/1 0474	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	POLYMOL EXTRA	PARACETAMOL + CAFFEINE	500 MG + 30 MG	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/02/2023
653	NDA/MAL/HDP/1 0477	CENTURION LABORATORIES PVT. LTD.	SHREEJI PHARMACEUTICAL S LIMITED	PENACAM	PIROXICAM	20 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	08/02/2023

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654	NDA/MAL/HDP/1 0483	NVS KENYA LTD	SURGIPHARM (U) LIMITED	PATIZRA	RANIBIZUMAB	10 MG/ML	NOVARTIS PHARMA STEIN AG STERILE OPERATIONS SOLID OPERATIONSNOWAR TIS PHARMA STEIN AG SCHAFFHAUSERSTRA SSE, 4332 STEIN - SWITZERLAND	SWITZERLAND	PARENTERAL ORDINARY VIALS	1.0X1.0X0.23 ML VIAL	08/02/2023
655	NDA/MAL/HDP/1 0484	INDIANA OPHTHALMICS	SWASTIK PHARMACEUTICAL LTD	TETROP	TETRACYCLINE HYDROCHLORIDE	1%W/W	INDIANA OPHTHALMICS135, 136, 137, GIDC ESTATE, WADHWAN- 363035	INDIA	OPHTHALMIC OINTMENTS	1.0X1.0X5.0 G TUBE	08/02/2023



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656	NDA/MAL/HDP/1 0485	ESKAYEF PHARMACEUTICAL S LTD.	SWASTIK PHARMACEUTICAL LTD	RIVAROX 15	RIVAROXABAN	15 MG	ESKAYEF BANGLADESH LTD- 400, TONGI INDUSTRIAL AREA, SQUIB ROAD TONGI- GAZIPUR BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	08/02/2023
657	NDA/MAL/HDP/1 0486	ESKAYEF PHARMACEUTICAL S LTD.	SWASTIK PHARMACEUTICAL LTD	RIVAROX 20	RIVAROXABAN	20 MG	ESKAYEF BANGLADESH LTD- 400, TONGI INDUSTRIAL AREA, SQUIB ROAD TONGI- GAZIPUR BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	08/02/2023

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658	NDA/MAL/HDP/1 0488	ESKAYEF PHARMACEUTICAL S LTD.	SWASTIK PHARMACEUTICAL LTD	GTN 2.6 SR	DILUTED NITROGLYCERIN	2.6 MG	ESKAYEF BANGLADESH LTD- 400, TONGI INDUSTRIAL AREA, SQUIB ROAD TONGI- GAZIPUR BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	08/02/2023
659	NDA/MAL/HDP/1 049	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOVATE	BETAMETHASONE VALERATE	0.1%W/W	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/2013

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660	NDA/MAL/HDP/1 0492	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	DOLUTEGRAVIR SODIUM TABLETS 50 MG	DOLUTEGRAVIR SODIUM	50 MG	MACLEODS PHARMACEUTICALS LIMITED, UNIT IIPLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN - 396210 (UT) - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BLISTER	08/02/2023
661	NDA/MAL/HDP/1 0493	CENTURION LABORATORIES PVT. LTD.	SHREEJI PHARMACEUTICAL S LIMITED	ROUNOX	TRAMADOL HYDROCHLORIDE	50 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	08/02/2023

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662	NDA/MAL/HDP/1 0496	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	IRIS SYRUP	DESLORATADINE	0.5 MG/ML	UNITED PHARMACEUTICALS MANUFACTURING LIMITED COMPANYAL- RAGEEM, SAHAB, P.O. BOX 60, AMMAN 11591 - JORDAN	JORDAN	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	08/02/2023
663	NDA/MAL/HDP/1 050	INTAS PHARMACEUTICAL S LIMITED	NORVIK ENTERPRISES LIMITED	AMTAS-10	AMLODIPINE	10MG	INTAS PHARMACEUTICALS LTD PLOT 457/458, SARKHEJ BAVLA HIGHWAY MATODA 382 210 TAL: SANAND, AHMEDABAD, INDIA INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI- 248197, DEHRADUN (UTTARAKHAND)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER, 10.0X10.0 TABLET BLISTER	01/07/2013

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664	NDA/MAL/HDP/10502	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	VORIOLE 200	VORICONAZOLE	200MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISION (PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325-TELENGANA, )	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	10/02/2023
665	NDA/MAL/HDP/10503	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	HI-ALFA SR 10	ALFUZOSIN HYDROCHLORIDE	10MG	AUROBINDO PHARMA LIMITED UNIT 3PLOT NO. 313, 314, BACHUPALLY, RR DIST. 500090	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023

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666	NDA/MAL/HDP/1 0505	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	OPTOR EYE DROPS	KETOROLAC TROMETHAMINE	0.5%W/V	ABACUS PARENTERAL DRUGS LIMITED PLOT 114, BLOCK 191, KINGA	UGANDA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML BOTTLE	08/02/2023
667	NDA/MAL/HDP/1 0506	PHARMATHEN S.A	GOODMAN INTERNATIONAL LTD	A-CNOTRENÂ® 10MG	ISOTRETINOIN	10MG	GAP S.A. (46 AGISSILAOU STR. 17341 AGIOS DIMITRIOS) PHARMATHEN INTERNATIONAL S.A (INDUSTRIAL PARK SAPES, RODOPI PREFECTURE, BLOCK NO. 5, RODOPI 69300 - GREECE) PHARMATHEN S.A (6, DERVENAKION STR. 15351 PALLINI ATHENS)	GREECE	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	10/02/2023

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668	NDA/MAL/HDP/1 0507	AUROLAB	SWASTIK PHARMACEUTICAL LTD	TOB - DEX	TOBRAMYCIN SULFATE + DEXAMETHASON E SODIUM PHOSPHATE	0.3%W/V + 0.1%W/V	AUROLAB .NO. 1, SIVAGANGAI MAIN ROAD, VEERAPANJANI, MADURAI 1 - 625 020	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	08/02/2023
669	NDA/MAL/HDP/1 0508	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	FIMABUTE-100	CEFIXIME TRIHYDRATE	100MG/5ML	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X60.0 ML BOTTLE	08/02/2023

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670	NDA/MAL/HDP/10511	VRUSHIK INVESTMENT (U) LTD.	SHREEJI PHARMACEUTICALS LIMITED	METO	METOCLOPRAMIDE HYDROCHLORIDE	10MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIOTECH PARK, MANJUSAR, TALSAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/02/2023
671	NDA/MAL/HDP/10519	PT SANBE FARMA	MEDVIN PHARMAS LIMITED	PLASMINEX	TRANEXAMIC ACID	500MG	PT SANBE FARMA UNIT 1JALAN INDUSTRI I NO. 9 RT. 01 RW.08, KELURAHAN UTAMA, KECAMATAN CIMAH SELATAN, KOTA CIMAH 40553 - INDONESIA	INDONESIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	08/02/2023



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672	NDA/MAL/HDP/1052	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	MICLOGEN	MICONAZOLE NITRATE+CLOBETASOLE PROPIONATE+GENTAMICIN SULPHATE	2.0%W/W+0.05%W/W+0.1W/W	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2013
673	NDA/MAL/HDP/10523	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICALS LTD	SYNRIAM DT	ARTEROLANE MALEATE + PIPERAQUINE PHOSPHATE	37.5 MG + 187.5 MG	SUN PHARMACEUTICAL IND. LTD PLOT NO. B-2, MADKAI INDUSTRIAL ESTATE, PONDA- GOA, INDIA-403404	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X3.0 TABLET BLISTER	08/02/2023

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674	NDA/MAL/HDP/1053	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOXIN-125 DT	AMOXICILLIN	125MG	MILAN LABORATORIES (INDIA) PVT LTD .PLOTS 63,67,87,35,36,64,65 , JAWAHAR CO-OP IND. ESTATE LTD, KAMOTHE, PANVEL (NAVI MUMBAI)	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/2013
675	NDA/MAL/HDP/10530	ZOTA HEALTHCARE LTD	HARLEYS UGANDA LIMITED	COXZOTA 120	ETORICOXIB	120MG	ZOTA HEATHCARE LIMITEDPLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NEAR SACHIN RAILWAY STATION, SACHIN, CITY: SURAT, DIST: SURAT, GUJARAT STATE - INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023

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676	NDA/MAL/HDP/1 0531	GLAXOSMITHKLINE LIMITED-	UNITED HEALTHCARE DISTRIBUTORS LTD	ENO CALCIUM ANTACID TABLETS	CALCIUM CARBONATE	500MG	GLAXOSMITHKLINE LIMITEDLIKONI ROAD, INDUSTRIAL AREA, P.O. BOX 78392-00507, VIWANDANI, NAIROBI GLAXOSMITHKLINE CONSUMER HEALTHCARE HOLDINGS (US) LLC320 SOUTH BROADWAY ST. LOUIS, MISSOURI, 63102 - UNITED STATES OF AMERICA	KENYA UNITED STATES	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X2.0X10 .0 TABLET BLISTER	08/02/2023
677	NDA/MAL/HDP/1 0532	ALKEM LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	TAXIM-O	CEFIXIME TRIHYDRATE	400MG	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X5.0 CAPSULE BLISTER	08/02/2023

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678	NDA/MAL/HDP/1 0535	FERRER INTERNATIONAL, S.A.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	ANGINOVAG	DEQUALINIUM CHLORIDE + TYROTHRINIC + B GLYCIRRHETINIC ACID (ENOXOLONE) + HYDROCORTISON E ACETATE + LIDOCAINE HYDROCHLORIDE	(100MG + 400MG + 60MG + 60MG+100MG) PER 100 ML	FERRER INTERNATIONAL, S.AC/ JOAN BUSCALLA, 1-9 08173 SANT CUGAT DEL VALLES,	SPAIN	ORAL TOPICAL SPRAYS WITHOUT GAS	1.0X1.0X10.0 ML BOTTLE	08/02/2023
679	NDA/MAL/HDP/1 0536	KLM LABORATORIES PVT. LTD.	REDDYS PHARMA LIMITED	MUPISOFT OINTMENT	MUPIROCIN	2.0% W/W	CURETECH SKINCAREPLOT NO. 33 & 34, PHASE IV, BHATOLI KALAN, BADDI DISTT. SOLAN (HP) 173205	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X5.0 G TUBE, 1.0X1.0X15.0 G TUBE	08/02/2023

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680	NDA/MAL/HDP/1 0537	KLM LABORATORIES PVT. LTD.	REDDYS PHARMA LIMITED	NIOSOL OINTMENT	CLOBETASOL PROPIONATE	0.05%W/W	CURETECH SKINCAREPLOT NO. 33 & 34, PHASE IV, BHATOLI KALAN, BADDI DISTT. SOLAN (HP) 173205	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X30.0 G TUBE	08/02/2023
681	NDA/MAL/HDP/1 0538	KLM LABORATORIES PVT. LTD.	REDDYS PHARMA LIMITED	SUDIF CREAM	FUSIDIC ACID	2.0 %W/W	CURETECH SKINCAREPLOT NO. 33 & 34, PHASE IV, BHATOLI KALAN, BADDI DISTT. SOLAN (HP) 173205	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X10.0 G TUBE	08/02/2023

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682	NDA/MAL/HDP/10539	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	ZOTAMET-850	METFORMIN HYDROCHLORIDE	850MG	ZOTA HEATHCARE LIMITED PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NEAR SACHIN RAILWAY STATION, SACHIN, CITY: SURAT, DIST: SURAT, GUJARAT STATE - INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/02/2023
683	NDA/MAL/HDP/1054	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AZ-250	AZITHROMYCIN	250MG	AGOG PHARMA LTD PLOT NO.33, SECTOR II, VASAI, TALUKA INDL CO-OP ESTATE LTD, GAURAI PADA, VASAI(E) DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X6.0 CAPSULE BLISTER	01/07/2011

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684	NDA/MAL/HDP/1 0540	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICAL S LTD	ATAZANAVIR AND RITONAVIR TABLETS	ATAZANAVIR SULFATE + RITONAVIR	300MG + 100MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE	08/02/2023
685	NDA/MAL/HDP/1 0544	AUROLAB	SWASTIK PHARMACEUTICAL LTD	ATROP	ATROPINE SULFATE	1%W/V	AUROLAB LIMITEDNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU INDIA	BRAZIL	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	08/02/2023

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686	NDA/MAL/HDP/1 0545	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	BRAMOL	PARACETAMOL	10MG/ML	BROOKES PHARMA (PRIVATE) LIMITED58 59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML VIAL	08/02/2023
687	NDA/MAL/HDP/1 0547	PROFARMA SH.A	JOINT MEDICAL STORE (UPMB - UCMB)	HALOPERIDOL SOLUTION FOR INJECTION 5MG/ML	HALOPERIDOL	5MG/ML	PROFARMA SH.AMYSLYM KETA,TIRANA	ALBANIA	PARENTERAL ORDINARY VIALS	1.0X2.0X5.0X1.0 ML VIAL	08/02/2023



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688	NDA/MAL/HDP/10551	SANJAR PHARMA LLP.	MOTI PHARMA (UGANDA) LIMITED	ADRENLIN	ADRENALINE ACID TARTRATE	1MG	SANJAR PHARMA LLPSURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0X1.0 MG AMPOULE	08/02/2023
689	NDA/MAL/HDP/10552	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	ZOPIMAC 2	ESZOPICLONE	2MG	MACLEODS PHARMACEUTICALS LIMITED, UNIT VIVILLAGE THEDA, KHARUNI LODHI MAJRA RD, TEHSIL BADDI N2, DISTRICT SOLAN, HIMACHAL PRADESH-174101	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X100.0 TABLET CONTAINER	08/02/2023

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690	NDA/MAL/HDP/1 0553	ACINO AG.	LABOREX UGANDA LIMITED	TITANAFIL 5	TADALAFIL	5MG	PHARMACTIVE ILAC SAN. VE TIC. A.S.CERKEZKOY ORGANIZE SANAYI BOLGESI KARAAGAC MAH. FATIH BULV. NO: 32 KAPAKLI/TEKIRDAG - 2820133250 - TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	08/02/2023
691	NDA/MAL/HDP/1 0554	ACINO AG	LABOREX UGANDA LIMITED	TITANAFIL 20	TADALAFIL	20MG	PHARMACTIVE ILAC SAN. VE TIC. A.S.CERKEZKOY ORGANIZE SANAYI BOLGESI KARAAGAC MAH. FATIH BULV. NO: 32 KAPAKLI/TEKIRDAG - 2820133250 - TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	08/02/2023

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692	NDA/MAL/HDP/1 0557	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	LOFNAC-50	DICLOFENAC SODIUM	50MG	BLISS GVS PHARMA LIMITED10,11 & 12,DEWAN UDYOG NAGAR,ALIYALI,PALG HAR,MAHARASHTRA 401404,INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	08/02/2023
693	NDA/MAL/HDP/1 0558	KLM LABORATORIES PVT. LTD.	REDDYS PHARMA LIMITED	NEOCLEAN GEL	CLINDAMYCIN PHOSPHATE + NICOTINAMIDE	1.0 %W/W + 4.0%W/W	CURETECH SKINCAREPLOT NO. 33 & 34, PHASE IV, BHATOLI KALAN, BADDI DISTT. SOLAN (HP) 173205	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X1.0X10.0 G TUBE	08/02/2023

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694	NDA/MAL/HDP/1 0559	KLM LABORATORIES PVT. LTD.	REDDYS PHARMA LIMITED	NIOSALIC OINTMENT	CLOBETASOL PROPIONATE + SALICYLIC ACID	0.05%W/W + 3.00W/W	CURETECH SKINCAREPLOT NO. 33 & 34, PHASE IV, BHATOLI KALAN, BADDI DISTT. SOLAN (HP) 173205	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X30.0 G TUBE, 1.0X1.0X20.0 G TUBE	08/02/2023
695	NDA/MAL/HDP/1 056	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOVATE-N OINTMENT	BETAMETHASONE + NEOMYCIN	0.1%W/W + 0.5% W/W	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X15.0 G TUBE	01/07/2013

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696	NDA/MAL/HDP/1 0561	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	WORIV	ALBENDAZOLE	400MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X1.0 TABLET BLISTER	08/02/2023
697	NDA/MAL/HDP/1 0562	EAST AFRICAN (INDIA) OVERSEAS	ROYAL PHARMA 2011 LIMITED	ACESON-P	ACECLOFENAC + PARACETAMOL	100MG + 500MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	08/02/2023

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698	NDA/MAL/HDP/1 0563	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ENARIV-10	ENALAPRIL MALEATE	10MG	EAST AFRICAN (INDIA) OVERSEAS (PLOT NO.1, PHARMACITY SELAQUI DEHRADUN " 248011 (U.K), INDIA)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	10/02/2023
699	NDA/MAL/HDP/1 0565	AUROLAB	SWASTIK PHARMACEUTICAL LTD	PILO	PILOCARPINE NITRATE	2%W/V	AUROLAB .NO. 1, SIVAGANGAI MAIN ROAD, VEERAPANJANI, MADURAI 1 - 625 020	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	08/02/2023

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700	NDA/MAL/HDP/1 0566	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROCARPINE	PILOCARPINE NITRATE	0.5%W/V	AUROLAB .NO. 1, SIVAGANGAI MAIN ROAD, VEERAPANJANI, MADURAI 1 - 625 020	INDIA	OPHTHALMIC DROPS	1.0X5.0X1.0 ML VIAL	08/02/2023
701	NDA/MAL/HDP/1 0567	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CELMAC 200	CELECOXIB	200MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	08/02/2023

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702	NDA/MAL/HDP/1 0568	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	AMADAY PL 5/4	AMLODIPINE BESILATE + PERINDOPRIL ERBUMINE	5 MG + 4 MG	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023
703	NDA/MAL/HDP/1 0569	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	AMADAY PL 5/8	AMLODIPINE BESILATE + PERINDOPRIL ERBUMINE	5MG + 8MG	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023



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704	NDA/MAL/HDP/1 057	NECTAR LIFSCIENCES LTD	SUPER MEDIC LTD	FIXINECT-200MG	CEFIXIME	200MG	NECTAR LIFE SCIENCES LTD-VILL. BHATOLIKALAN, ADJOINING JHARMJRI, E.P.I.P TEL. NALAGARH, DISTT. SOLAN, H.P.-173205 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2013
705	NDA/MAL/HDP/1 0570	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	AMADAY PL 10/4	AMLODIPINE BESILATE + PERINDOPRIL ERBUMINE	10 MG + 4 MG	NALAGARH, DISTT. SOLAN, H.P.-173205 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023

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706	NDA/MAL/HDP/1 0571	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	AMADAY PL 10/8	AMLODIPINE BESILATE + PERINDOPRIL ERBUMINE	10MG + 8MG	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023
707	NDA/MAL/HDP/1 0572	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	NAT-B FORTE	THIAMINE MONONITRATE (VITAMIN B1) + PYRIDOXINE HYDROCHLORIDE (VITAMIN B6) + METHYLCOBALA MIN (VITAMIN B12) + FOLIC ACID + D-ALPHA- TOCOPHEROL ACETATE + VITAMIN A + VITAMIN D3 + COPPER SULPHATE	100 MG + 200 MG + 500 MCG + 200 MCG + 200 IU + 5000 IU + 400 IU + 1.0 MG + 0.20 MG + 15.0 MG	MEGA LIFESCIENCES PUBLIC CO. LTDPLANT 1; 384 MOO 4, SOI 6, BANGPOO INDUSTRIAL ESTATE, PATTANA 3 ROAD, PHRAEKSA, MUEANG, SAMUTPRAKARN 10280 THAILAND	THAILAND	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	08/02/2023

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708	NDA/MAL/HDP/1 0578	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	OCORTIN	HYDROCORTISON E	1%W/W	KREMOINT PHARMA PVT LTD. B-8, ADDITIONAL AMBERNATH M.I.D.C, OPP. ANAND NAGIAR POLICE CHECK POST, AMBERNATH (E), DIST. THANE.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	08/02/2023
709	NDA/MAL/HDP/1 0579	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	BENZYL BENZOATE APPLICATION BP	BENZYL BENZOATE	25%W/V	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	TOPICAL EXTERNAL EMULSIONS	1.0X100.0 ML BOTTLE	08/02/2023

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710	NDA/MAL/HDP/1 0593	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	MOMRIV	MOMETASONE FUROATE	0.1%W/W	EAST AFRICAN (INDIA) OVERSEAS (PLOT NO.1, PHARMACITY SELAQUI DEHRADUN “ 248011 (U.K), INDIA)	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	06/03/2023
711	NDA/MAL/HDP/1 0597	MEDISEL(K) LTD	SUPER MEDIC LTD	GABANERVE	GABAPENTIN + METHYLCOBALA MIN	300MG + 500MCG	CORONA REMEDIES PVT. LTDVILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	15/02/2023

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712	NDA/MAL/HDP/10598	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	MIXIF	CEFIXIME TRIHYDRATE	400MG	DAR AL DAWA (NA'UR PRINCE HASHEM BIN AL-HUSSEIN STREET P.O. BOX 9364 AMMAN 11191 JORDAN)	JORDAN	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X5.0 CAPSULE BLISTER	21/03/2023
713	NDA/MAL/HDP/10600	MEDISEL(K) LTD	AIVEEN (U) LIMITED	OSTEOCERIN	GLUCOSAMINE SULPHATE POTASSIUM CHLORIDE + METHYL SULPHONYL METHANE (MSM) + DIACEREIN	750MG + 250MG + 50MG	CORONA REMEDIES PVT. LTD VILLAGE JATOLI, POST OFFICE-OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	15/02/2023

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714	NDA/MAL/HDP/10602	WORLD MEDICINE DÜNYA İLAÇ SAN. VE TİC. A.Ş.	GOODMAN INTERNATIONAL LTD	ZIROMIN 200 MG/5 ML	AZITHROMYCIN DIHYDRATE	200 MG/5 ML	WORLD MEDICINE ILAC SAN VE TIC A.S. (15 TEMMUZ MAHALLESİ, CAMI YOLU CADDESİ, NO: 50 K:4 WM PLAZA, GUNESIL- BAGCILAR/INSTANB UL, TURKEY)	TURKEY	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X30.0ML BOTTLE	06/06/2023
715	NDA/MAL/HDP/10604	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	PIPERATAZ 4.5	PIPERACILLIN + TAZOBACTAM	4 G + 0.5 G	UNI MEDICOLABSUNI MEDICOLABS, PLOT NO. 21-22, PHARMACITY, SELAQUI, DEHRADUN - 248011	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X4.5 G VIAL	15/02/2023

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716	NDA/MAL/HDP/1 0606	MEDISEL(K) LTD	AIVEEN (U) LIMITED	EMADON SYRUP	ONDANSETRON HYDROCHLORIDE	2MG/5ML	CORONA REMEDIES PVT. LTDVILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X30.0 ML BOTTLE	15/02/2023
717	NDA/MAL/HDP/1 0607	CADILA PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S LTD.	DOLAC	KETOROLAC TROMETHAMINE	10 MG	CADILA PHARMACEUTICALS LTD1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDABAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET STRIP	15/02/2023

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718	NDA/MAL/HDP/1 0609	FDC LIMITED -	AIVEEN (U) LIMITED	OCUDOR	DORZOLAMIDE HYDROCHLORIDE	2%W/V	FDC LIMITED- WALUJ.PLOT B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 (DIST AURANGABAD)	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	15/02/2023
719	NDA/MAL/HDP/1 061	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	BISACODYL TABLETS	BISACODYL	5MG	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010



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720	NDA/MAL/HDP/10615	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	LEVOZIN 5	LEVOCETIRIZINE DIHYDROCHLORIDE	5MG	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	15/02/2023
721	NDA/MAL/HDP/10616	COSMOS LTD.	ASTRA PHARMA (U) LIMITED	GLYSIT 5	DAPAGLIFLOZIN	5MG	COSMOS LTD..RANGWE ROAD OFF, LUNA LUNGA ROAD, INDUSTRIAL AREA - NAIROBI	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	15/02/2023

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722	NDA/MAL/HDP/1 0617	COSMOS LTD.	ASTRA PHARMA (U) LIMITED	GLYSIT 10	DAPAGLIFLOZIN	10MG	COSMOS LTD..RANGWE ROAD OFF, LUNA LUNGA ROAD, INDUSTRIAL AREA - NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	15/02/2023
723	NDA/MAL/HDP/1 0618	BHARAT SERUMS & VACCINES LTD.	ABACUS PHARMA (AFRICA) LIMITED	FOLIGRAF 150 I.U	RECOMBINANT - HUMAN FOLLICLE STIMULATING HORMONE (R- HFSH)	150 I.U/1ML	BHARAT SERUM AND VACCINES LIMITEDPLOT NO. K- 27 ADDITIONAL M.I.D.C INDIA	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0X1.0 ML PRE FILLED SYRINGE	15/02/2023

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724	NDA/MAL/HDP/1 0619	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	DEXİREN	DEXKETOPROFEN TROMETAMOL	50MG/2ML	IDOL LLAC DOLUM A.SDAVUTPASA CADDESI. CEBE ALI BEY SOK. NO. 20 34010/ DAVUTPASA - TOPKAPI / ISTANBUL	TURKEY	PARENTERAL ORDINARY AMPOULES	1.0X1.0X6.0X2.0 ML AMPOULE	15/02/2023
725	NDA/MAL/HDP/1 062	VENUS REMEDIES LTD	HARLEYS UGANDA LIMITED	VANCONEX-CP	VANCOMYCIN	500MG	VENUS REMEDIES LIMITED UNIT II HILL TOP INDUSTRIAL ESTATE JHARMAJRI EPIP PHASE I BHATOLI BADDI (HP) 173205 INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	01/07/2013

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726	NDA/MAL/HDP/1 0621	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	PENIREN	PHENOXYMETHYL PENICILLIN POTASSIUM	250MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	15/02/2023
727	NDA/MAL/HDP/1 0622	CENTURION LABORATORIES PVT. LTD.	SHREEJI PHARMACEUTICAL S LIMITED	PANTOPRAM 40	PANTOPRAZOLE SODIUM SESQUIHYDRATE	40 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

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728	NDA/MAL/HDP/1 0623	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	STERIREN	CHLORHEXIDINE GLUCONATE	5% W/V	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X5.0 L CONTAINER	15/02/2023
729	NDA/MAL/HDP/1 0624	MSN LABORATORIES PRIVATE LIMITED,	ABACUS PHARMA (AFRICA) LIMITED	MIBZO	BORTEZOMIB	3.5 MG/VIAL	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISION (PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA, )	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X3.5 MG VIAL	21/03/2023

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730	NDA/MAL/HDP/1 0625	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	ESOGRESS 40	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40 MG	STANFORD LABORATORIES PRIVATE LIMITED (A SUBSIDIARY COMPANY OF LA RENON HEALTHCARE PRIVATE LIMITED)8, INDUSTRIAL AREA, MEHATPUR - 174315, HIMACHAL PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
731	NDA/MAL/HDP/1 0631	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICAL S LTD	RYALTRIS	OLOPATADINE HYDROCHLORIDE + MOMETASONE FUROATE	665 MCG/25 MCG	GLENMARK PHARMACEUTICALS LIMITED-UNIT IIIVILLAGE KISHANPURA, BADDI- NALAGARH ROAD TEHSIL BADDI, DIST. SOLAN, BADDI 173205 INDIA	INDIA	NASAL SYSTEMIC DROPS	1.0X1.0X240.0 METERED DOSE BOTTLE	15/02/2023

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732	NDA/MAL/HDP/1 0634	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROFLU-CARE	PARACETAMOL + CAFFEINE + CHLORPHENIRAM INE MALEATE + PHENYLEPHRINE HYDROCHLORIDE	500MG + 30MG + 2MG + 10MG	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X6.0 TABLET BLISTER, 1.0X50.0X4.0 TABLET BLISTER,	15/02/2023
733	NDA/MAL/HDP/1 0637	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	SETRIZIN	CETIRIZINE	10MG	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	15/02/2023

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734	NDA/MAL/HDP/1 0640	FAES FARMA S.A	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DISTEM	METHOCARBAMO L + PARACETAMOL	380 MG + 300 MG	FAES FARMA SAMAXIMO AGUIRRE 14. 48940 LEIOA – SPAIN	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	15/02/2023
735	NDA/MAL/HDP/1 0649	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	ESOCID 40	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023



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736	NDA/MAL/HDP/1 065	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	SLIPIZEM-5	DIAZEPAM	5MG	BLISS GVS PHARMA LIMITEDNO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	RECTAL SYSTEMIC ADULT SUPPOSITORIES	1.0X5.0 SUPPOSITORY BLISTER	01/07/2007
737	NDA/MAL/HDP/1 0652	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	Z-OFLOX 200	OFLOXACIN	200MG	ZOTA HEATHCARE LIMITEDPLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NEAR SACHIN RAILWAY STATION, SACHIN, CITY: SURAT, DIST: SURAT, GUJARAT STATE - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	15/02/2023

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738	NDA/MAL/HDP/1 0653	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	COXZOTA-60	ETORICOXIB	60MG	ZOTA HEATHCARE LIMITEDPLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NEAR SACHIN RAILWAY STATION, SACHIN, CITY: SURAT, DIST: SURAT, GUJARAT STATE - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
739	NDA/MAL/HDP/1 0654	ALTHEA PHARMA PVT LTD.	JOINT MEDICAL STORE (UPMB - UCMB)	COMPOUND SODIUM LACTATE INTRAVENOUS INFUSION	SODIUM LACTATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE + CALCIUM CHLORIDE	0.320%W/V + 0.600%W/V + 0.040%W/V + 0.027%W/V	ALTHEA PHARMA PRIVATE LIMITEDWORKS: PLOT NO. 374, SHED NO. 'E', ALPHA INDL. PARK, ATHIAWAD, DABHEL, NANI DAMAN - 396210 (U.T.), INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	15/02/2023

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740	NDA/MAL/HDP/1 0660	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	AZITIZ-250	AZITHROMYCIN DIHYDRATE	250MG	ZOTA HEATHCARE LIMITEDPLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NEAR SACHIN RAILWAY STATION, SACHIN, CITY: SURAT, DIST: SURAT, GUJARAT STATE - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	15/02/2023
741	NDA/MAL/HDP/1 0661	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	LIVOTA-750	LEVOFLOXACIN HEMIHYDRATE	750MG	ZOTA HEATHCARE LIMITEDPLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NEAR SACHIN RAILWAY STATION, SACHIN, CITY: SURAT, DIST: SURAT, GUJARAT STATE - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	15/02/2023

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742	NDA/MAL/HDP/1 0662	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	TOMOZA	MOSAPRIDE CITRATE DIHYDRATE	5MG	ZOTA HEATHCARE LIMITEDPLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NEAR SACHIN RAILWAY STATION, SACHIN, CITY: SURAT, DIST: SURAT, GUJARAT STATE - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
743	NDA/MAL/HDP/1 0663	FERRER INTERNATIONAL, S.A.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TRAMAPA 37.5 MG/325 MG	TRAMADOL HYDROCHLORIDE + PARACETAMOL	37.5 MG/325 MG	FERRER INTERNATIONAL, S.AC/ JOAN BUSCALLA, 1-9 08173 SANT CUGAT DEL VALLES,	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	15/02/2023

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744	NDA/MAL/HDP/1 0664	FDC LTD	AIVEEN (U) LIMITED	OCUDORT-T	DORZOLAMIDE HYDROCHLORIDE + TIMOLOL MALEATE	(20 MG + 5 MG)/ML	FDC LIMITED, WALUJ .PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	15/02/2023
745	NDA/MAL/HDP/1 0668	LUPIN LIMITED	AIVEEN (U) LIMITED	DOLUTEGRAVIR SODIUM/LAMIVU DINE/TENOFOVIR DISOPROXIL FUMERATE 50MG/300MG/30 0MG	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE	50 MG + 300 MG + 300 MG	LUPIN LIMITED NAGPURPLOT NO. 6A, SECTOR 17, SPECIAL ECONOMIC ZONE, MIHAN, NAGPUR 441108, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X60.0 TABLET CONTAINER	15/02/2023

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746	NDA/MAL/HDP/1 067	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	IBUPARA	IBUPROFEN+PAR ACETAMOL	200MG+ 250MG/10ML	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2010
747	NDA/MAL/HDP/1 0673	EAST AFRICAN (INDIA) OVERSEAS	ROYAL PHARMA 2011 LIMITED	CETARIV	CETIRIZINE HYDROCHLORIDE	5MG/5ML	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE	15/02/2023

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748	NDA/MAL/HDP/1 0678	KESAR PHARMA	ABACUS PHARMA (AFRICA) LIMITED	ARTELUM	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	KESAR PHARMA PVT LTD PLOT SURVEY NO. 50/2. VILLAGE BILSHWARPURA CHHATRAL - 382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X24.0 TABLET BLISTER	15/02/2023
749	NDA/MAL/HDP/1 0679	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	PG-75	PREGABALIN	75 MG	ZOTA HEALTHCARE LIMITED PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY STATION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER	15/02/2023

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750	NDA/MAL/HDP/1 0681	BIODEAL LABORATORIES LTD PLOT NO.123	ABACUS PHARMA (AFRICA) LIMITED	PODOSAL OINTMENT	PODOPYLLUM RESIN + SALICYLIC ACID	20%W/W + 25%W/W	BIODEAL LABOARATORIES LTD (123, LUNGA LUNGA ROAD, INDUSTRIAL AREA, NAIROBI)	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X3.0X10.0 G TUBE	07/05/2024
751	NDA/MAL/HDP/1 0688	MEGA LIFSCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	UROKA	DUTASTERIDE	0.5 MG	MEGA LIFSCIENCES PUBLIC CO. LTDPLANT 1; 384 MOO 4, SOI 6, BANGPOO INDUSTRIAL ESTATE, PATTANA 3 ROAD, PHRAEKSA, MUEANG, SAMUTPRAKARN 10280 THAILAND	THAILAND	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	15/02/2023



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752	NDA/MAL/HDP/1 0689	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	LOSARZED-100	LOSARTAN POTASSIUM	100 MG	ZOTA HEALTHCARE LIMITED PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY STATION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
753	NDA/MAL/HDP/1 069	CIRON DRUGS & PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	K-ONE INJECTION	PHYTOMENADIO NE	10MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X1.0 ML AMPOULE	01/07/2014

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754	NDA/MAL/HDP/1 0690	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	PROTAC-40	PANTOPRAZOLE SODIUM	40 MG	SUNRISE INTERNATIONAL LABS LTD PLOT NO. 100, LANE-5, SECTOR II, PHASE-II, IDA, CHERLAPALLY INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
755	NDA/MAL/HDP/1 0691	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEUROGLOPENTI N 400 MG	GABAPENTIN	400MG	GLOBAL NAPI PHARMACEUTICALS- 2ND INDUSTRIAL ZONE, ST 18, 6TH OCTOBER CITY	EGYPT	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	15/02/2023

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756	NDA/MAL/HDP/1 0692	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEUROGLOPENTI N 300 MG	GABAPENTIN	300MG	GLOBAL NAPI PHARMACEUTICALS- 2ND INDUSTRIAL ZONE, ST 18, 6TH OCTOBER CITY	EGYPT	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	15/02/2023
757	NDA/MAL/HDP/1 0696	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	CELEBIB CAPSULES 200MG	CELECOXIB	200MG	MACLEODS PHARMACEUTICALS LIMITED, UNIT VIVILLAGE THEDA, KHARUNI LODHI MAJRA RD, TEHSIL BADDI N2, DISTRICT SOLAN, HIMACHAL PRADESH-174101	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	15/02/2023

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758	NDA/MAL/HDP/1 0697	BHARAT SERUMS & VACCINES LTD.	ABACUS PHARMA (AFRICA) LIMITED	ASPORELIX	CETRORELIX ACETATE	0.25MG	BHARAT SERUM AND VACCINES LIMITEDPLOT NO. K- 27 ADDITIONAL M.I.D.C INDIA	INDIA	PARENTERAL ORDINARY I V VIALS	1.0X0.25 MG VIAL + 1*1ML GLASS AMPOULE OF WFI	15/02/2023
759	NDA/MAL/HDP/1 0706	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	NTSUGA 500	METFORMIN HYDROCHLORIDE	500 MG	BIOMATRIX HEALTHCARE PRIVATE LIMITEDSURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

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760	NDA/MAL/HDP/1 0707	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	ZOPIMAC 3	ESZOPICLONE	3MG	MACLEODS PHARMACEUTICALS LIMITED, UNIT VIVILLAGE THEDA, KHARUNI LODHI MAJRA RD, TEHSIL BADDI N2, DISTRICT SOLAN, HIMACHAL PRADESH-174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X100.0 TABLET CONTAINER	15/02/2023
761	NDA/MAL/HDP/1 0708	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	CAFENOL	ACETYLSALICYLIC ACID + CAFFEINE	375MG + 25MG	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO. LR 209/6554, MOGADISHU ROAD INDUSTRIAL AREA, NAIROBI KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X8.0X20.0 TABLET BLISTER	15/02/2023

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762	NDA/MAL/HDP/1 0709	CADILA HEALTHCARE LIMITED "ZYDUS TOWER" -	ABACUS PHARMA (AFRICA) LIMITED	VINGLYN M 50/850	VILDAGLIPTIN + METFORMIN HYDROCHLORIDE	50 MG + 850 MG	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
763	NDA/MAL/HDP/1 0710	CADILA HEALTHCARE LIMITED;	ABACUS PHARMA (AFRICA) LIMITED	OXALGIN GEL	DICLOFENAC DIETHYLAMINE+ METHYL SALICYLATE + VIRGIN LINSEED OIL + CAPSAICIN + RACEMENTHOL	1.0%W/W + 10.0%W/W + 3.0%W/W + 0.05%W/W + 5.0%W/W	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X1.0X30.0 G TUBE	15/02/2023

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764	NDA/MAL/HDP/1 0715	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	VILDARIL M 50/500	VILDAGLIPTIN + METFORMIN HYDROCHLORIDE	50 MG + 500MG	AJANTA PHARMA LIMITEDPLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT- 392130	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
765	NDA/MAL/HDP/1 0716	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	VILDARIL M 50/850	VILDAGLIPTIN + METFORMIN HYDROCHLORIDE	50 MG + 850 MG	AJANTA PHARMA LIMITEDPLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT- 392130	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

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766	NDA/MAL/HDP/1 0717	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	VILDARIL M 50/1000	VILDAGLIPTIN + METFORMIN HYDROCHLORIDE	50 MG + 1000 MG	AJANTA PHARMA LIMITEDPLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRIC: BHARUCH,GUJARAT- 392130	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
767	NDA/MAL/HDP/1 0719	HETERO LABS LTD	AIVEEN (U) LIMITED	GOAB 5	SOLIFENACIN SUCCINATE	5 MG	M/S. ANNORA PHARMA PRIVATE LIMITEDSY. NO. 261, ANNARAM VILLAGE, GUMMADIDALA MANDAL, SANGAREDDY DISTRICT, TELENGANA STATE – 502313, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023



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768	NDA/MAL/HDP/1 072	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CO-ANGINET 80/12.5MG	VALSARTAN + HYDROCHLOROT HIAZIDE	80MG + 12.5MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD .57 UBAYBIN MUAATH STREET AL RAGEEM- SAHAB, AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013
769	NDA/MAL/HDP/1 0720	HETERO LABS LTD	AIVEEN (U) LIMITED	GOAB 10	SOLIFENACIN SUCCINATE	10MG	M/S. ANNORA PHARMA PRIVATE LIMITEDSY. NO. 261, ANNARAM VILLAGE, GUMMADIDALA MANDAL, SANGAREDDY DISTRICT, TELENGANA STATE – 502313, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

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770	NDA/MAL/HDP/1 0721	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	FLEXABENZ GEL	DICLOFENAC DIETHYLMAINE + LINSEED OIL + METHYL SALICYLATE + MENTHOL + CYCLOBENZAPRIN E HYDROCHLORIDE	1.0%W/W + 3.0%W/W + 10.0%W/W + 5.0%W/W + 2.0%W/W	OXALIS LABS LIMITEDVILLAGE THEDA, P.O LODHIMAJRA, TEHSIL BADDI DIST: SOLAN (H.P.) PIN CODE: 174101 - INDIA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X1.0X30.0 G TUBE	15/02/2023
771	NDA/MAL/HDP/1 0723	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	INSULIN H MIX	RECOMBINANT HUMAN INSULIN + RECOMBINANT PROTAMINE - HUMAN INSULIN	(30IU + 70IU)/ML	SOUTH EGYPT DRUG INDUSTRIES COMPANY (SEDICO)- FIRST INDUSTRIAL ZONE, 6TH OF OCTOBER CITY - EGYPT	EGYPT	PARENTERAL ORDINARY S C VIALS	1.0X1.0X10.0 ML VIAL	15/02/2023

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772	NDA/MAL/HDP/1 0724	MERIDIAN ENTERPRISES PRIVATE LIMITED.	VIDA AFRICA LTD	MONIZOL 3	MICONAZOLE NITARATE	400MG	MERIDIAN ENTERPRISES PVT. LTD-PLOT NO. 418, G.I.D.C., KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	VAGINAL SUPPOSITORIES	1X1X3 PESSARY SACHET	20/09/2023
773	NDA/MAL/HDP/1 0725	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BESICOR 2.5	BISOPROLOL FUMARATE	2.5MG	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

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774	NDA/MAL/HDP/1 0726	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BESICOR 5	BISOPROLOL FUMARATE	5MG	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
775	NDA/MAL/HDP/1 0727	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BESICOR 10	BISOPROLOL FUMARATE	10MG	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

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776	NDA/MAL/HDP/1 0728	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	RAPI-COOL	CHOLINE SALICYLATE + LIDOCAINE HYDROCHLORIDE	8.70% W/W + 2.00% W/W	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X10.0 G TUBE	15/02/2023
777	NDA/MAL/HDP/1 0729	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	BRISCORIL	SALBUTAMOL SULPHATE + BROMHEXINE HYDROCHLORIDE + GUAIFENESIN	(1MG + 2MG + 50MG ) PER 5ML	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	15/02/2023

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778	NDA/MAL/HDP/1 0730	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	UNICHLOR 25	CHLORTHALIDON E	25MG	UNICHEM LABORATORIES LIMITED (C-31,32 & D-10, INDUSTRIAL AREA, MEERUT ROAD, GHAZIABAD, U.P. )	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	06/03/2023
779	NDA/MAL/HDP/1 0731	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	UNICHLOR 50	CHLORTHALIDON E	50 MG	UNICHEM LABORATORIES LIMITED (C-31,32 & D-10, INDUSTRIAL AREA, MEERUT ROAD, GHAZIABAD, U.P. )	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	06/03/2023

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780	NDA/MAL/HDP/1 074	NECTAR LIFESCIENCES LTD	SUPER MEDIC LTD	CEFUAXIT	CEFUROXIME	500MG	NECTAR LIFE SCIENCES LTD-VILL. BHATOLIKALAN, ADJOINING JHARMJRI, E.P.I.P TEL. NALAGARH, DISTT. SOLAN, H.P.-173205 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2013
781	NDA/MAL/HDP/1 0742	CADILA HEALTHCARE LIMITED "ZYDUS TOWER" -	ABACUS PHARMA (AFRICA) LIMITED	VINGLYN	VILDAGLIPTIN	50 MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

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782	NDA/MAL/HDP/1 0743	CADILA HEALTHCARE LIMITED "ZYDUS TOWER" -	ABACUS PHARMA (AFRICA) LIMITED	VINGLYN M 50/500	VILDAGLIPTIN + METFORMIN HYDROCHLORIDE	50 MG + 500 MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
783	NDA/MAL/HDP/1 0748	KESAR PHARMA	VEERAM HEALTHCARE (U) LIMITED	LULI CREAM	LULICONAZOLE	1% W/W	KESAR PHARMA PVT LTD PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X10.0 G TUBE	15/02/2023



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784	NDA/MAL/HDP/1 0750	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	RESTOCIN PLUS	PARACETAMOL + DEXTROMETHOR PHAN HYDROBROMIDE + PHENYLEPHRINE HYDROCHLORIDE + CHORPHENIRAMI NE MALEATE	500 MG + 15 MG + 10 MG + 2 MG	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	15/02/2023
785	NDA/MAL/HDP/1 0753	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	HISTALIN 8	BETAHISTINE DIHYDROCHLORID E	8 MG	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

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786	NDA/MAL/HDP/1 0754	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	HISTALIN 16	BETAHISTINE DIHYDROCHLORID E	16 MG	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
787	NDA/MAL/HDP/1 0755	NEXT WAVE (INDIA)	DAVIMED PHARMA LIMITED	ZADYCINE-250	AZITHROMYCIN DIHYDRATE	250 MG	NEXT WAVERAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	15/02/2023

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788	NDA/MAL/HDP/1 0756	NEXT WAVE (INDIA)	DAVIMED PHARMA LIMITED	DAVIGRA 100	SILDENAFIL CITRATE	100 MG	NEXT WAVERAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X1.0 TABLET BLISTER	15/02/2023
789	NDA/MAL/HDP/1 0757	NEXT WAVE (INDIA)	DAVIMED PHARMA LIMITED	ZADYCINE-500	AZITHROMYCIN DIHYDRATE	500 MG	NEXT WAVERAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	15/02/2023

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790	NDA/MAL/HDP/1 0758	NEXT WAVE (INDIA)	DAVIMED PHARMA LIMITED	DAVIZOLE	ALBENDAZOLE	400 MG	NEXT WAVERAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X1.0 TABLET BLISTER	15/02/2023
791	NDA/MAL/HDP/1 076	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNICAST 4MG	MONTELUKAST SODIUM	4MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTDP.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL- RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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792	NDA/MAL/HDP/1 0760	TORQUE PHQRCEAUTICALS PVT LTD	SHURIK LTD	SKINNCARE	CLOBETASOL PROPIONATE + SALICYLIC ACID	0.05% W/W+ 3.00%W/W	TORQUE PHARMACEUTICALS PVT. LTD. UNIT-1, VILLAGE- ISSAPUR, DAPPAR, POST- DAPPAR, PUNJAB- 140506	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X20.0 G TUBE	15/02/2023
793	NDA/MAL/HDP/1 0761	WORLD MEDICINE Ā°LAĀž SAN. VE TIC. A.Āž.	GOODMAN INTERNATIONAL LTD	ZIROMIN	AZITHROMYCIN DIHYDRATE	500MG	WORLD MEDICINE ILAC SAN VE TIC A.S. (15 TEMMUZ MAHALLESİ, CAMI YOLU CADDESİ, NO: 50 K:4 WM PLAZA, GUNESIL- BAGCILAR/INSTANB UL, TURKEY)	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	21/03/2023

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794	NDA/MAL/HDP/1 0763	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROCORT	TRIAMCINOLONE ACETONIDE	40 MG/ML	AUROLAB LIMITEDNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0X1.0 ML VIAL	15/02/2023
795	NDA/MAL/HDP/1 0764	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	CLOPIDIV	CLOPIDOGREL HYDROGEN SULPHATE	75MG	HOVID BERHAD,LOT 56442, 7 1/2 MILES JALAN IPOH/CHEMOR 31200, CHEMOR PERAK	MALAYSIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

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796	NDA/MAL/HDP/1 0765	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HEXGABALIN 75	PREGABALIN	75MG	GLOBAL NAPI PHARMACEUTICALS- 2ND INDUSTRIAL ZONE, ST 18, 6TH OCTOBER CITY	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	15/02/2023
797	NDA/MAL/HDP/1 0766	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TRAMA-50	TRAMADOL HYDROCHLORIDE	50MG	CACHET PHARMACEUTICAL PVT LTD.VILLAGE- THANA, NEAR BADDI, TEHSIL_NALAGARH, DIST. SOLAN, HIMACHAL PRADESH- 173205	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	15/02/2023

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798	NDA/MAL/HDP/1 0768	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	NEBUNTA 5	NEBIVOLOL HYDROCHLORIDE	5 MG	AJANTA PHARMA LIMITEDPLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT- 392130	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
799	NDA/MAL/HDP/1 0769	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMOXIREN-500	AMOXICILLIN TRIHYDRATE	500MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	15/02/2023



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800	NDA/MAL/HDP/1 0776	CENTAUR PHARMACEUTICAL S PVT. LTD.	GITTOES PHARMACEUTICAL S LIMITED	LEEFLOX	LEVOFLOXACIN HEMIHYDRATE	0.5%W/V	CENTAUR PHARMACEUTICALS PVT. LTD (PLANT 1)PLOT 3,5B, 2C TIVIM INDUSTRIAL ESTATE, KARASVADA, MAPUSA, GOA 403526	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	15/02/2023
801	NDA/MAL/HDP/1 078	MICRO LABS LTD	LABOREX UGANDA LIMITED	LEVOBACT INFUSION	LEVOFLOXACIN HEMIHYDRATE	500MG	AHLCON PARENTERALS (INDIA) LTDSP-917- 918, PHASE-III BHIWADI-301019, ALWAR, RAJASTHAN	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2013

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802	NDA/MAL/HDP/1079	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOG-QUININE SYRUP	QUININE HYDROCHLORIDE	100MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2000
803	NDA/MAL/HDP/10792	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	NEBIMAC 5	NEBIVOLOL HYDROCHLORIDE	5 MG	MACLEODS PHARMACEUTICALS LIMITED, UNIT VIVILLAGE THEDA, KHARUNI LODHI MAJRA RD, TEHSIL BADDI N2, DISTRICT SOLAN, HIMACHAL PRADESH-174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER	03/05/2023

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804	NDA/MAL/HDP/10795	PROFARMA SH.A	JOINT MEDICAL STORE (UPMB - UCMB)	DIAZEPAM 10MG/2ML	DIAZEPAM	10MG/2ML	PROFARMA SH.A MYSLYM KETA, TIRANA	ALBANIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X2.0 ML AMPOULE	03/05/2023
805	NDA/MAL/HDP/1080	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZOCEF 250 TABLETS	CEFUROXIME AXETIL	250MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER, 1.0X1.0X10.0 TABLET BLISTER	01/07/2009

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806	NDA/MAL/HDP/1 0806	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	LOSARZED-50	LOSARTAN POTASSIUM	50MG	ZOTA HEALTHCARE LIMITED PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY STATION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	03/05/2023
807	NDA/MAL/HDP/1 0807	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	RESTOCIN PLUS	PARACETAMOL + DEXTROMETHOR PHAN HYDROBROMIDE + CHLORPHENAMIN E MALEATE + PHENYLEPHRINE HYDROCHLORIDE	(250MG + 10MG + 2MG + 5MG) PER 5ML	LINCOLN PHARMACEUTICALS LTD ,.,10,12,13, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ-382721 TA: KALOL, DIST. GHANDINAGAR, GUJARAT	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	03/05/2023

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808	NDA/MAL/HDP/1 0808	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	ROSUNA-10	ROSUVASTATIN CALCIUM	ROSUNA-10	ZOTA HEALTHCARE LIMITED PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY STATION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	03/05/2023
809	NDA/MAL/HDP/1 0816	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	AMITRYP-25	AMITRIPTYLINE HYDROCHLORINE	25 MG	LINCOLN PHARMACEUTICALS LTD ,,10,12,13, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ-382721 TA: KALOL, DIST. GHANDINAGAR, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	03/05/2023

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810	NDA/MAL/HDP/1 0818	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	LINFLOX	OFLOXACIN	0.3 % W/V	LINCOLN PHARMACEUTICALS LTD .,10,12,13, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ-382721 TA: KALOL, DIST. GHANDINAGAR, GUJARAT	INDIA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML BOTTLE	03/05/2023
811	NDA/MAL/HDP/1 082	DAWA LIMITED	SUPER MEDIC LTD	DACOF PAEDIATRIC	DIPHENHYDRAMINE HYDROCHLORIDE + SODIUM CITRATE + MENTHOL	75MG + 28.5MG + 0.55MG	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2013

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812	NDA/MAL/HDP/10821	PROFARMA SH.A	JOINT MEDICAL STORE (UPMB - UCMB)	ADRENALINE 1 MG/1ML	ADRENALINE HYDROGEN TARTRATE	1 MG/1ML	PROFARMA SH.AMYSLYM KETA,TIRANA	ALBANIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE	03/05/2023
813	NDA/MAL/HDP/10822	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	ACECLAV 228.5	AMOXICILLIN TRIHYDRATE + CLAVULANIC ACID	(200MG + 28.5 MG) PER 5ML	MEDICEF PHARMANO. 28, PHASE 1, EPIP, JHARRMAJRI, BADDI, DIST SOLAN (HP)	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	03/05/2023

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814	NDA/MAL/HDP/1 0823	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	VACODIL 12.5	CARVEDILOL	12.5MG	AUROBINDO PHARMA LIMITED UNIT 3PLOT NO. 313, 314, BACHUPALLY, RR DIST. 500090	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	06/06/2023
815	NDA/MAL/HDP/1 0824	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	OLANGEM OD 5	OLANZAPINE	5MG	AUROBINDO PHARMA LTD, UNIT VIISY. NO. 411/P, 425/P, 434/P, 435/P & 458/P, PLOT NO. S1 (PART), SPECIAL ECONOMIC ZONE (SEZ), TSIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHRLA MANDAL, MAHABOOB NAGA DISTRICT, PIN CODE: 509302,	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X4.0X7.0 TABLET BLISTER	06/06/2023



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816	NDA/MAL/HDP/1 0825	NOVARTIS OVERSEAS INVESTMENT	SURGIPHARM (U) LIMITED	UPERIO 50MG	SACUBITRIL + VALSARTAN	24.3MG + 25.7MG	NOVARTIS FARMA S.P.A.-NOVARTIS FARMA S.P.A. VIA PROVINCIALE SCHITO 131, 80058 TORRE ANNUNZIATA, ITALY	ITALY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	06/06/2023
817	NDA/MAL/HDP/1 0826	NOVARTIS OVERSEAS INVESTMENT	SURGIPHARM (U) LIMITED	UPERIO 100MG	SACUBITRIL + VALSARTAN	48.6MG +51.4MG	NOVARTIS FARMA S.P.A.-NOVARTIS FARMA S.P.A. VIA PROVINCIALE SCHITO 131, 80058 TORRE ANNUNZIATA, ITALY	ITALY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	06/06/2023

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818	NDA/MAL/HDP/1 0827	NOVARTIS OVERSEAS INVESTMENT	SURGIPHARM (U) LIMITED	UPERIO 200MG	SACUBITRIL + VALSARTAN	97.2MG + 102.8MG	NOVARTIS FARMA S.P.A.-NOVARTIS FARMA S.P.A. VIA PROVINCIALE SCHITO 131, 80058 TORRE ANNUNZIATA, ITALY	ITALY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER	06/06/2023
819	NDA/MAL/HDP/1 0828	TORRENT PHARAMACEUTICA LS LTD	KARURI PHARMACEUTICAL S LTD.	FENOTOR 200	FENOFIBRATE	200MG	TORRENT PHARMACEUTICALS LIMITEDPLOT NO. Z104-106, DAHEJ SEZ PART II, TALUKA: VAGRA, DIST.: BHARUCH-392130, GUJARAT- INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	06/06/2023

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820	NDA/MAL/HDP/1 0829	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	FENOTOR 67	FENOFIBRATE	67 MG	TORRENT PHARMACEUTICALS LIMITED PLOT NO. Z104-106, DAHEJ SEZ PART II, TALUKA: VAGRA, DIST.: BHARUCH-392130, GUJARAT- INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	06/06/2023
821	NDA/MAL/HDP/1 083	GALPHA LABORATORIES LTD	DAWASANA PHARMACEUTICALS LTD	CHOCOFER SYRUP	IRON + FOLIC ACID	50MG + 0.5MG /5ML	GALPHA LABORATORIES LIMITED VILLAGE "A" THANA BADDI, TEHSIL BADDI SOLAN HIMACHAL PRADESH-173 205 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2013

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822	NDA/MAL/HDP/1 0830	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	MUSCUREL	THIOLCHICOSI DE	8 MG	BILIM ILAC SAN.VE TIC.A.SGEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY	TURKEY	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	06/06/2023
823	NDA/MAL/HDP/1 0831	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LASTAVIN 80	VALSARTAN	80 MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	19/06/2023

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824	NDA/MAL/HDP/1 0832	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	LASTAVIN 160	VALSARTAN	160MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	06/06/2023
825	NDA/MAL/HDP/1 0833	AUROBINDO PHARMA LIMITED	GITTOES PHARMACEUTICAL S LIMITED	MOLNAFLU	MOLNUPIRAVIR	200MG	AUROBINDO PHARMA LIMITED, UNIT - XV PLOT NO. 17A, E BONANGI (V), PARAWADA (M), VISAKHAPATNAM DISTRICT, ANDHRA PRADESH. PIN: 531021 AUROBINDO PHARMA LIMITED UNIT 3PLOT NO. 313, 314, BACHUPALLY, RR DIST. 500090	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X40.0 CAPSULE BOTTLE	06/06/2023

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826	NDA/MAL/HDP/1 0834	MEGA LIFSCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	PANSIPTIN 100	SITAGLIPTIN HYDROCHLORIDE	100MG	SAG MANUFACTURING S.LCARRETERA NACIONAL 1 KM 36, SAN AGUSTIN DEL GUADALIX, 28750, SPAIN	SPAIN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER,1.0X2.0X14 .0 TABLET BLISTER	06/06/2023
827	NDA/MAL/HDP/1 0835	MEGA LIFSCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	PANSIPTIN 50	SITAGLIPTIN HYDROCHLORIDE	50MG	SAG MANUFACTURING S.LCARRETERA NACIONAL 1 KM 36, SAN AGUSTIN DEL GUADALIX, 28750, SPAIN	SPAIN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X18.0 TABLET BLISTER,1.0X2.0X14 .0 TABLET BLISTER	06/06/2023

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828	NDA/MAL/HDP/1 0836	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	PANSIPTIN 25	SITAGLIPTIN HYDROCHLORIDE	25MG	SAG MANUFACTURING S.LCARRETERA NACIONAL 1 KM 36, SAN AGUSTIN DEL GUADALIX, 28750, SPAIN	SPAIN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X16.0 TABLET BLISTER,1.0X2.0X14 .0 TABLET BLISTER	06/06/2023
829	NDA/MAL/HDP/1 0838	SHANGHAI DESANO BIO- PHARMACEUTICAL CO., LTD	TATA UGANDA LIMITED	DOLUTEGRAVIR TABLETS 50MG	DOLUTEGRAVIR SODIUM	50MG	SHANGHAI DESANO BIO- PHARMACEUTICAL CO., LTD1479, ZHANGHENG ROAD, CHINA (SHANGHAI) PILOT FREE TRADE ZONE, SHANGHAI 201203 - CHINA	CHINA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	06/06/2023

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830	NDA/MAL/HDP/1 0839	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	ZEEDERM	ZINC OXIDE	15%W/W	STEDMAN PHARMACEUTICALS PVT. LTD.C-4, SIDCO PHARMACEUTICALS COMPLEX, ALATHUR, THIRUPORUR- 603 110, TAMIL NADU INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	06/06/2023
831	NDA/MAL/HDP/1 084	DAWA LIMITED	SUPER MEDIC LTD	DAWA-CPM	CHLORPHENIRAM INE MALEATE	4MG	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2013



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832	NDA/MAL/HDP/10840	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	DREZ THROAT SPRAY	POVIDONE IODINE	0.45%W/V	STEDMAN PHARMACEUTICALS PVT. LTD. (C-4, SIDCO PHARMACEUTICALS COMPLEX, ALATHUR, THIRUPORUR- 603 110, TAMIL NADU INDIA)	INDIA	ORAL TOPICAL SPRAYS WITHOUT GAS	1.0X1.0X50.0ML CONTAINER	06/06/2023
833	NDA/MAL/HDP/10841	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DUTABIT PLUS 0.5/0.4	DUTASTERIDE + TAMSULOSIN HYDROCHLORIDE	0.5 MG + 0.4 MG	AUROBINDO PHARMA LTD, UNIT VIISY. NO. 411/P, 425/P, 434/P, 435/P & 458/P, PLOT NO. S1 (PART), SPECIAL ECONOMIC ZONE (SEZ), TSIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHRLA MANDAL, MAHABOOB NAGA DISTRICT, PIN CODE: 509302,	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	06/06/2023

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

834	NDA/MAL/HDP/1 0842	WOCKHARDT LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	EMROK	LEVONADIFLOXAC IN	800 MG / 100ML	WOCKHARDT LIMITED BIOTECH PARK, H-14/2, M.I.D.C, WALUJ, AURANGABAD - 431136, INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML VIAL	06/06/2023
835	NDA/MAL/HDP/1 0851	DEVA HOLDING A.S	SHREEJI PHARMACEUTICAL S LIMITED	LOSAPRES PLUS 50 MG / 12.5 MG	LOSARTAN POTASSIUM + HYDROCHLOROT HIAZIDE	50 MG + 12.5 MG	DEVA HOLDING A.S (CERKEZKOY PRODUCTION SITE)CERKEZKOY ORGANIZE SANAYI BOLGESI. KARAAGAC MAH. ATATURK CAD. NO: 32 59510 KAPAKLI/TEKIRDAG/ TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	03/05/2023

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836	NDA/MAL/HDP/1 0852	INFUGEN PHARMA PVT. LTD.	TATA UGANDA LIMITED	INTRAM	TRAMADOL HYDROCHLORIDE	50MG	FREDUN PHARMACEUTICALS LIMITED,14,15,16 - ZORABIAN INDUSTRIAL COMPLEX, VEOOR, PALGHAR (E), THANE	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	03/05/2023
837	NDA/MAL/HDP/1 0854	CENTAUR PHARMACEUTICAL S PVT. LTD.	GITTOES PHARMACEUTICAL S LIMITED	GLIMITAB 2 TABLETS	GLIMEPIRIDE	2MG	CENTAUR PHARMACEUTICALS PVT. LTD (PLANT 1) (PLOT 3,5B, 2C TIVIM INDUSTRIAL ESTATE, KARASVADA, MAPUSA, GOA 403526 )	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	25/05/2023

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838	NDA/MAL/HDP/1 086	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	SYNOGEN TABLETS	DIACEREIN + METHYL SULPHONYL METHANE + GLUCOSAMINE SULPHATE	50MG +250MG + 750MG	NEM LABORATORIES LIMITED133 KRISHNA IND. ESTATE, VASAI (E), THANE – 401 210, MAHARASHTRA – INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2012
839	NDA/MAL/HDP/1 087	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOCYCLINE	TETRACYCLINE	3%W/W	AGOG PHARMA LTD.PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/2013

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

840	NDA/MAL/HDP/1 0873	MARCYRL PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TORSAMOLEX 10MG	TORSEMIDE	10 MG	MARCYRL PHARMACEUTICAL INDUSTRIES WESTERN EXTEENSION-PARTS NUMBER 5/6/7/8/9/10/11/12- BLOCK 20005, EL OBOUR CITY	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	17/08/2023
841	NDA/MAL/HDP/1 0874	: ALKEM LABORATORIES LIMITEDV	ABACUS PHARMA (AFRICA) LIMITED	PAN IV	PANTOPRAZOLE SODIUM	40MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X40.0 MG VIAL (+ 10 ML OF 0.9%W/V SODIUM CHLORIDE INJECTION, LDPE AMPOULE)	17/08/2023

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

842	NDA/MAL/HDP/1-0878	LUPIN LIMITED-	AIVEEN (U) LIMITED	LINEZOLID 600 MG TABLETS	LINEZOLID	600MG	LUPIN LTD198-202, NEW INDUSTRIAL AREA NO. 2, MANDIDEEP, BHOPAL-462 046, DIST. RAISEN, MADIA PRADESH INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	17/08/2023
843	NDA/MAL/HDP/1-0879	LUPIN LIMITED-	AIVEEN (U) LIMITED	ISONIAZID TABLETS 300MG	ISONIAZID	300MG	LUPIN LIMITED A-28/1 MIDC CHIKALTHANA AURANGABAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	17/08/2023

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

844	NDA/MAL/HDP/1 0880	TABROS PHARMA	HEALTHCARE LTD.	HEMSAMIC CAPSULE	TRANEXAMIC ACID	500MG	TABROS PHARMAL- 20/B SECTOR 22 FB INDUSTRIAL AREA KARACHI PAKISTAN	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	24/07/2023
845	NDA/MAL/HDP/1 0881	MEGA LIFSCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	PANFOR PR-750	METFORMIN HYDROCHLORIDE	750MG	INVENTIA HEALTHCARE LIMITEDF-1 - F-1/1 - F75/1, ADDITIONAL AMBERNATH MIDC, AMBERNATH EAST 421506, DIST. THANE, MAHARASHTRA - INDIA	INDIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER	17/08/2023

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

846	NDA/MAL/HDP/1 0882	BHARAT SERUMS & VACCINES LTD.	ABACUS PHARMA (AFRICA) LIMITED	FOLIGRAF 1200 IU	RECOMBINANT - HUMAN FOLLICLE STIMULATING HORMONE (R- HFSH)	1200IU/VIAL (MULTIDOSE)	BHARAT SERUM AND VACCINES LIMITEDPLOT NO. K- 27 ADDITIONAL M.I.D.C INDIA	INDIA	PARENTERAL ORDINARY DRY AMPOULES	1.0X1.0 VIAL 1 PREFILLED SYRINGE OF DILUENT + 15 DISPOSABLE SYRINGES]	17/08/2023
847	NDA/MAL/HDP/1 0883	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	DAPAGLIFLOZIN TABLETS 10 MG	DAPAGLIFLOZIN PROPANEDIOL	10MG	CIPLA LIMITEDPLOT NOS. L-139, S-103 & M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA, 403 722 - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	17/08/2023



## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

848	NDA/MAL/HDP/1 0884	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	MALOTEM 80/480MG	ARTEMETHER + LUMEFANTRINE	80 MG + 480 MG	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X6.0 TABLET BLISTER	17/08/2023
849	NDA/MAL/HDP/1 0885	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	NEBIMAC 10	NEBIVOLOL HYDROCHLORIDE	10MG	MACLEODS PHARMACEUTICALS LIMITED (BLOCK -N1)BLOCK N1, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, HIMACHAL PRADESH -174101,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X7.0 TABLET BLISTER	17/08/2023

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850	NDA/MAL/HDP/10886	LINCOLN PHARMACEUTICALS LIMITED	METRO PHARMACEUTICALS LIMITED	CLOTRILIN-V	CLOTRIMAZOLE	2%W/W	LINCOLN PHARMACEUTICALS LTD (10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA)	INDIA	VAGINAL CREAMS	1.0X1.0X15.0 G TUBE	28/08/2023
851	NDA/MAL/HDP/10888	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	COVIFOR	REMDESIVIR	100MG/VIAL	ASPIRO PHARMA LIMITEDSY. NO. 321, BIOTECH PARK, PHASE-III, KARKAPATLA, MARKOOK MANDAL, SIDDIPET DISTRICT-502 281, TELANGANA, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X100.0 MG VIAL	17/08/2023

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

852	NDA/MAL/HDP/1 0889	WORLD MEDICINE İLAÇ SAN. VE TİC. A.Ş.	GOODMAN INTERNATIONAL LTD	PIRETİKOL PLUS	PARACETAMOL + CHLORPHENIRAM INE MALEATE + PHENYLEPHRINE HYDROCHLORIDE	(160 MG + 1 MG + 2.5 MG)/5 ML	WORLD MEDICINE İLAÇ SAN VE TİC A.S.15 TEMMUZ MAHALLESİ, CAMI YOLU CADDESİ, NO: 50 K:4 WM PLAZA, GÜNEŞİL- BAĞCILAR/İSTANB UL, TURKEY	TURKEY	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	16/04/2024
853	NDA/MAL/HDP/1 0890	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	ZIQUANTA	PRAZICUANTEL	600MG	HETERO LABS LIMITED (UNIT V)SY. NO. 439, 440, 441 & 458, POLEPALLY VILLAGE, JADCHERLA MANDAL MAHABOBNAGAR DISTRICT, PIN-509 301, TELANGANA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X6.0 TABLET CONTAINER,1.0X10 0.0 TABLET CONTAINER,1.0X50 0.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	17/08/2023

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854	NDA/MAL/HDP/10891	LINCOLN PHARMACEUTICALS LTD.	METRO PHARMACEUTICALS LIMITED	BINAFIN	TERBINAFINE HYDROCHLORIDE	1%W/W	LINCOLN PHARMACEUTICALS LTD (10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA)	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	28/08/2023
855	NDA/MAL/HDP/10894	REYOUNG PHARMACEUTICAL CO LTD	BIOGEN PHARMA LIMITED	FRUSOGEN	FUROSEMIDE	20MG/2ML	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE	17/08/2023

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856	NDA/MAL/HDP/1 0896	REYOUNG PHARMACEUTICAL CO LTD	BIOGEN PHARMA LIMITED	AMPIGEN	AMPICILLIN SODIUM + CLOXACILLIN SODIUM	(250MG + 250MG)VIAL	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X0.5 G VIAL	17/08/2023
857	NDA/MAL/HDP/1 0897	HILTON PHARMA (PVT) LTD	BOOTS PHARMACEUTICAL S LIMITED	DAPA	DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE	5MG	HILTON PHARMACEUTICALS (PVT) LIMITEDPLOT NO. 13-14, SECTOR 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X14.0 TABLET BLISTER	17/08/2023

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858	NDA/MAL/HDP/1 0898	HILTON PHARMA (PVT) LTD	BOOTS PHARMACEUTICAL S LIMITED	ROLIP EZE TABLETS	ROSUVASTATIN CALCIUM + EZETIMIBE	20MG +10MG	HILTON PHARMACEUTICALS (PVT) LIMITED PLOT NO. 13-14, SECTOR 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	17/08/2023
859	NDA/MAL/HDP/1 0900	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	TRAMADOL DENK	TRAMADOL HYDROCHLORIDE	100MG/2 ML	SOLUPHARM GMBH INDUSTRIESTRASSE 3, 34212 MELSUNGEN	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X2.0 ML AMPOULE	17/08/2023

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860	NDA/MAL/HDP/1 0903	MEGA LIFSCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	BIDSIPTIN	VILDAGLIPTIN	50MG	SAG MANUFACTURING S.LCARRETERA NACIONAL 1 KM 36, SAN AGUSTIN DEL GUADALIX, 28750, SPAIN	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023
861	NDA/MAL/HDP/1 0904	MEGA LIFSCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	UROKA PLUS	DUTASTERIDE + TAMSULOSIN HYDROCHLORIDE	0.5MG + 0.4MG	SAG MANUFACTURING S.LCARRETERA NACIONAL 1 KM 36, SAN AGUSTIN DEL GUADALIX, 28750, SPAIN	SPAIN	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	17/08/2023

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862	NDA/MAL/HDP/10905	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	VERQUVO 2.5 MG TABLET	VERICIGUAT	2.5MG	BAYER PHARMA AG (51368 LEVERKUSEN,)	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X14.0 TABLET BLISTER, 1.0X28.0 TABLET CONTAINER	28/08/2023
863	NDA/MAL/HDP/10906	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	VERQUVO 5MG TABLET	VERICIGUAT	5MG	BAYER PHARMA AG (51368 LEVERKUSEN,)	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X14.0 TABLET BLISTER, 1.0X28.0 TABLET CONTAINER	28/08/2023



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864	NDA/MAL/HDP/10907	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	VERQUVO 10 MG TABLET	VERICIGUAT	10MG	BAYER PHARMA AG (51368 LEVERKUSEN,)	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X14.0 TABLET BLISTER, 1.0X28.0 TABLET CONTAINER	28/08/2023
865	NDA/MAL/HDP/10908	BDR PHARMACEUTICALS INTERNATIONAL PVT LTD	ONCOPHARM (U) LTD	LIVONIBE	SORAFENIB TOSYLATE	20 MG	BDR PHARMACEUTICALS INTERNATIONAL PRIVATE LIMITEDR.S. NO. 578, NR, EFFLUENT CHANNEL ROAD,; VILLAGE - LUNA, TAL-PADRA; DIST - VADODARA - 391440; GUJARAT - INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	17/08/2023

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866	NDA/MAL/HDP/1 0909	NEXT WAVE (INDIA)	DAVIMED PHARMA LIMITED	CADZOLE	CLOTRIMAZOLE	1% W/W	NEXT WAVERAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	17/08/2023
867	NDA/MAL/HDP/1 0910	NEXT WAVE (INDIA)	DAVIMED PHARMA LIMITED	DAVI-IBU	IBUPROFEN	200MG	NEXT WAVERAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	17/08/2023

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868	NDA/MAL/HDP/10911	NEXT WAVE (INDIA)	DAVIMED PHARMA LIMITED	DAVIZOLE	ALBENDAZOLE	200MG/5ML	NEXT WAVERAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	ORAL LIQUID ORDINARY EMULSIONS	1.0X1.0X10.0 ML BOTTLE	17/08/2023
869	NDA/MAL/HDP/10912	NEXT WAVE (INDIA)	DAVIMED PHARMA LIMITED	FLUZINE	CETIRIZINE DIHYDROCHLORIDE	10MG	NEXT WAVERAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	17/08/2023

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870	NDA/MAL/HDP/10914	DAVIMED PHARMA LIMITED	DAVIMED PHARMA LIMITED	HI CEF 250	CEFALEXIN MONOHYDRATE	250 MG	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	17/08/2023
871	NDA/MAL/HDP/10915	DAVIMED PHARMA LIMITED	DAVIMED PHARMA LIMITED	DAVICEF 1 G	CEFTRIAXONE SODIUM	1G/VIAL	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X10.0 ML VIAL	17/08/2023

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872	NDA/MAL/HDP/1 0916	DAVIMED PHARMA LIMITED	DAVIMED PHARMA LIMITED	CEFOTEC	CEFOTAXIME SODIUM	1G/VIAL	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	PARENTERAL RETARD DRY VIALS	1.0X1.0X1.0 G VIAL	17/08/2023
873	NDA/MAL/HDP/1 0917	DAVIMED PHARMA LIMITED	DAVIMED PHARMA LIMITED	CEFTRIAZONE	CEFTRIAZONE SODIUM	1G/VIAL	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X25.0X1.0X1.0 G VIAL	17/08/2023

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874	NDA/MAL/HDP/1 0918	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	ESUPRONE	ESOMEPRAZOLE SODIUM	40 MG/VIAL	BLISS INDASI LIFESCIENCE PRIVATE LIMITED PLOT NO. 73 TO 76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN- 396 210	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X40.0 MG VIAL + 1*10 ML, SODIUM CHLORIDE IN LDPE PACK	17/08/2023
875	NDA/MAL/HDP/1 0919	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	SANFIXIME 400	CEFIXIME TRIHYDRATE	400MG	EAST AFRICAN (INDIA) OVERSEAS (PLOT NO.1, PHARMACITY SELAQUI DEHRADUN "â€”" 248011 (U.K), INDIA)	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	05/09/2023

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876	NDA/MAL/HDP/1 0920	ACINO AG.	LABOREX UGANDA LIMITED	PARACONICA™ PLUS 500 MG/150 MG	PARACETAMOL + IBUPROFEN	500 MG + 150 MG	SIGMA LABORATORIES PRIVATE LIMITED6, 7, 8 TIVIM INDUSTRIAL ESTATE, TIVIM, MAPUSA 403526, GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	17/08/2023
877	NDA/MAL/HDP/1 0921	AVACARE GLOBAL	GOODMAN INTERNATIONAL LTD	AVAFLOX 500	LEVOFLOXACIN HEMIHYDRATE	500 MG	WORLD MEDICINE ILAC SAN VE TIC A.S.15 TEMMUZ MAHALLESİ, CAMI YOLU CADDESİ, NO: 50 K:4 WM PLAZA, GUNESIL- BAGCILAR/INSTANB UL, TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X7.0 TABLET BLISTER	17/08/2023

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878	NDA/MAL/HDP/10922	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	LABCLAV 1G TABLETS	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	875MG + 125MG	LABORATORY & ALLIED LTD PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, NEXT TO LIBRA HOUSE, MOMBASA ROAD- NAIROBI - KENYA	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X2.0X7.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER	17/08/2023
879	NDA/MAL/HDP/10923	BAROQUE PHARMACEUTICALS PVT LTD	JEET PHARMACEUTICALS LIMITED	ROSUSTAR 10MG	ROSUVASTATIN CALCIUM	10MG	BAROQUE PHARMACEUTICALS PVT. LTD (PLOT 192/2&3, SOKHADA-388 620 KHAMBHAT. DIST. ANAND GUJARAT INDIA)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	05/09/2023



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880	NDA/MAL/HDP/1 0924	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	METOPRIX 10	METOCLOPRAMI DE	10 MG	BIOMATRIX HEALTHCARE PRIVATE LIMITEDSURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	17/08/2023
881	NDA/MAL/HDP/1 0925	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	HERPIRAX 200	ACICLOVIR	200 MG	BIOMATRIX HEALTHCARE PRIVATE LIMITEDSURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023

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882	NDA/MAL/HDP/1 0926	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	ACELEVO 500	LEVOFLOXACIN HEMIHYDRATE	500 MG	BIOMATRIX HEALTHCARE PRIVATE LIMITEDSURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	17/08/2023
883	NDA/MAL/HDP/1 0927	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	ACELEVO 750	LEVOFLOXACIN HEMIHYDRATE	750MG	BIOMATRIX HEALTHCARE PRIVATE LIMITEDSURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	17/08/2023

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884	NDA/MAL/HDP/1 0928	FAROMED LIFESCIENCES LLP	METRO PHARMACEUTICAL S LIMITED	FIX-A	CEFIXIME TRIHYDRATE	100MG/5ML	THE ACME LABORATORIES LIMITEDDHULIVITA, DHAMRAI, DHAKA - 1350, BANGLADESH	BANGLADESH	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X75.0 ML BOTTLE	17/08/2023
885	NDA/MAL/HDP/1 0931	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	UNIDROL 10	ALFUZOSIN HYDROCHLORIDE	10 MG	UNICHEM LABORATORIES LTDUNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023

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886	NDA/MAL/HDP/1 0932	SHREEJI CARE LIMITED	SHREEJI CARE LIMITED	CALCIGLO-L	CALCIUM LACTATE	300MG	GLOBELA PHARMA PVT.LTD.357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	17/08/2023
887	NDA/MAL/HDP/1 0933	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	P-ALAXIN	DIHYDROARTEMI SININ + PIPERAQUINE PHOSPHATE	20 MG + 160 MG	BLISS GVS PHARMA LIMITED10,11 & 12,DEWAN UDYOG NAGAR,ALIYALI,PALG HAR,MAHARASHTRA 401404,INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X3.0 TABLET BLISTER,1.0X2.0X3. 0 TABLET BLISTER	17/08/2023

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888	NDA/MAL/HDP/1 0934	FAROMED LIFSCIENCES LLP	METRO PHARMACEUTICAL S LIMITED	ALERCON	OLOPATADINE HYDROCHLORIDE	1 MG/ML	THE ACME LABORATORIES LIMITEDDHULIVITA, DHAMRAI, DHAKA - 1350, BANGLADESH	BANGLADESH	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	17/08/2023
889	NDA/MAL/HDP/1 0935	FAROMED LIFSCIENCES LLP	METRO PHARMACEUTICAL S LIMITED	SUPERPIME 1G IM/IV INJECTION	CEFEPIME HYDROCHLORIDE	1 G/VIAL	THE ACME LABORATORIES LIMITEDDHULIVITA, DHAMRAI, DHAKA - 1350, BANGLADESH	BANGLADESH	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	17/08/2023

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890	NDA/MAL/HDP/1 0936	LINCOLN PHARMACEUTICAL S LTD.	METRO PHARMACEUTICAL S LIMITED	TEARLIN-0.5 %	CARMELLOSE SODIUM	0.5% W/V	LINCOLN PHARMACEUTICALS LTD (10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA)	INDIA	OPHTHALMIC DROPS	1.0X1.0X10.0ML BOTTLE	05/09/2023
891	NDA/MAL/HDP/1 0937	LINCOLN PHARMACEUTICAL S LTD.	METRO PHARMACEUTICAL S LIMITED	TEARLIN-1 %	CARMELLOSE SODIUM	1.0% W/V	LINCOLN PHARMACEUTICALS LTD (10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA)	INDIA	OPHTHALMIC DROPS	1.0X1.0X10.0ML BOTTLE	05/09/2023

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892	NDA/MAL/HDP/1 0938	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	ATORKEY 80	ATORVASTATIN CALCIUM TRIHYDRATE	80 MG	AUROBINDO PHARMA LIMITED, UNIT - XV PLOT NO. 17A, E BONANGI (V), PARAWADA (M), VISAKHAPATNAM DISTRICT, ANDHRA PRADESH. PIN: 531021	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023
893	NDA/MAL/HDP/1 0939	WOCKHARDT LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	EMROK O	ALALEVONADIFLO XACIN	500 MG	WOCKHARDT LIMITED -BIOTECH PARK, H-14/2, M.I.D.C, WALUJ, AURANGABAD - 431136, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X2.0 TABLET BLISTER	17/08/2023

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894	NDA/MAL/HDP/1094	MICRO LABS LTD	LABOREX UGANDA LIMITED	GRAMOCEF-O-100	CEFIXIME	100MG/5ML	MICRO LABS LTD-NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2013
895	NDA/MAL/HDP/10940	BRAWN LABORATORIES LTD	PLANET PHARMACEUTICALS UGANDA LTD	MASTIC-LC	MONTELUKAST SODIUM + LEVOCETIRIZINE DIHYDROCHLORIDE	10MG + 5MG	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	17/08/2023



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896	NDA/MAL/HDP/1 0944	TORRENT PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S LTD.	TORLEVA 500MG	LEVETIRACETAM	500MG	TORRENT PHARMACEUTICALS LTD .,INDRAD - 382721, TAL: KADI, CITY - INDRAD, DIST. MEHSANA, GUJARAT STATE - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023
897	NDA/MAL/HDP/1 0945	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	XYLOPIL-2%	LIDOCAINE HYDROCHLORIDE	20MG/ML	PSYCHOTROPICS INDIA LTD PLOT NO. 12 & 12A, INDUSTRIAL PARK-II, PHASE-1, VILLAGE SALEMPUR, MEHDOOD-2 HARIDWAR-249403, UTTARAKHAND INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X30.0 ML VIAL (CLEAR GLASS VIAL)	17/08/2023

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898	NDA/MAL/HDP/1 0946	MACLEODS PHARMACEUTICAL S LTD	AIVEEN (U) LIMITED	MONTEMAC-10	MONTELUKAST SODIUM	10MG	MACLEODS PHARMACEUTICALS LIMITED, UNIT VIVILLAGE THEDA, KHARUNI LODHI MAJRA RD, TEHSIL BADDI N2, DISTRICT SOLAN, HIMACHAL PRADESH-174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023
899	NDA/MAL/HDP/1 0947	MACLEODS PHARMACEUTICAL S LTD	AIVEEN (U) LIMITED	OLMESAR H	OLMESARTAN MEDOXOMIL + HYDROCHLOROT HIAZIDE	20 MG + 12.5 MG	MACLEODS PHARMACEUTICALS LIMITED, UNIT VIVILLAGE THEDA, KHARUNI LODHI MAJRA RD, TEHSIL BADDI N2, DISTRICT SOLAN, HIMACHAL PRADESH-174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	17/08/2023

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900	NDA/MAL/HDP/1 0948	WALLACE PHARMACEUTICAL S PVT. LTD	STAR PHARMACEUTICAL S LTD	FLUCOLD	PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + CHLORPHENAMIN E MALEATE	500 MG + 10 MG + 2 MG	WALLACE PHARMACEUTICALS PVT LTDBHATIAN, NALAGARH, DIST. SOLAN HP 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X5.0X10.0 TABLET BLISTER	17/08/2023
901	NDA/MAL/HDP/1 0949	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	CLAMOXIN-375 TABLETS	AMOXICILLIN SODIUM + POTASSIUM CLAVULANATE	250MG + 125 MG	MEDOPHARM PVT LIMITEDNO. 50 KAYARAMBEDU VILLAGE, GUDUVANCHERY- 603202	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	17/08/2023

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902	NDA/MAL/HDP/1 095	MICRO LABS LTD	LABOREX UGANDA LIMITED	EROSTINE-20	EBASTINE	20MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2012
903	NDA/MAL/HDP/1 0950	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICAL S LTD	DICORATE ER 500	DIVALPROEX SODIUM	500 MG	SUN PHARMA LABORATORIES LIMITED6-9, EPIP, KARTHOLI, BARI BRAHMANA, JAMMU - 181133 (JAMMU AND KASHMIR) - INDIA	INDIA	ORAL SOLID RETARD COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER	17/08/2023

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904	NDA/MAL/HDP/10951	THE UNITED PHARMACEUTICALS MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VIVAZAC PLUS	IRBESARTAN + HYDROCHLOROTHIAZIDE	300MG + 25MG	UNITED PHARMACEUTICALS MANUFACTURING LIMITED COMPANY (AL-RAGEEM, SAHAB, P.O. BOX 60, AMMAN 11591 - JORDAN)	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/08/2023
905	NDA/MAL/HDP/10952	MINAPHARM PHARMACEUTICAL & CHEMICAL INDUSTRIES	SWASTIK PHARMACEUTICAL LTD	HYDROQUINE	HYDROXYCHLOROQUINE SULPHATE	200 MG	MINAPHARM COMPANY FOR PHARMACEUTICALS AND CHEMICAL INDUSTRIESPARTS NO. 15/4; 16/4, INDUSTRIAL ZONE A2 - 10TH OF RAMADHAN CITY - EGYPT	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	17/08/2023

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906	NDA/MAL/HDP/1 0953	KOPRAN LIMITED	TATA UGANDA LIMITED	LOKIT HP	CLARITHROMYCIN + TINIDAZOLE + OMEPRAZOLE	250 MG + 500 MG + 20 MG	KOPRAN LIMITEDVILLAGE - SAVROLI (KHOPOLI), TALUKA - KHALAPUR, DIST. RAIGAD 410202, MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY COMBINATION PACK COATED TABLETS	1.0X7.0X1.0X1.0X6. 0 TABLET STRIP (EACH STRIP CONTAINS 2 TABLETS OF CLARITHROMYCIN + 2 TABLETS OF TINIDAZOLE + 2 CAPSULES OF OMEPRAZOLE)	17/08/2023
907	NDA/MAL/HDP/1 0954	RENATA LIMITED	UHAI PHARMACY	FUROCEF®	CEFUROXIME AXETIL	500MG	RAJENDRAPUR POTENT PRODUCT FACILITY (RPPF), RENATA LIMITEDNOYAPARA, BHAWAL MIRZAPUR, RAJENDRAPUR, GAZIPUR 1700 - BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X6.0 TABLET BLISTER	17/08/2023

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908	NDA/MAL/HDP/1 0956	RENATA LIMITED	UHAI PHARMACY	ZITHRIN	AZITHROMYCIN	500MG	RENATA LIMITED RAJENDRAPUR GENERAL FACILITY, NOYAPARA BHAWAL MIRZAPUR RAJENDRAPUR GAZIPUR, 1700 BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X5.0 TABLET BLISTER	17/08/2023
909	NDA/MAL/HDP/1 0957	ORCHIDIA PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CO-AVAZIR	TOBRAMYCIN + DEXAMETHASON E	(3 MG + 1 MG)/ML	ORCHIDIA PHARMACEUTICAL INDUSTRIESAL OBOUR CITY INDUSTRIAL ZONE, AREA 14, 15 - PLOT NO. 12011 - CAIRO - EGYPT	EGYPT	OPHTHALMIC SUSPENSIONS	1.0X1.0X5.0 ML BOTTLE	17/08/2023

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910	NDA/MAL/HDP/10958	ORCHIDIA PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ALPHANOVA	BRIMONIDINE TARTRATE	0.15%W/V	ORCHIDIA PHARMACEUTICAL INDUSTRIESAL OBOUR CITY INDUSTRIAL ZONE, AREA 14, 15 - PLOT NO. 12011 - CAIRO - EGYPT	EGYPT	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	17/08/2023
911	NDA/MAL/HDP/10959	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	VALMACA 160/10	AMLODIPINE BESYLATE + VALSARTAN	10 MG + 160 MG	MACLEODS PHARMACEUTICALS LIMITED. .BLOCK N1, N2 & N3, VILLAGE THEDA P.O MANPURA, TEHSIL NALAGARH, DIST SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	17/08/2023



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912	NDA/MAL/HDP/1 096	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ARTEMETHER	ARTEMETHER	80MG/ML	SANJAR PHARMA LLP HIMATNAGAR- VIJOPUR HIGHWAY, DEDHROTA HIMATNAGAR 383 220, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE,1.0X1.0X 8.0X1.0 ML AMPOULE	01/07/2014
913	NDA/MAL/HDP/1 0960	AXA PARENTERALS LTD	VITACARE LIMITED	AXADEX D5	GLUCOSE ANHYDROUS	5% W/V	AXA PARENTERALS LTD PLOT NO. 936, 937 & 939, VILLAGE KISHANPUR, JAMALPUR ROORKEE- 247667, DIST. HARIDWAR, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES	1.0X100.0 ML BOTTLE	17/08/2023

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914	NDA/MAL/HDP/1 0961	ADWIA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LEPTROGINE 25MG	LAMOTRIGINE	25 MG	ADWIA S.A.E.1ST INDUSTRIAL ZONE A1, 10TH OF RAMADAN CITY, EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023
915	NDA/MAL/HDP/1 0962	MYLAN LABORATORIES LIMITED-	KIMSY MEDS LTD	DARUNAVIR/RITO NAVIR TABLETS 400 MG/50 MG	DARUNAVIR ETHANOLATE + RITONAVIR	400 MG + 50 MG	MYLAN LABORATORIES LTD .F/4 & F/12, MALEGAON MIDC, SINNAR, NASHIK-422 113, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X60.0 TABLET CONTAINER	17/08/2023

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916	NDA/MAL/HDP/1 0963	PHARMATHEN S.A	GOODMAN INTERNATIONAL LTD	MEPERYA	MEROPENEM TRIHYDRATE	1G	DEMO SA (21ST KM NATIONAL ROAD, ATHENS, LAMIA 14568 KRYONERI, ATHENS)	GREECE	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL	14/08/2023
917	NDA/MAL/HDP/1 0964	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AZIREN	AZITHROMYCIN DIHYDRATE	500MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	17/08/2023

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918	NDA/MAL/HDP/1 0965	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	MPHETAS-500	MYCOPHENOLAT E MOFETIL	500MG	INTAS PHARMACEUTICALS LTD ..PLOT NO. 457- 458 VILL MATODA BAVLA ROAD TA SANAND DIST AHMEDABAD PIN- 382 210 GUJARART STATE	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	17/08/2023
919	NDA/MAL/HDP/1 0966	EUGIA PHARMA SPECIALITIES LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	SKYTINIB 12.5	SUNITINIB MALATE	12.5 MG	EUGIA PHARMA SPECIALITIES LIMITEDSURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X7.0 CAPSULE BLISTER	17/08/2023

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920	NDA/MAL/HDP/1 0967	EUGIA PHARMA SPECIALITIES LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	SKYTINIB 25	SUNITINIB MALATE	25 MG	EUGIA PHARMA SPECIALITIES LIMITED SURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X7.0 CAPSULE BLISTER	17/08/2023
921	NDA/MAL/HDP/1 0968	HALEWOOD LABORATORIES PVT. LTD.	AIVEEN (U) LIMITED	ELECTRORUSH POWDER ORS BP	SODIUM CHLORIDE + POTASSIUM CHLORIDE + TRISODIUM CITRATE DIHYDRATE + DEXTROSE ANHYDROUS	2.60 G + 1.50 G + 2.90 G + 13.50 G	HALEWOOD LABORATORIES PVT. LIMITED 319, PHASE - II, GIDC, VATVA, AHMEDABAD - 382445, GUJARAT	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X10.0X20.5 G SACHET	17/08/2023

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922	NDA/MAL/HDP/1 0969	FDC LTD	AIVEEN (U) LIMITED	VITCOFOL	FERROUS FUMARATE + FOLIC ACID + CYANOCOBALAMI N	(100MG + 0.5MG + 5MCG)/5ML	FDC LIMITED, WALUJ .PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	17/08/2023
923	NDA/MAL/HDP/1 0970	UMEDICA LABORATORIES PVT LTD	VITACARE LIMITED	OLMETAN- H2O/12.5 MG	OLMESARTAN MEDOXOMIL + HYDROCHLOROT HIAZIDE	20 MG + 12.5 MG	UMEDICA LABORATORIES PVT. LTD (PLOT 221-GIDC, 2ND PHASE, VAPI 396195 GUJARAT )	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/08/2023

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924	NDA/MAL/HDP/10971	AL ANDALOUS FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TIRATAM 1000MG	LEVETIRACETAM	1000MG	AL ANDALOUS FOR PHARMACEUTICAL INDUSTRIESPART NO. 7/6 - 6TH INDUSTRIAL AREA - 6TH OCTOBER CITY - GIZA	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	17/08/2023
925	NDA/MAL/HDP/10972	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	OLANGEM OD 15	OLANZAPINE	15MG	AUROBINDO PHARMA LTD, UNIT VIISY. NO. 411/P, 425/P, 434/P, 435/P & 458/P, PLOT NO. S1 (PART), SPECIAL ECONOMIC ZONE (SEZ), TSIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHRLA MANDAL, MAHABOOB NAGA DISTRICT, PIN CODE: 509302,	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X4.0X7.0 TABLET BLISTER	17/08/2023

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926	NDA/MAL/HDP/10973	SWISS PARENTERALS LTD.	SHREEJI PHARMACEUTICALS LIMITED	ADRENALINE INJECTION BP 1MG/ML 1ML	ADRENALINE ACID TARTRATE	1MG/ML	SWISS PARENTERALS LIMITED (UNIT-1)808, 809, 810, KERALA INDUSTRIAL ESTATE, GIDC, NR. BAVLA, AHMEDABAD - 382220, GUJARAT - INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0X1.0 ML AMPOULE	17/08/2023
927	NDA/MAL/HDP/10974	EUGIA PHARMA SPECIALITIES LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SKYTINIB 50	SUNITINIB MALATE	50 MG	EUGIA PHARMA SPECIALITIES LIMITED SURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL-MALKAJIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X7.0 CAPSULE BLISTER	17/08/2023



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928	NDA/MAL/HDP/1 0975	VERVE HUMAN CARE LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	BUPIVER-H	BUPIVACAINE HYDROCHLORIDE	5MG/ML	VERVE HUMAN CARE LABORATORIES PLOT NO. 15A PHARMACITY, SELAQUI, DEHRADUN, UTTARAKHAND, 248011, INDIA.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X4.0 ML AMPOULE	17/08/2023
929	NDA/MAL/HDP/1 0976	SAGA LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	PARAGESIC	DICLOFENAC SODIUM + PARACETAMOL + CHLORZOXAZONE	50 MG + 325 MG + 250 MG	SAGA LABORATORIES .198/2 & 198/3, CHACHRAWADI, VASNA NO. CLARIS LIFE SCIENCE, TA SANAND, DIST. DIST: AHMEDABAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER	17/08/2023

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930	NDA/MAL/HDP/10977	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	FIRIALTAA®	FINERENONE	10MG	BAYER PHARMA AG (51368 LEVERKUSEN,)	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	28/08/2023
931	NDA/MAL/HDP/10978	AL ANDALOUS FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ANDORIVABAN	RIVAROXABAN	10MG	AL ANDALOUS FOR PHARMACEUTICAL INDUSTRIESPART NO. 7/6 - 6TH INDUSTRIAL AREA - 6TH OCTOBER CITY - GIZA	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	17/08/2023

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

932	NDA/MAL/HDP/1 0979	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	FIRIALTAA®	FINERENONE	20MG	BAYER PHARMA AG ( 51368 LEVERKUSEN,)	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	28/08/2023
933	NDA/MAL/HDP/1 0980	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MEFENEC PLUS	MEFENAMIC ACID + DICYCLOMINE HYDROCHLORIDE	250 MG + 20 MG	RAVIAN LIFE SCIENCE PVT. LIMITED PLOT NO. 34, SECTOR: 8A, SIDCUL, IIE, HARIDWAR - 249403, UTTARAKHAND	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

934	NDA/MAL/HDP/1 0982	COMED CHEMICALS LTD.	LEGIT MEDEQ 2007 LIMITED	RAPCO-DSR	RABEPRAZOLE SODIUM + DOMPERIDONE	20 MG + 30 MG	COMED CHEMICALS LTD (UNIT-III)VILL: DASSOMATRA BADDI, NALAGARGH ROAD DISTRICT: SOLAN, PIN.173205 HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	17/08/2023
935	NDA/MAL/HDP/1 0983	AGIO PHARMACEUTICAL S LTD	ROYAL PHARMA 2011 LIMITED	ENALAPRIL-AGIO TABLET	ENALAPRIL MALEATE	5MG	AGIO PHARMACEUTICALS LIMITED.T- 81, 82, MIDC, BHOSARI, PUNE - 411 026 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	17/08/2023

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936	NDA/MAL/HDP/1 0984	AGIO PHARMACEUTICAL S LTD	ROYAL PHARMA 2011 LIMITED	ENALAPRIL-AGIO TABLET	ENALAPRIL MALEATE	10MG	AGIO PHARMACEUTICALS LIMITED.T- 81, 82, MIDC, BHOSARI, PUNE - 411 026 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	17/08/2023
937	NDA/MAL/HDP/1 0985	APEX LABORATORIES PRIVATE LIMITED	NORVIK ENTERPRISES LIMITED	ZINCOVIT DROPS	VITAMIN A (AS PALMITATE) + RRR -ALPHA- TOCOPHERYL ACETATE + COLECALCIFEROL + THIAMINE HYDROCHLORIDE + RIBOFLAVIN SODIUM PHOSPHATE + PYRIDOXINE HYDROCHLORIDE + ASCORBIC ACID + DEXPANTHENOL + NICOTINAMIDE	(2500.00 IU + 2.50 MG + 200.00 IU + 1.00 MG + 1.00 MG + 0.50 MG + 40.00 MG + 1.00 MG + 10.00 MG + 13.30 MG + 10.00 MG)ML	APEX LABORATORIES PRIVATE LIMITED (PLANT III)510 KUNNAM VILLAGE AND POST, THENNERI (VIA) SRIPERUMBUDUR TK KANCHEEPURAM DISTRICT, PIN CODE: 631 604, TAMIL NADU	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X1.0X5.0 ML BOTTLE (AMBER GLASS BOTTLE)	17/08/2023

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938	NDA/MAL/HDP/1 0986	THE SEARLE COMPANY LIMITED	SURGIPHARM (U) LIMITED	JENTIN MET	SITAGLIPTIN PHOSPHATE MONOHYDRATE + METFORMIN HYDROCHLORIDE	50 MG + 1000 MG	SEARLE PAKISTAN LTD..F-319, S.I.T.E., OPP. KESC POWER STATION, KARACHI	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	17/08/2023
939	NDA/MAL/HDP/1 0987	LUPIN LIMITED-	AIVEEN (U) LIMITED	LAMIVUDINE AND TENOFIVIR DISOPROXIL FUMARATE TABLETS 300MG AND 300 MG	LAMIVUDINE + TENOFIVIR DISOPROXIL FUMARATE	300 MG + 300 MG	LUPIN LTD PLOT NO. 6A, SECTOR 17, SPECIAL ECOOMIC ZONE, MIHAN, NAGPUR 441108, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	17/08/2023

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940	NDA/MAL/HDP/1 0988	Y.S.P. INDUSTRIES (M) SDN. BHD.	ROYAL PHARMA 2011 LIMITED	LACTUL	LACTULOSE	670MG/ML	Y.S.P INDUSTRIES (M) SDN BHN.LOT 3, 5 & 7, JALAN P/7, SECTION 13, KAWASAN PENDUSTRIAN BANDAR BARU BANGI, 43000, KAJANG, SELANGOR, MALAYSIA	MALAYSIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE (AMBER PET BOTTLE)	17/08/2023
941	NDA/MAL/HDP/1 0989	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	BINFIN 5	FINASTERIDE	5MG	HETERO LABS LIMITED (UNIT III)...22-110, I.D.A, JEEEDIMETLA, HYDERABAD-500 055, ANDHRA PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER	17/08/2023

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942	NDA/MAL/HDP/1099	GLENMARK PHARMACEUTICAL LTD.	STAR PHARMACEUTICALS LTD	MOMATE F CREAM	FUSIDIC ACID+MOMETASONE FUROATE	2.1%W/W + 0.1W/W	GLENMARK PHARMACEUTICALS LTD UNIT II.UNIT II VILLAGE BHATTANWALA NALAGARH DIST SOLAN HIMACHAL PRADESH	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE	01/07/2012
943	NDA/MAL/HDP/10990	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BISODAC-HF 10	BISOPROLOL FUMARATE	10MG	AUROBINDO PHARMA LIMITED, UNIT - XV PLOT NO. 17A, E BONANGI (V), PARAWADA (M), VISAKHAPATNAM DISTRICT, ANDHRA PRADESH. PIN: 531021	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	17/08/2023



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944	NDA/MAL/HDP/10991	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	IXAROLA 10 FILM-COATED TABLETS	RIVAROXABAN	10MG	BAYER PHARMA AG (51368 LEVERKUSEN,)	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X14.0 TABLET BLISTER, 1.0X2.0X14.0 TABLET BLISTER	28/08/2023
945	NDA/MAL/HDP/10992	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	IXAROLA 20 FILM-COATED TABLETS	RIVAROXABAN	20MG	BAYER PHARMA AG (51368 LEVERKUSEN,)	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X14.0 TABLET BLISTER, 1.0X2.0X14.0 TABLET BLISTER	28/08/2023

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946	NDA/MAL/HDP/10993	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	IXAROLA 15 FILM-COATED TABLETS	RIVAROXABAN	15MG	BAYER PHARMA AG (51368 LEVERKUSEN,)	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X14.0 TABLET BLISTER, 1.0X2.0X14.0 TABLET BLISTER	28/08/2023
947	NDA/MAL/HDP/10994	DINLAS PHARMA EPZ LIMITED	AFRICURE PHARMACEUTICALS U LIMITED	PARADOL	PARACETAMOL	500MG	DINLAS PHARMA EPZ LIMITED PLOT NO. LR 7149/121, MOMBASA ROAD, SYOKIMAU	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	17/08/2023

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948	NDA/MAL/HDP/1 0998	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	MOCIN	MOXIFLOXACIN HYDROCHLORIDE	400MG/100ML	ABACUS PARENTERAL DRUGS LIMITED PLOT 114, BLOCK 191, KINGA	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	17/08/2023
949	NDA/MAL/HDP/1 0999	MARCYRL PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	URICODROP	FEBUXOSTAT	80MG	MARCYRL PHARMACEUTICAL INDUSTRIES WESTERN EXTENSION-PARTS NUMBER 5/6/7/8/9/10/11/12- BLOCK 20005, EL OBOUR CITY	EGYPT	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023

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950	NDA/MAL/HDP/1 100	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOVIR SKIN CREAM	ACICLOVIR	5% W/W	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE,1.0X5.0 G TUBE	01/07/2013
951	NDA/MAL/HDP/1 1000	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	SINUTAB SINUS PAIN NON- DROWSY	PARACETAMOL + PSEUDOEPHEDRI NE HYDROCHLORIDE	500 + 30 MG	JOHNSON & JOHNSON (PTY) LTD241 MAIN ROAD, RETREAT, 7945, CAPE TOWN	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	17/08/2023

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952	NDA/MAL/HDP/1 1001	UNISON PHARMACEUTICAL S PVT. LTD.	HARLEYS UGANDA LIMITED	AKILOS-CR	ACECLOFENAC	200MG	UNISON PHARMACEUTICALS PRIVATE LIMITED – UNIT 1UNIT I, C/6, STEEL TOWN, OPP. NOVA PETRO, MORAIYA, TA. SANAND, DIST.: AHMEDABAD - 382213, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	17/08/2023
953	NDA/MAL/HDP/1 1002	CENTAUR PHARMACEUTICAL S PVT. LTD.	GITTOES PHARMACEUTICAL S LIMITED	MICONA VAGINAL CREAM	MICONAZOLE NITRATE	2%W/W	CENTAUR PHARMACEUTICALS PVT. LTD (PLANT 2) (PLOT NO 39- 41TIVIM INDUSTRIAL ESTATE, KARASWADA - MAPUSA, GOA- 403526)	INDIA	VAGINAL CREAMS	1.0X1.0X40.0 G TUBE	29/08/2023

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954	NDA/MAL/HDP/1 1003	MEGA LIFSCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	BAROLE	RABEPRAZOLE	20MG	NAPROD LIFE SCIENCES PVT. LTDG- 17/1, MIDC TARAPUR IND. AREA, BOISAR, 401506 MAHARASHTRA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 MG VIAL	17/08/2023
955	NDA/MAL/HDP/1 1004	FAROMED LIFSCIENCES LLP	METRO PHARMACEUTICAL S LIMITED	FAST 125	PARACETAMOL	125MG	THE ACME LABORATORIES LIMITEDDHULIVITA, DHAMRAI, DHAKA - 1350, BANGLADESH	BANGLADESH	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY STRIP	17/08/2023

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956	NDA/MAL/HDP/1 1012	COSMOS LTD.	ASTRA PHARMA (U) LIMITED	CEMET 400	CIMETIDINE	400MG	COSMOS LTD..RANGWE ROAD OFF, LUNA LUNGA ROAD, INDUSTRIAL AREA - NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997
957	NDA/MAL/HDP/1 1015	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	HYDROCORTISON E CREAM BP	HYDROCORTISON E ACETATE	1% W/W	CIRON DRUGS PHARMACEUTICALS PRIVATE LIMITEDPLOT NO. 35- 37, 43-45, CFC-B, DEWAN UDHYOG NAGAR, ALIYALI, PALGHAR " " " " " " 401404, MAHARASHTRA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	12/13/2023

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958	NDA/MAL/HDP/1 1016	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	LEDOBOOK 15	LENALIDOMIDE	15MG	EUGIA PHARMA SPECIALITIES LIMITEDSURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X7.0 CAPSULE BLISTER	12/13/2023
959	NDA/MAL/HDP/1 1017	AUROBINDO	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	LEDOBOOK 25	LENALIDOMIDE	25MG	EUGIA PHARMA SPECIALITIES LIMITEDSURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X7.0 CAPSULE BLISTER	12/13/2023



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960	NDA/MAL/HDP/1 1018	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MEDWIN	MEDROXYPROGE STERONE	150MG/ML	EUGIA PHARMA SPECIALITIES LIMITEDSURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0X1.0 ML PRE FILLED SYRINGE	12/13/2023
961	NDA/MAL/HDP/1 1019	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	LEDOBOOK 5	LENALIDOMIDE	5MG	EUGIA PHARMA SPECIALITIES LIMITEDSURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X7.0 CAPSULE BLISTER	12/13/2023

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962	NDA/MAL/HDP/1 102	MATRIX UGANDA LTD	ROYAL PHARMA 2011 LIMITED	OVUREX	CLOMIPHENE	50MG	Y.S.P INDUSTRIES (M) SDN BDH LOT 3,5 & 7 P/7 SECTION 13 KAWASAN PERINDUSTRIAN BANDAR BARU BANGI 43000 KAJANG SELANGOR DARUL EHSAN	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1.0X10 .0 TABLET BLISTER	01/07/2011
963	NDA/MAL/HDP/1 1020	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	IBUPLUS	IBUPROFEN + PARACETAMOL	100MG/125MG	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X60.0 ML BOTTLE	12/13/2023

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964	NDA/MAL/HDP/1 1021	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	INTAFERON	IRON SUCROSE	100MG/5ML.	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X5.0 ML AMPOULE	12/13/2023
965	NDA/MAL/HDP/1 1022	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CEFIXIME QUIX DISPERSIBLE TABLETS 200MG	CEFIXIME TRIHYDRATE	200MG	M/S SCOTT-EDIL ADVANCE RESEARCH LABORATORIES AND EDUCATION LIMITEDHILL-TOP, INDUSTRIAL AREA, BHATOLI KALAN, BADDI, DISTT. SOLAN (HP) - 173205, INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X10.0 TABLET BLISTER	12/13/2023

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966	NDA/MAL/HDP/1 1023	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	MOXVID	AMOXICILLIN TRIHYDRATE	125 MG/5 ML	M/S SCOTT-EDIL ADVANCE RESEARCH LABORATORIES AND EDUCATION LIMITEDHILL-TOP, INDUSTRIAL AREA, BHATOLI KALAN, BADDI, DISTT. SOLAN (HP) - 173205, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X100.0 ML CONTAINER	12/13/2023
967	NDA/MAL/HDP/1 1024	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LTD	CLONAPIN-2	CLONAZEPAM	2MG	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023

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968	NDA/MAL/HDP/1 1025	LINCOLN PHARMACEUTICAL S LIMITED	METRO PHARMACEUTICAL S LTD	DYGYL	METRONIDAZOLE BENZOATE	125MG/5ML	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	12/13/2023
969	NDA/MAL/HDP/1 1026	LINCOLN PHARMACEUTICAL S LIMITED	METRO PHARMACEUTICAL S LTD	TELMISIN	TELMISARTAN	40 MG	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023

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970	NDA/MAL/HDP/1 1027	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	CEFIMCZ-400	CEFIXIME	400 MG	ZEISS PHARMA LIMITEDIGC,SIDCO, PHASE II, SAMBA, JAMMU - 184121,(J&K)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	12/13/2023
971	NDA/MAL/HDP/1 1028	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	APLENE 50	PREGABALIN	50MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	12/13/2023

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972	NDA/MAL/HDP/1 1029	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	APLENE 75	PREGABALIN	75MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	12/13/2023
973	NDA/MAL/HDP/1 103	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOCIN CREAM	NEOMYCIN SULPHATE	0.5% W/W	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2014

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974	NDA/MAL/HDP/1 1030	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	APLENE 150	PREGABALIN	150MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	12/13/2023
975	NDA/MAL/HDP/1 1031	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	NIZACARD 500	RANOLAZINE	500MG	HETERO LABS PRIVATE LIMITED UNIT IIISURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) JEEDIMETLA, HYDERABAD-500 055, TELANGANA STATE,	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023



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976	NDA/MAL/HDP/1 1032	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	NIZACARD 1000	RANOLAZINE	1000MG	HETERO LABS PRIVATE LIMITED UNIT IISURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) JEEDIMETLA, HYDERABAD-500 055, TELANGANA STATE	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023
977	NDA/MAL/HDP/1 1033	KESAR PHARMA	JEET PHARMACEUTICAL S LIMITED	FLUPLEX	PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + CHLORPHENIRAM INE MALEATE + CAFFEINE ANHYDROUS	500MG + 10MG + 2MG + 30MG	KESAR PHARMA PVT LTD PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X1.0X4.0 TABLET STRIP	12/13/2023

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978	NDA/MAL/HDP/1 1034	ARCELIA LIFE SCIENCES LTD.	PLUTO PHARMACEUTICAL S LIMITED	ARCELIAÂ® ESOMEPRAZOLE TABLETS 40 MG	ESOMEPRAZOLE MAGNESIUM DIHYDRATE	40 MG	ASSOCIATED BIOTECHVILLAGE: KISHANPURA, GUGUMAJRA ROAD, BADDI THE: NALAGARH HIMACHAL PRADESH 174101 - INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	12/13/2023
979	NDA/MAL/HDP/1 1035	ARCELIA LIFE SCIENCES LTD.	PLUTO PHARMACEUTICAL S LIMITED	ARCELIAÂ® ESOMEPRAZOLE TABLETS 20 MG	ESOMEPRAZOLE MAGNESIUM DIHYDRATE	20 MG	ASSOCIATED BIOTECHVILLAGE: KISHANPURA, GUGUMAJRA ROAD, BADDI THE: NALAGARH HIMACHAL PRADESH 174101 - INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	12/13/2023

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980	NDA/MAL/HDP/1 1036	ARCELIA LIFE SCIENCES LTD.	PLUTO PHARMACEUTICAL S LIMITED	DROCELIA	DROTAVERINE HYDROCHLORIDE	40 MG/2 ML	SANJAR PHARMA LLPSURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1X1X5X2X0 ML AMPOULE	12/13/2023
981	NDA/MAL/HDP/1 1037	FERRER INTERNATIONAL, S.A.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DISLEP 25	LEVOSULPIRIDE	25MG	DOPPEL FARMACEUTICI SRL,VIA VOLTURNO 48-20089 QUINTO DE STAMPI, ROZZANO (MI)	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X20.0 TABLET BLISTER	12/13/2023

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982	NDA/MAL/HDP/1 1038	AUROBINDO	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DELOHIST 5	DES Loratadine	5MG	AUROBINDO PHARMA LIMITED, UNIT - XV PLOT NO. 17A, E BONANGI (V), PARAWADA (M), VISAKHAPATNAM DISTRICT, ANDHRA PRADESH. PIN: 531021	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023
983	NDA/MAL/HDP/1 1039	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	LIGNOCAIN	LIDOCAINE	20 MG/ML	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X30.0 ML VIAL	12/13/2023

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984	NDA/MAL/HDP/1 104	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	LIPIDUCE 10	ATORVASTATIN	10MG	HOVID BERHAD, LOT 56442, 7 1/2 MILES JALAN IPOH/CHEMOR 31200, CHEMOR PERAK	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X3.0 TABLET BLISTER	01/07/2014
985	NDA/MAL/HDP/1 1041	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICAL S LIMITED	ROMYCIN	AZITHROMYCIN DIHYDRATE	500MG	NABIQASIM INDUSTRIES (PVT) LTD .17/24 KORANGI INDUSTRIAL AREA KORANGI KARACHI	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X3.0 TABLET BLISTER	12/13/2023

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986	NDA/MAL/HDP/1 1042	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	MOVFOR	MOLNUPIRAVIR	200MG	HETERO LABS LIMITED (UNIT V)SY. NO. 439, 440, 441 & 458, POLEPALLY VILLAGE, JADCHERLA MANDAL MAHABOBNAGAR DISTRICT, PIN-509 301, TELANGANA, INDIA	INDIA	ORAL SOLID RETARD OTHER CAPSULES	1.0X40.0 CAPSULE CONTAINER, 1.0X4.0X10.0 CAPSULE BLISTER	12/13/2023
987	NDA/MAL/HDP/1 1043	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DIAZAC 5	DAPAGLIFLOZIN	5MG	AJANTA PHARMA LIMITEDPLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT- 392130	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023

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988	NDA/MAL/HDP/1 1044	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DIAZAC 10	DAPAGLIFLOZIN	10MG	AJANTA PHARMA LIMITED PLOT NO.Z/103/A, DAHEJ SEZ PART 11, DISTRICT: BHARUCH, GUJARAT- 392130	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023
989	NDA/MAL/HDP/1 1047	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	MURAXAL -10	ALFUZOSIN HYDROCHLORIDE	10MG	MICRO LABS LIMITED, HOSURNO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA	INDIA	ORAL SOLID RETARD TABLETS	1.0X1.0X10.0 TABLET BLISTER	12/13/2023

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990	NDA/MAL/HDP/1 1048	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	APRETUDE 600 MG	CABOTEGRAVIR	200MG/ML	GLAXO OPERATIONS UK LIMITEDHARMIRE ROAD, BARNARD CASTLE, DURHAM, DL 12 8DT - UNITED KINGDOM	UNITED KINGDOM	PARENTERAL ORDINARY VIALS	1.0X25.0X3.0 ML VIAL, 1.0X5.0X3.0 ML VIAL	12/13/2023
991	NDA/MAL/HDP/1 1049	NEXT WAVE (INDIA)	DAVIMED PHARMA LIMITED	XYM-KID	SIMETHICONE + DILL OIL + FENNEL OIL	40MG + 0.005ML + 0.0007ML	NEXT WAVERAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X15.0 ML BOTTLE	12/13/2023



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992	NDA/MAL/HDP/1 1050	SURGE LABORATORIES (PVT) LTD,	JEET PHARMACEUTICAL S LIMITED	SERGIFEX 1G	CEFTRIAXONE SODIUM	1 G/VIAL	SURGE LABORATORIES (PVT) LTD.,,10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN.	PAKISTAN	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	12/13/2023
993	NDA/MAL/HDP/1 1051	SURGE LABORATORIES (PVT) LTD,	JEET PHARMACEUTICAL S LIMITED	SERGIFEX 2G	CEFTRIAXONE SODIUM	2 G/VIAL	SURGE LABORATORIES (PVT) LTD.,,10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN.	PAKISTAN	PARENTERAL ORDINARY DRY VIALS	1.0X2.0 G VIAL	12/13/2023

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994	NDA/MAL/HDP/1 1052	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AKO-PAS	ACECLOFENAC + PARACETAMOL + SERRATIOPEPTID ASE	100 MG + 325 MG + 15 MG	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	12/13/2023
995	NDA/MAL/HDP/1 1053	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	OLODINE	OLOPATADINE HYDROCHLORIDE	0.1% W/V	ABACUS PARENTERAL DRUGS LIMITEDPLOT 114, BLOCK 191, KINGA	UGANDA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML CONTAINER	12/13/2023

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996	NDA/MAL/HDP/1 1054	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	TORA	TOBRAMYCIN SULPHATE	0.3% W/V	ABACUS PARENTERAL DRUGS LIMITEDPLOT 114, BLOCK 191, KINGA	UGANDA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML CONTAINER	12/13/2023
997	NDA/MAL/HDP/1 1055	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	TORA-D	TOBRAMYCIN SULPHATE + DEXAMETHASON E SODIUM PHOSPHATE	0.3%W/V + 0.1%W/V	ABACUS PARENTERAL DRUGS LIMITEDPLOT 114, BLOCK 191, KINGA	UGANDA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML CONTAINER	12/13/2023

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998	NDA/MAL/HDP/1 1056	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	VOLDIC Â® 1% EMULGEL	DICLOFENAC DIETHYLAMINE	1%W/W	PHARMA INTERNATIONAL COMPANY ,AL- QASTAL AREA, AIRPORT ROAD, P.O. BOX 334 AL JUBAIHA, 11941, AMMAN - JORDAN	JORDAN	TOPICAL EXTERNAL GELS AND SOLS	1.0X1.0X30.0 G TUBE	12/13/2023
999	NDA/MAL/HDP/1 1057	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	SHELTRIZINE	CETIRIZINE HYDROCHLORIDE	10MG	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO. LR 209/6554, MOGADISHU ROAD INDUSTRIAL AREA, NAIROBI KENYA	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	12/13/2023

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1000	NDA/MAL/HDP/1 1058	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	EXYT-200	ALBENDAZOLE	200MG/5ML	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X10.0 ML BOTTLE	12/13/2023
1001	NDA/MAL/HDP/1 1059	AURA LIFECARE PVT. LTD.	REDDYS PHARMA LIMITED	AURADERM-0.05	CLOBETASOL	0.05%W/W	AURA LIFECARE PRIVATE LIMITEDSURVEY NO. 254/14/1, JAROD- SAVLI ROAD, P.O. KARACHIYA, 391 520, TAL. SAVLI, DIST. VADODARA - INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X10.0 G TUBE, 1.0X1.0X15.0 G TUBE	12/13/2023

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1002	NDA/MAL/HDP/1 106	EVA PHARMA	UNITED HEALTHCARE DISTRIBUTORS LTD	DIACEREIN	DIACEREIN	50MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER,1.0X2.0X10 .0 CAPSULE BLISTER	01/07/2013
1003	NDA/MAL/HDP/1 1060	WORLD MEDICINE S.A. SAN. VE TIC. A.Ş.	GOODMAN INTERNATIONAL LTD	ROXIPIME	CEFEPIME HYDROCHLORIDE	1G/VIAL	PHARMAVISION SAN. VE TIC. A.S.DAVUTPASA CAD. NO: 145 ZEYTINBURNU / ISTANBUL - TURKEY	TURKEY	PARENTERAL RETARD DRY VIALS	1.0X1.0X1.0 G VIAL	12/13/2023

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1004	NDA/MAL/HDP/1 1061	MIDASCARE PHARMACEUTICAL S PRIVATE LIMITED,	ABACUS PHARMA (AFRICA) LIMITED	MISTDRESS	LIDOCAINE + CETRIMIDE	1%W/W + 0.10%W/W	MIDAS CARE PHARMACEUTICALS PVT LTD.B-16 MIDC, WALUJ AURANGABAD 431136, MAHARASHTRA, INDIA	INDIA	TOPICAL EXTERNAL SPRAYS WITHOUT GAS	1.0X100.0 ML CANNISTER	12/13/2023
1005	NDA/MAL/HDP/1 1062	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	GAVISIL	ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE	250MG + 250MG + 50MG	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X200.0 ML BOTTLE	12/13/2023

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1006	NDA/MAL/HDP/1 1063	PHARMA BAVARIA INTERNACIONAL(P BI) PORTUGUAL	GOODMAN INTERNATIONAL LTD	COMBOFUSIV	PARACETAMOL + IBUPROFEN	10MG/ML + 3MG/ML	S.M. FARMACEUTICI S.R.L.ZONA INDUSTRIALE, 85050 TITO (PZ)	ITALY	PARENTERAL ORDINARY VIALS	1.0X10.0X100.0 ML VIAL	12/13/2023
1007	NDA/MAL/HDP/1 1064	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	ISONIAZID DISPERSIBLE TABLETS 100 MG	ISONIAZID	100 MG	OXALIS LABS LIMITEDVILLAGE THEDA, P.O LODHIMAJRA, TEHSIL BADDI DIST: SOLAN (H.P.) PIN CODE: 174101 - INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET STRIP	12/13/2023



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1008	NDA/MAL/HDP/1 1065	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	AROX	MOXIFLOXACIN HYDROCHLORIDE	0.5% W/V	JAMJOOM PHARMACEUTICALS COMPANY PLOT NO: ME1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 - KINGDOM OF SAUDI ARABIA	SAUDI ARABIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	12/13/2023
1009	NDA/MAL/HDP/1 1066	MACARTHYS LABORATORIES LTD	LABOREX UGANDA LIMITED	COLISTIMETHATE SODIUM 1 MIU	COLISTIMETHATE SODIUM	1MU/VIAL	ALTAN PHARMACEUTICALS S.A.AVDA. DE LA CONSTITUCION 198 - 199, POLIGONO INDUSTRIAL MONTE BOYAL, CASARRUBIOS DE MONTE, 45950 TOLEDO - SPAIN	SPAIN	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X1.0 MU VIAL	12/13/2023

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1010	NDA/MAL/HDP/1 1067	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	LEVAUR 250	LEVETIRACETAM	250MG	AUROBINDO PHARMA LIMITED, UNIT - XV PLOT NO. 17A, E BONANGI (V), PARAWADA (M), VISAKHAPATNAM DISTRICT, ANDHRA PRADESH. PIN: 531021	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023
1011	NDA/MAL/HDP/1 1068	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	LEVAUR 500	LEVETIRACETAM	500MG	AUROBINDO PHARMA LIMITED, UNIT - XV PLOT NO. 17A, E BONANGI (V), PARAWADA (M), VISAKHAPATNAM DISTRICT, ANDHRA PRADESH. PIN: 531021	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023

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1012	NDA/MAL/HDP/1 1069	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	LEVAUR 1000	LEVETIRACETAM	1000MG	AUROBINDO PHARMA LIMITED, UNIT - XV PLOT NO. 17A, E BONANGI (V), PARAWADA (M), VISAKHAPATNAM DISTRICT, ANDHRA PRADESH. PIN: 531021	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023
1013	NDA/MAL/HDP/1 1070	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	JITRIT-5	TOFACINIB	5MG	MICRO LABS LIMITED, HOSURNO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X15.0 TABLET BLISTER	12/13/2023

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1014	NDA/MAL/HDP/1 1071	MYLAN PHARMACEUTICAL S PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	OGIVRIÁ,,ç 440 MG	TRASTUZUMAB	440MG/VIAL	BIOCON BIOLOGICS LIMITEDSPECIAL ECONOMIC ZONE, PLOT NO. 2, 3, 4 & 5, PHASE - IV, BOMMASANDRA- JIGANI LINK ROAD, BOMMASANDRA POST, BENGALURU - 560099, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X440.0 MG VIAL	12/13/2023
1015	NDA/MAL/HDP/1 1072	MEDOPHARM	NUGEN PHARMACEUTICAL S UGANDA LIMITED	NUNINE	QUININE SULFATE	300MG	MEDOPHARMNO. 34B, INDUSTRIAL AREA, MALUR- 563160, KARNATAKA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	12/13/2023

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1016	NDA/MAL/HDP/1 1073	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	PARACO-DENK 500/30	PARACETAMOL + CODEINE PHOSPHATE HEMIHYDRATE	500 MG + 30 MG	DENK PHARMACEUTICAL GMBH PRODUCTION AND WAREHOUSING - HERTERICHSTR. 1-3 D-81479 MUNICH GERMANY. QUALITY CONTROL LABORATORY - BAYERWALDSTR. 7-9 D-82538 GERETSRIED, GERMANY. HIGH- RACK WAREHOUSING "Ä" GEWERBERING 11 D- 82140 OLCHING,	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	12/13/2023
1017	NDA/MAL/HDP/1 1074	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	FAMYTEC	MISOPROSTOL	200MCG	MYLAN LABORATORIES LIMITED PLOT NO. 20 & 21, PHARMEZ, SARKHEJ - BAVLA, NATIONAL HIGHWAY NO. 8 - A, NEAR VILLAGE - MATODA, TAL - SANAND, DIST., AHMEDABAD - 382213	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	12/13/2023



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1020	NDA/MAL/HDP/1 1078	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	B-LACT	LACTULOSE	3.35GM/5ML	FRESENIUS KABI AUSTRIA GMBHETERMANNNS TRASSE 17, A-4020 LINZ	AUSTRIA	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	02/02/2024
1021	NDA/MAL/HDP/1 1079	MEDOPHARM	PLANET PHARMACEUTICAL S UGANDA LTD	MIRAFOLIC	FOLIC ACID	5MG	MEDOPHARMNO. 34B, INDUSTRIAL AREA, MALUR- 563160, KARNATAKA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X100.0X10.0 TABLET BLISTER, 1.0X10.0X10.0 TABLET BLISTER, 1.0X50.0X10.0 TABLET BLISTER	02/02/2024

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1022	NDA/MAL/HDP/1 1080	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	OLMAT-AMH	OLMESARTAN MEDOXOMIL + AMLODIPINE BESILATE + HYDROCHLOROT HIAZIDE	20MG + 5MG + 12.5MG	MICRO LABS LIMITED, HOSURNO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/02/2024
1023	NDA/MAL/HDP/1 1081	INFUGEN PHARMA PVT. LTD.	GITTOES PHARMACEUTICALS LIMITED	INFUROXIM	CEFUROXIME SODIUM	750MG	ZEISS PHARMACEUTICALS PRIVATE LIMITED PLOT NO. 72 EPIP-PHASE-1 JHARMAJRI BADDI DISTRICT SOLAN (H.P.)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X750.0 MG VIAL	02/02/2024



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1024	NDA/MAL/HDP/1 1082	UNITED PHARMACEUTICAL S MANUFACTURING LIMITED COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VIVAZAC PLUS	IRBESARTAN + HYDROCHLOROT HIAZIDE	150 MG + 12.5 MG	UNITED PHARMACEUTICALS MANUFACTURING LIMITED COMPANYAL- RAGEEM, SAHAB, P.O. BOX 60, AMMAN 11591 - JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/02/2024
1025	NDA/MAL/HDP/1 1083	ASPIRO PHARMA LIMITED.	AIVEEN (U) LIMITED	CANDIVOR 200 MG/VIAL	VORICONAZOLE	200MG	ASPIRO PHARMA LIMITEDSY. NO. 321, BIOTECH PARK, PHASE-III, KARKAPATLA, MARKOOK MANDAL, SIDDIPET DISTRICT- 502 281, TELANGANA, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X200.0 MG VIAL	02/02/2024

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1026	NDA/MAL/HDP/1 1084	MEGA LIFSCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	INVEL FORTE L	METRONIDAZOLE + MICONAZOLE NITRATE + LIDOCAINE	750 MG + 200 MG + 100 MG	BLISS GVS PHARMA LTD PLOT NO. 11, SURVEY NO. 38/1, DEWAN UDYOG NAGAR, ALIYALI, PALGHAR, MAHARASHTRA 401404, INDIA	INDIA	VAGINAL SUPPOSITORIES	1.0X1.0X7.0 SUPPOSITORY STRIP, 1.0X2.0X7.0 SUPPOSITORY STRIP	02/02/2024
1027	NDA/MAL/HDP/1 1085	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EMITINO INJECTION	ONDANSETRON HYDROCHLORIDE	4MG/2ML	SAKAR HEALTHCARE PVT LTDBLOCK NO. 10-13, NR. M.N DESAI PETRO PUMP, SARKHEJ-BAVLA ROAD, CHANGODAR, DIST: AHMEDABAD- 382213, GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0X2.0 ML AMPOULE	02/02/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1028	NDA/MAL/HDP/1 1086	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	ERYBRU 500	ERYTHROMYCIN STEARATE	500MG	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	02/02/2024
1029	NDA/MAL/HDP/1 1088	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	DARUNAVIR 400 MG	DARUNAVIR	400MG	LAURUS LABS LTD (UNIT 2)PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X60.0 TABLET BOTTLE	02/02/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1030	NDA/MAL/HDP/1 109	DAWA LIMITED	SUPER MEDIC LTD	DAWA-CPM	CHLORPHENIRAM INE MALEATE	2MG/5ML	DAWA PHARMACEUTICALS LIMITEDPLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2014
1031	NDA/MAL/HDP/1 1090	LES LABORATOIRES SERVIER	HARLEYS UGANDA LIMITED	DIAMICRON MR 60 MG	GLICLAZIDE	60MG	LES LABORATOIRES SERVIER INDUSTRIE (LSI)905 ROUTE DE SARAN 45520 GIDY - FRANCE	FRANCE	ORAL SOLID RETARD TABLETS	1.0X2.0X15.0 TABLET BLISTER	02/02/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1032	NDA/MAL/HDP/1 1094	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	FETNAL 500	CEFUROXIME AXETIL	500MG	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	02/02/2024
1033	NDA/MAL/HDP/1 1098	VERVE HUMAN CARE LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	ADEVER	ADRENALINE ACID TARTRATE	1MG/ML	VERVE HUMAN CARE LABORATORIESPLOT NO. 15A PHARMACITY, SELAQUI, DEHRADUN, UTTARAKHAND, 248011, INDIA.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	02/02/2024

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1034	NDA/MAL/HDP/1 1101	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	CLARITHROMYCIN 500 MG	CLARITHROMYCIN	500MG	SANDOZ S.R.LSTR. LIVEZENI NR. 7A 540472 TARGU- MURES ROMANIA	ROMANIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	02/02/2024
1035	NDA/MAL/HDP/1 1102	ENCORE HEALTHCARE PVT. LTD.	REDDYS PHARMA LIMITED	ONTADEX 50MG	TRAMADOL HYDROCHLORIDE	50MG	ENCORE HEALTHCARE PVT LTDD-5, MIDC AREA, PAITHAN- 431148, DIST. AURANGABAD, MAHARASHTRA - INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	02/02/2024

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1036	NDA/MAL/HDP/1 1103	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ASTRA PHARMA (U) LIMITED	LOXIBS 50	LOSARTAN POTASSIUM	50MG	CACHET PHARMACEUTICAL PVT LTD.VILLAGE- THANA, NEAR BADDI, TEHSIL_NALAGARH, DIST. SOLAN, HIMACHAL PRADESH- 173205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/02/2024
1037	NDA/MAL/HDP/1 1104	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ASTRA PHARMA (U) LIMITED	ROSUCACH 10	ROSUVASTATIN CALCIUM	10MG	CACHET PHARMACEUTICAL PVT LTD.VILLAGE- THANA, NEAR BADDI, TEHSIL_NALAGARH, DIST. SOLAN, HIMACHAL PRADESH- 173205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/02/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1038	NDA/MAL/HDP/1 1105	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD.	HEALTHCARE LTD.	TELOSIN	TAMSULOSIN HYDROCHLORIDE	0.4MG	AL FAZAL PHARMA INDUSTRIES (PVT) LTD PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	02/02/2024
1039	NDA/MAL/HDP/1 1106	SCOTT-EDIL ADVANCE RESEARCH LABORATORIES & EDUCATION LTD.,	ROYAL PHARMA 2011 LIMITED	SCOTXONE-1G	CEFTRIAXONE SODIUM	1G	M/S SCOTT-EDIL ADVANCE RESEARCH LABORATORIES AND EDUCATION LIMITED HILL-TOP, INDUSTRIAL AREA, BHATOLI KALAN, BADDI, DISTT. SOLAN (HP) - 173205, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL	02/02/2024



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1040	NDA/MAL/HDP/1 1107	ZIM LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	AZITO 500	AZITHROMYCIN DIHYDRATE	500MG	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	02/02/2024
1041	NDA/MAL/HDP/1 1109	LEBEN LABORATORIES PVT. LTD	MALIX PHARMA (U) LIMITED	BETALEB-N CREAM	BETAMETHASONE VALERATE + NEOMYCIN SULPHATE	0.1%W/W + 0.5%W/W	LEBEN LABORATORIES PVT LTD .L-14 PHASE III MIDC AKOLA 444 104	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	02/02/2024

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1042	NDA/MAL/HDP/1 111	DAWA LIMITED	SUPER MEDIC LTD	FAST-ACT GEL	DICLOFENAC DIETHYLAMINE + METHYL SALICYLATE + LINSEED OIL + MENTHOL CRYSTALS	1.16%W/W + 10%W/W + 3%W/W + 5%W/W	DAWA PHARMACEUTICALS LIMITED PLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE	01/07/2013
1043	NDA/MAL/HDP/1 1110	SAGA LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	GLIBEMET 500/2.5	METFORMIN HYDROCHLORIDE + GLIBENCLAMIDE	500 MG + 2.5 MG	SAGA LABORATORIES .198/2 & 198/3, CHACHRAWADI, VASNA NO. CLARIS LIFE SCIENCE, TA SANAND, DIST. DIST: AHMEDABAD	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	02/02/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1044	NDA/MAL/HDP/1 1111	RUSAN PHARMA LTD.	NORVIK ENTERPRISES LIMITED	ADDNOK	BUPRENORPHINE HYDROCHLORIDE	8MG	RUSAN PHARMA LTDKHASRA NO. 122MI, CENTRAL HOPE TOWN, BEHIND PHARMA CITY, SELAQUI, DEHRADUN- 248197, UTTARAKHAND, INDIARUSAN PHARMA LIMITEDPLOT NO. 59 - 65, SECTOR II, KANDLA SPECIAL ECONOMIC ZONE, GANDHIDHAM KLITCH 370 230	INDIA	ORAL SOLID ORDINARY SUBLINGUAL TABLETS	1.0X1.0X7.0 TABLET BLISTER, 1.0X4.0X7.0 TABLET BLISTER	02/02/2024
1045	NDA/MAL/HDP/1 1112	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	BETASONE	BETAMETHASONE VALERATE	0.1%W/W	HOVID BERHAD (IPOH SITE)121, JALAN TUNKU ABDUL RAHMAN 30010 IPOH PERAK	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	02/02/2024

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1046	NDA/MAL/HDP/1 1113	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	ATRONA-20	ATORVASTATIN CALCIUM	20MG	ZOTA HEATHCARE LIMITED PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NEAR SACHIN RAILWAY STATION, SACHIN, CITY: SURAT, DIST: SURAT, GUJARAT STATE - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/02/2024
1047	NDA/MAL/HDP/1 1114	FAROMED LIFSCIENCES LLP	METRO PHARMACEUTICAL S LIMITED	APTIN M 50/500 F/C TABLET	VILDAGLIPTIN + METFORMIN HYDROCHLORIDE	50MG + 500MG	ADVANCED CHEMICAL INDUSTRIES (ACI) LIMITED (7, HAJEEGONJ ROAD, GOODNYL, NARAYANGONJ - 1400)	BANGLADESH	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	20/05/2024

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1048	NDA/MAL/HDP/1115	FAROMED LIFSCIENCES LLP	METRO PHARMACEUTICALS LIMITED	SITOMET 50/500	SITAGLIPTIN PHOSPHATE MONOHYDRATE + METFORMIN HYDROCHLORIDE	50 MG + 500 MG	ADVANCED CHEMICAL INDUSTRIES (ACI) LIMITED (7, HAJEENJ ROAD, GOODNYL, NARAYANGONJ - 1400)	BANGLADESH	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	10/01/2024
1049	NDA/MAL/HDP/1116	FAROMED LIFSCIENCES LLP	METRO PHARMACEUTICALS LIMITED	SITOMET 50/1000	SITAGLIPTIN PHOSPHATE MONOHYDRATE + METFORMIN HYDROCHLORIDE	50 MG + 1000 MG	ADVANCED CHEMICAL INDUSTRIES (ACI) LIMITED (7, HAJEENJ ROAD, GOODNYL, NARAYANGONJ - 1400)	BANGLADESH	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	10/01/2024

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1050	NDA/MAL/HDP/1 1117	FAROMED LIFESCIENCES LLP	METRO PHARMACEUTICALS LIMITED	FAST 250 SUPPOSITORY	PARACETAMOL	250MG	THE ACME LABORATORIES LIMITEDDHULIVITA, DHAMRAI, DHAKA - 1350, BANGLADESH	BANGLADESH	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY STRIP	02/02/2024
1051	NDA/MAL/HDP/1 1118	LUPIN LIMITED-	AIVEEN (U) LIMITED	MOXIFLOXACIN	MOXIFLOXACIN HYDROCHLORIDE	400 MG	LUPIN LIMITEDUNIT- 2, PLOT NO. M-2 & M-2-A, SPECIAL ECONOMIC ZONE, PHASE II, MISC. ZONE, APPAREL PARK, DIST. DHAR - M.P. PITHAMPUR, 454775, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	02/02/2024

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1052	NDA/MAL/HDP/1 1119	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	ETIMICOL 10	EZETIMIBE	10MG	AUROBINDO PHARMA LTD, UNIT VIISY. NO. 411/P, 425/P, 434/P, 435/P & 458/P, PLOT NO. S1 (PART), SPECIAL ECONOMIC ZONE (SEZ), TSIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHRLA MANDAL, MAHABOOB NAGA DISTRICT, PIN CODE: 509302,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/02/2024
1053	NDA/MAL/HDP/1 1120	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	VALABIN 500	VALACICLOVIR HYDROCHLORIDE	500MG	AUROBINDO PHARMA LIMITED, UNIT III SURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELENGANA (STATE)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X6.0X7.0 TABLET BLISTER	02/02/2024

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1054	NDA/MAL/HDP/1 1128	ATCO LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BETAMET-N	BETAMETHASONE AS VALERATE + NEOMYCIN SULPHATE	0.1% W/W + 0.5% W/W	ATCO LABORATORIES LIMITED-B-18, S.I.T.E, KARACHI - 74700	PAKISTAN	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X15.0 G TUBE	12/13/2023
1055	NDA/MAL/HDP/1 1129	EAST AFRICAN (INDIA) OVERSEAS	ABACUS PHARMA (AFRICA) LIMITED	PARARIV-I	IBUPROFEN + PARACETAMOL	100 MG + 162.5 MG	EAST AFRICAN (INDIA) OVERSEAS- PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	12/13/2023



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1056	NDA/MAL/HDP/1 113	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	ALCID-YELLOW	MULTI- INGREDIENT	MULTI- INGREDIENT	TORQUE PHARMACEUTICALS PVT LTDISAAPUR P.O DAPPAR 140056 INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X400.0 ML BOTTLE,1.0X160.0 ML BOTTLE	01/07/1997
1057	NDA/MAL/HDP/1 1130	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	VINGLYN M 50/1000	VILDAGLIPTIN + METFORMIN HYDROCHLORIDE	50 MG + 1000 MG	EAST AFRICAN (INDIA) OVERSEAS- PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023

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1058	NDA/MAL/HDP/1 1135	MEGA LIFSCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	PANFOR PR-500	METFORMIN HYDROCHLORIDE	500MG	INVENTIA HEALTHCARE LIMITED-F-1 - F-1/1 - F75/1, ADDITIONAL AMBERNATH MIDC, AMBERNATH EAST 421506, DIST. THANE, MAHARASHTRA - INDIA	INDIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER	12/13/2023
1059	NDA/MAL/HDP/1 1136	KESAR PHARMA	ABACUS PHARMA (AFRICA) LIMITED	ALZOL	ALBENDAZOLE	400 MG	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X1.0 TABLET BLISTER	12/13/2023

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1060	NDA/MAL/HDP/1 1137	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	DARUNIVIR AND RITONIVIR TABLETS	DARUNAVIR ETHANOLATE + RITONAVIR	800 MG + 100 MG	HETERO LABS PRIVATE LIMITED UNIT III-SURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) JEEDIMETLA, HYDERABAD-500 055, TELANGANA STATE,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET CONTAINER,1.0X18 0.0 TABLET CONTAINER	12/13/2023
1061	NDA/MAL/HDP/1 1138	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ASTRA PHARMA (U) LIMITED	CABALIN 150	PREGABALIN	150 MG	CACHET PHARMACEUTICALS PVT LTD .-VILLAGE THANA, BADDI, TEHSIL-NALAGARH DIST. SOLAN, HIMACHAL PRADESH- 173205	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X12.0 CAPSULE BLISTER	12/13/2023

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1062	NDA/MAL/HDP/1 1139	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	EMTRICITABINE AND TENOFOVIR ALAFENAMIDE TABLETS	EMTRICITABINE + TENOFOVIR ALAFENAMIDE	200 MG + 25 MG	LAURUS LABS LTD (UNIT 2)-PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE	12/13/2023
1063	NDA/MAL/HDP/1 114	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	TRANGEL ULTRA	DICLOFENAC/MET HYL SALICYLATE/MEN THOL/CAPSICUM OLEORESIN	10MG/80MG/60M G/0.15MG	NEM LABORATORIES LIMITED133 KRISHNA IND. ESTATE, VASAI (E), THANE – 401 210, MAHARASHTRA – INDIA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G CONTAINER	01/07/2012

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1064	NDA/MAL/HDP/1 1140	SINOVAC BIOTECH CO LTD	BHL HEALTHCARE LIMITED	HEALIVE (JUNIOR USE)	INACTIVATED HEPATITIS A VIRUS ANTIGEN, TZ84 STRAIN PRODUCED IN HUMAN DIPLOID (2BS) CELLS ADSORBED ON ALUMINIUM HYDROXIDE	250 IU/1.0 ML	SINOVAC BIOTECH COMPANY LIMITED - CHANGPING SITE- NO. 15, ZHITONG ROAD, CHANGPING DISTRICT, BEIJING, 102200 - CHINA	CHINA	PARENTERAL ORDINARY VIALS	1.0X1.0X0.5 ML VIAL,1.0X1.0X0.5 ML PRE- FILLED SYRINGE	12/13/2023
1065	NDA/MAL/HDP/1 1141	SINOVAC BIOTECH CO LTD	BHL HEALTHCARE LIMITED	HEALIVE (ADULT USE)	INACTIVATED HEPATITIS A VIRUS ANTIGEN, TZ84 STRAIN PRODUCED IN HUMAN DIPLOID (2BS) CELLS ADSORBED ON ALUMINIUM HYDROXIDE	250 IU/1.0 ML	SINOVAC BIOTECH COMPANY LIMITED - CHANGPING SITE- NO. 15, ZHITONG ROAD, CHANGPING DISTRICT, BEIJING, 102200 - CHINA	CHINA	PARENTERAL ORDINARY VIALS	1.0X1.0X1.0 ML VIAL,1.0X1.0X1.0 ML PRE- FILLED SYRINGE	12/13/2023

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1066	NDA/MAL/HDP/1 1142	PSYCHOTROPICS INDIA LTD-	BIOGEN PHARMA LIMITED	CEFTRIONE-1	CEFTRIAZONE SODIUM	1G/VIAL	PSYCHOTROPICS INDIA LTD-PLOT NO. 12 & 12A, INDUSTRIAL PARK-II, PHASE-1, VILLAGE SALEMPUR, MEHDOOD-2 HARIDWAR-249403, UTTARAKHAND INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL	12/13/2023
1067	NDA/MAL/HDP/1 1143	HILTON PHARMA (PVT) LTD	BOOTS PHARMACEUTICAL S LIMITED	ROLIP EZE	ROSUVASTATIN CALCIUM + EZETIMIBE	5MG +10MG	HILTON PHARMACEUTICALS (PVT) LIMITED-PLOT NO. 13-14, SECTOR 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	12/13/2023

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1068	NDA/MAL/HDP/1 1144	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	EFAVIRENZ, LAMIVUDINE AND TENOFVIR DISOPROXIL FUMARATE TABLETS	EFAVIRENZ + LAMIVUDINE + TENOFVIR DISOPROXIL FUMARATE	400MG + 300MG + 300 MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED (CIPLAQCIL)-PLOT 1- 7, 1ST RING ROAD, LUZIRA INDUSTRIAL PARK	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE	12/13/2023
1069	NDA/MAL/HDP/1 1145	NEXT WAVE (INDIA)	DAVIMED PHARMA LIMITED	CADZOLE-V	CLOTRIMAZOLE	100 MG	NEXT WAVE- RAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	VAGINAL TABLETS	1.0X1.0X6.0 TABLET STRIP	12/13/2023

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1070	NDA/MAL/HDP/1 1147	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	MEMTIN 10	MEMANTINE HYDROCHLORIDE	10 MG	UNICHEM LABORATORIES LTD- UNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023
1071	NDA/MAL/HDP/1 1148	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	CONAZ CREAM	KETOCONAZOLE	2% W/W	ATCO LABORATORIES LIMITED-B-18, S.I.T.E, KARACHI - 74700	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X1.0X10.0 G TUBE	12/13/2023



## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1072	NDA/MAL/HDP/1149	JAMJOOM PHARMACEUTICALS COMPANY	MU PHARMA CO - SMC LIMITED	LICAN	LULICONAZOLE	1% W/W	JAMJOOM PHARMACEUTICALS COMPANY - PLOT NO: ME1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 - KINGDOM OF SAUDI ARABIA	SAUDI ARABIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	12/13/2023
1073	NDA/MAL/HDP/1150	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	LABCLAV 625MG TABLETS	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500 MG + 125 MG	LABORATORY & ALLIED LTD -PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, NEXT TO LIBRA HOUSE, MOMBASA ROAD- NAIROBI - KENYA	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER,1.0X2.0X7.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	12/13/2023

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1074	NDA/MAL/HDP/1 1151	BAROQUE PHARMACEUTICAL S PVT LTD	JEET PHARMACEUTICAL S LIMITED	NUROQ 75	PREGABALIN	75 MG	BAROQUE PHARMACEUTICAL PVT LTD-192/2 & 3, SOKHADA, 388620, TA: KHAMHAT DIST. ANANT (GUJARAT)	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	12/13/2023
1075	NDA/MAL/HDP/1 1152	BAROQUE PHARMACEUTICAL S PVT LTD	JEET PHARMACEUTICAL S LIMITED	COCEL	CELECOXIB	200 MG	BAROQUE PHARMACEUTICAL PVT LTD-192/2 & 3, SOKHADA, 388620, TA: KHAMHAT DIST. ANANT (GUJARAT)	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	12/13/2023

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1076	NDA/MAL/HDP/1 1153	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	XAFARIV 15	RIVAROXABAN	15 MG	MYLAN LABORATORIES LIMITED-NO. H-12 & H-13, MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD - 431 136, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	12/13/2023
1077	NDA/MAL/HDP/1 1154	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	XAFARIV 20	RIVAROXABAN	20 MG	MYLAN LABORATORIES LIMITED-NO. H-12 & H-13, MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD - 431 136, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	12/13/2023

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1078	NDA/MAL/HDP/1 1155	IDA FOUNDATYION	KIMSY MEDS LTD	BENZATHINE BENZYL PENICILLIN 1.2MIU	BENZATHINE BENZYL PENICILLIN	1.2 MIU	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X15.0 ML VIAL	12/13/2023
1079	NDA/MAL/HDP/1 1156	IDA FOUNDATION	KIMSY MEDS LTD	BENZATHINE BENZYL PENICILLIN 2.4MIU	BENZATHINE BENZYL PENICILLIN	2.4 MIU	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X15.0 ML VIAL	12/13/2023

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1080	NDA/MAL/HDP/1 1157	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	DOVATO 50MG/300MG	DOLUTEGRAVIR + LAMIVUDINE	50 MG + 300 MG	GLAXOSMITHKLINE, LLC1011 NORTH ARENDELL AVENUE ZEBULON, NORTH CAROLINA 27597	UNITED STATES	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE	02/02/2024
1081	NDA/MAL/HDP/1 1158	MARCYRL PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TORSAMOLEX 20MG	TORSEMIDE	20MG	MARCYRL PHARMACEUTICAL INDUSTRIES WESTERN EXTEENSION-PARTS NUMBER 5/6/7/8/9/10/11/12- BLOCK 20005, EL OBOUR CITY	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	02/02/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1082	NDA/MAL/HDP/1 1159	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TIBAN 20	TENEGLIPTIN HYDROBROMIDE HYDRATE	20MG	AJANTA PHARMA LIMITEDB-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD MAHARASHTRA STATE INDIA 431 128	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/02/2024
1083	NDA/MAL/HDP/1 1160	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	ROSUNA-5	ROSUVASTATIN CALCIUM	5MG	ZOTA HEATHCARE LIMITEDPLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NEAR SACHIN RAILWAY STATION, SACHIN, CITY: SURAT, DIST: SURAT, GUJARAT STATE - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/02/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1084	NDA/MAL/HDP/1161	CACHET PHARMACEUTICALS PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EMITINO-8 INJECTION	ONDANSETRON HYDROCHLORIDE	8MG/4ML	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN " 248011 (U.K), INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0X4.0 ML AMPOULE	02/02/2024
1085	NDA/MAL/HDP/1162	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICALS LTD)	TATA UGANDA LIMITED	RABZOL	RABEPRAZOLE SODIUM	20MG	NAPROD LIFE SCIENCES PVT. LTDG-17/1, MIDC TARAPUR IND. AREA, BOISAR, 401506 MAHARASHTRA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X20.0 MG VIAL, 1.0X1.0X20.0 G VIAL	02/02/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1086	NDA/MAL/HDP/1 1163	UNIMED LABORATORIES.	OMAB UGANDA LIMITED	CIPROJECT	CIPROFLOXACIN	200MG	UNIMED LABORATORIES P.O. BOX 38 - I.Z. KALAA KEBIRA - 4060 KALAA KEBIRA - TUNISIA	TUNISIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X100.0 ML BAG	02/02/2024
1087	NDA/MAL/HDP/1 1164	IDA FOUNDATION	KIMSY MEDS LTD	BENZATHINE BENZYL PENICILLIN 5MIU	BENZATHINE BENZYL PENICILLIN	5 MIU	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X15.0 ML VIAL	12/13/2023



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1088	NDA/MAL/HDP/1 1165	IDA FOUNDATYION	KIMSY MEDS LTD	BENZATHINE BENZYL PENICILLIN 1MIU	BENZATHINE BENZYL PENICILLIN	1MIU	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X15.0 ML VIAL	12/13/2023
1089	NDA/MAL/HDP/1 1166	GLOBELA PHARMA PVT. LTD.	ROYAL PHARMA 2011 LIMITED	PYLOGLOB KIT	CLARITHROMYCIN + OMEPRAZOLE + TINIDAZOLE	250 MG + 20 MG + 500 MG	GLOBELA PHARMA PVT.LTD.357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY COMBINATION PACK COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	21/02/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1090	NDA/MAL/HDP/1 1167	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	XAGULANT 2.5	APIXABAN	2.5 MG	MYLAN LABORATORIES LIMITED-NO. H-12 & H-13, MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD - 431 136, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	12/13/2023
1091	NDA/MAL/HDP/1 1168	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	XAGULANT 5	APIXABAN	5 MG	MYLAN LABORATORIES LIMITED-NO. H-12 & H-13, MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD - 431 136, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	12/13/2023

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1092	NDA/MAL/HDP/1 1169	IDA FOUNDATYION	KIMSY MEDS LTD	DICLOFENAC SODIUM	DICLOFENAC SODIUM	75MG/3ML	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X3.0 ML AMPOULE	12/13/2023
1093	NDA/MAL/HDP/1 117	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	TETRACYCLINE EYE OINTMENT USP 1%	TETRACYCLINE	1%W/W	NEM LABORATORIES LIMITED133 KRISHNA IND. ESTATE, VASAI (E), THANE – 401 210, MAHARASHTRA – INDIA	INDIA	OPHTHALMIC OINTMENTS	1.0X20.0X3.5 G TUBE	01/07/2013

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1094	NDA/MAL/HDP/1 1170	JEVIANA HEALTH CARE LLP,	MARVIN PHARMA LIMITED	MARIPRAZOLE	OMEPRAZOLE SODIUM	40 MG/VIAL	SANJAR PHARMACEUTICALS LIMITED-SURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X40.0 MG VIAL + 1*10 ML, WATER FOR INJECTION IN LDPE AMPOULE	12/13/2023
1095	NDA/MAL/HDP/1 1171	BIOMATRIX HEALTHCARE PVT LTD.-	MEDIWORLD PHARMA AFRICA LTD	PRIMECIP	CIPROFLOXACIN HYDROCHLORIDE	500 MG	BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	12/13/2023

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1096	NDA/MAL/HDP/1 1172	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	GLANTRIM	DORZOLAMIDE HYDROCHLORIDE + TIMOLOL MALEATE	2%W/V + 0.5%W/V	ATCO LABORATORIES LIMITEDB-18, S.I.T.E, KARACHI - 74700	PAKISTAN	OPHTHALMIC LIQUIDS	1.0X1.0X5.0 ML BOTTLE	02/02/2024
1097	NDA/MAL/HDP/1 1173	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	WINOLAP 0.1	OLOPATADINE HYDROCHLORIDE	0.1%W/V	ATCO LABORATORIES LIMITEDB-18, S.I.T.E, KARACHI - 74700	PAKISTAN	OPHTHALMIC LIQUIDS	1.0X1.0X5.0 ML BOTTLE	02/02/2024

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1098	NDA/MAL/HDP/1 1174	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	WINOLAP 0.2%	OLOPATADINE HYDROCHLORIDE	0.2%W/V	ATCO LABORATORIES LIMITEDB-18, S.I.T.E, KARACHI - 74700	PAKISTAN	OPHTHALMIC LIQUIDS	1.0X1.0X2.5 ML BOTTLE	02/02/2024
1099	NDA/MAL/HDP/1 1175	ADWIA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	URIPAN XR	OXYBUTYNIN HYDROCHLORIDE	10MG	ADWIA S.A.E.1ST INDUSTRIAL ZONE A1, 10TH OF RAMADAN CITY, EGYPT	EGYPT	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/02/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1100	NDA/MAL/HDP/1 1176	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BORTEBIN	BORTEZOMIB	3.5MG	EUGIA PHARMA SPECIALITIES LIMITEDSURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X3.5 MG VIAL	02/02/2024
1101	NDA/MAL/HDP/1 1177	ADWIA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LEPTROGINE 200 MG	LAMOTRIGINE	200MG	ADWIA S.A.E.1ST INDUSTRIAL ZONE A1, 10TH OF RAMADAN CITY, EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/02/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1102	NDA/MAL/HDP/1 1178	UNIMED LABORATORIES.	OMAB UGANDA LIMITED	SYNERGIC 500	IMIPENEM + CILASTATIN	500 MG + 500 MG	UNIMED LABORATORIESP.O. BOX 38 - I.Z. KALAA KEBIRA - 4060 KALAA KEBIRA - TUNISIA	TUNISIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X20.0 ML VIAL	02/02/2024
1103	NDA/MAL/HDP/1 1179	UNIMED LABORATORIES.	OMAB UGANDA LIMITED	TAZOBACT 4G/500 MG	PIPERACILLIN SODIUM + TAZOBACTAM SODIUM	4G + 500MG	UNIMED LABORATORIESP.O. BOX 38 - I.Z. KALAA KEBIRA - 4060 KALAA KEBIRA - TUNISIA	TUNISIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X4.5 G VIAL	02/02/2024



## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1104	NDA/MAL/HDP/1118	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ELAXIM 52.5	TENECTEPLASE (RECOMBINANT TISSUE PLASMINOGEN ACTIVATOR), (TNK-T-PA)	52.5	GENNOVA BIOPHARMACEUTICALS LIMITED BLOCK 1, PLOT NO. P-1 AND P-2, ITBT PARK, PHASE II, MIDC, HINJAWADI, PUNE - 411057	INDIA	PARENTERAL ORDINARY I V VIALS	1.0X52.5 MG VIAL + (1*10ML AMPOULE WFI)	01/07/2013
1105	NDA/MAL/HDP/11182	INDIANA OPHTHALMICS	SWASTIK PHARMACEUTICAL LTD	AYZEECON	AZITHROMYCIN DIHYDRATE	1%W/W	INDIANA OPHTHALMICS 135, 136, 137, GIDC ESTATE, WADHWAN-363035	INDIA	OPHTHALMIC OINTMENTS	1.0X1.0X5.0 G TUBE	02/02/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1106	NDA/MAL/HDP/1 1189	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	CLEOBACT 150	CLINDAMYCIN HYDROCHLORIDE	150 MG	BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	12/13/2023
1107	NDA/MAL/HDP/1 1190	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	ACNEX	CLINDAMYCIN PHOSPHATE	1% W/W	NANZ MED SCIENCE PHARMA PVT. LTD- RAMPUR GHAT, PAONTA SAHIB, DISTRICT SIRMOUR- 173025, HIMACHAL PRADESH, INDIA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X15.0 G TUBE	12/13/2023

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1108	NDA/MAL/HDP/1 1191	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	FUNGIDERM	CLOTRIMAZOLE + ZINC OXIDE + DIMETHICONE	1% W/W + 1.75% W/W + 2.50% W/W	NANZ MED SCIENCE PHARMA PVT. LTD- RAMPUR GHAT, PAONTA SAHIB, DISTRICT SIRMOUR- 173025, HIMACHAL PRADESH, INDIA	INDIA	TOPICAL EXTERNAL DUSTING POWDERS	1.0X50.0 G BOTTLE	12/13/2023
1109	NDA/MAL/HDP/1 1192	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	ERINOCIN 250	ERYTHROMYCIN STEARATE	250 MG	BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	12/13/2023

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1110	NDA/MAL/HDP/1 1193	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	WELGRA 100	SILDENAFIL CITRATE	100 MG	AKUMS DRUGS AND PHARMACEUTICALS- 19,20,21, SEC.6-A, IIE, SIDCUL, RANIPUR,HARIDWAR- 249403, UTTARAKHAND, INDIAINDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	12/13/2023
1111	NDA/MAL/HDP/1 1194	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	UNOKETRO	KETOROLAC TROMETHAMINE	30 MG/ML	AKUMS DRUGS & PHARMACEUTICALS LTD ,-2,3,4,5, SECTOR 6B, SIDCUL, I.I.E, RANIPUR, HARIDWAR-249403, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0X1.0 ML AMPOULE	12/13/2023

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1112	NDA/MAL/HDP/1 1195	FAROMED LIFSCIENCES LLP	METRO PHARMACEUTICAL S LIMITED	WINOP 60	KETOROLAC TROMETHAMINE	60MG/2ML	THE ACME LABORATORIES LIMITED-DHULIVITA, DHAMRAI, DHAKA - 1350, BANGLADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X2.0 ML AMPOULE	12/13/2023
1113	NDA/MAL/HDP/1 1196	FAROMED LIFSCIENCES LLP	METRO PHARMACEUTICAL S LIMITED	PERMIN	PERMETHRIN	5%W/W	THE ACME LABORATORIES LIMITED-DHULIVITA, DHAMRAI, DHAKA - 1350, BANGLADESH	BANGLADESH	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	12/13/2023

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1114	NDA/MAL/HDP/1 1197	LINCOLN PHARMACEUTICAL S LIMITED	METRO PHARMACEUTICAL S LIMITED	MYCOFIL	MYCOPHENOLAT E MOFETIL	500 MG	LINCOLN PHARMACEUTICALS LTD-10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	12/13/2023
1115	NDA/MAL/HDP/1 1198	ARCELIA LIFE SCIENCES LTD.	NOVOMED HEALTHCARE LIMITED	GENTAMICIN SULPHATE	GENTAMICIN SULPHATE	80MG/2ML	SANJAR PHARMA LLP SURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X2.0 ML VIAL	12/13/2023

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1116	NDA/MAL/HDP/1 1199	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DYMET-500	METFORMIN HYDROCHLORIDE	500 MG	BAFNA PHARMACEUTICALS LIMITED UNIT II-NO. 147, MADHAVARAM RED HILLS ROAD, GRANTLYON VILLAGE, VADAKARAI POST, CHENNAI, TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023
1117	NDA/MAL/HDP/1 1200	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	HYTAN – 80	TELMISARTAN	80MG	BAFNA PHARMACEUTICALS LIMITED UNIT II-NO. 147, MADHAVARAM RED HILLS ROAD, GRANTLYON VILLAGE, VADAKARAI POST, CHENNAI, TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023

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1118	NDA/MAL/HDP/1 1201	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	HYTAN – 40	TELMISARTAN	40MG	BAFNA PHARMACEUTICALS LIMITED UNIT II-NO. 147, MADHAVARAM RED HILLS ROAD, GRANTLYON VILLAGE, VADAKARAI POST, CHENNAI, TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023
1119	NDA/MAL/HDP/1 1202	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	IRNIZET 40	IRINOTECAN HYDROCHLORIDE TRIHYDRATE	20MG/ML	EUGIA PHARMA SPECIALITIES LIMITED-SURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X2.0 ML VIAL	12/13/2023



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1120	NDA/MAL/HDP/1 1203	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	AUROPODOX 40	CEFPODOXIME PROXETIL	40MG PER 5ML	AUROBINDO PHARMA LIMITED, FORMULATIONS UNIT-VI- R7- AUROBINDO PHARMA LIMITED, FORMULATIONS UNIT-VI SY.NO.329/39 & 329/47 CHITKUL(V) PATANCHERU MANDAL, SANGA REDDY DISTTELANGANA502 307	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X100.0 ML BOTTLE	12/13/2023
1121	NDA/MAL/HDP/1 1204	KLM LABORATORIES PVT. LTD.	REDDYS PHARMA LIMITED	NIOFINE CREAM	TERBINAFINE HYDROCHLORIDE	1.0% W/W	CURETECH SKINCARE PLOT NO. 33 & 34, PHASE IV, BHATOLI KALAN, BADDI DISTT. SOLAN (HP) 173205	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	12/13/2023

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1122	NDA/MAL/HDP/1 1205	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	20M	MANNITOL	20% W/V	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED-SURVEY NO. 199 TO 201 & 208 TO 210, MF01 AND MF02 VILLAGE- VASNA CHACHARWADI, TAL. SANAND DISTRICT. AHMEDABAD-382 213	INDIA	PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES	1.0X1.0X500.0 ML BOTTLE	12/13/2023
1123	NDA/MAL/HDP/1 1206	XL LABORATORIES PRIVATE LIMITED	ROYAL PHARMA 2011 LIMITED	FLAMO 400	IBUPROFEN	400 MG	XL LABORATORIES PRIVATE LIMITED-A- 141, EPIP INDUSTRIAL AREA, NEEMRANA, DIST. ALWAR, RAJASTHAN - 301705 (INDIA)	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X6.0X1.0X10.0 CAPSULE BLISTER	12/13/2023

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1124	NDA/MAL/HDP/1 1208	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROZMET - 500	METFORMIN	500 MG	EAST AFRICAN (INDIA) OVERSEAS- PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	12/13/2023
1125	NDA/MAL/HDP/1 1209	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	RO-VIT-K 10	PHYTOMENADIO NE	10MG/ML	SANJAR PHARMACEUTICALS LIMITED-SURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0X1.0 ML AMPOULE	12/13/2023

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1126	NDA/MAL/HDP/1 122	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABCHLOR EAR DROPS	CHLORAMPHENIC OL	5%W/V	ABACUS PARENTERAL DRUGS LIMITEDBLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	OTIC DROPS	1.0X10.0 ML VIAL,1.0X5.0 ML VIAL	01/07/2013
1127	NDA/MAL/HDP/1 123	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOPAR	PARACETAMOL	500 MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER	01/07/2012

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1128	NDA/MAL/HDP/1 1232	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	PLERISTEM	PLERIXAFOR	24MG/1.2ML	EUGIA PHARMA SPECIALITIES LIMITEDSURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X1.2.0 ML VIAL	22/03/2024
1129	NDA/MAL/HDP/1 1233	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICAL S LTD)	PLANET PHARMACEUTICAL S UGANDA LTD	AMCARDIA-10	AMLODIPINE BESYLATE	10 MG	UNIQUE PHARMACEUTICAL LABS LIMITED. .PLOT NO. 215-219 AND 304-308, GIDC INDUSTRIAL ESTATE, PANOLI - 394 116, DIST: BHARUCH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	22/03/2024

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1130	NDA/MAL/HDP/1 1234	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	MOXILEB 250 DT	AMOXICILLIN TRIHYDRATE	250MG	LEBEN LABORATORIES PVT LTD .L-14 PHASE III MIDC AKOLA 444 104	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	22/03/2024
1131	NDA/MAL/HDP/1 1235	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	QUALITY CHEMICALS LTD	ZENTAIR 1.0MG	ENTECAVIR	1.0MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED (CIPLAQCIL)PLOT 1- 7, 1ST RING ROAD, LUZIRA INDUSTRIAL PARK	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	22/03/2024

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1132	NDA/MAL/HDP/1 1236	REDDYS PHARMA LIMITED	REDDYS PHARMA LIMITED	AURATRIM-GB	BETAMETHASONE DIPROPIONATE + CLOTRIMAZOLE + GENTAMICIN SULFATE	0.05% W/W + 1.0% W/W + 0.1% W/W	AURA LIFECARE PRIVATE LIMITEDSURVEY NO. 254/14/1, JAROD- SAVLI ROAD, P.O. KARACHIYA, 391 520, TAL. SAVLI, DIST. VADODARA - INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE, 1.0X30.0 G TUBE	22/03/2024
1133	NDA/MAL/HDP/1 1237	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	PERILIN	METOCLOPRAMI DE HYDROCHLORIDE	10MG/2ML	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	22/03/2024

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1134	NDA/MAL/HDP/1 1238	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	DESLORA-5	DESLORATADINE	5MG	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	22/03/2024
1135	NDA/MAL/HDP/1 1239	NEM LABORATORIES (PVT) LTD	RENE PHARMACY LTD	TIGBODERM -G CREAM	CLOTRIMAZOLE + GENTAMICIN SULFATE + BETAMETHASONE DIPROPIONATE	1% W/W + 0.1% W/W + 0.05% W/W	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE, 1.0X30.0 G TUBE	22/03/2024



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1136	NDA/MAL/HDP/1 124	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGO SCRUB	CHLORHEXIDINE GLUCONATE	4%W/V	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X1.0X500.0 ML BOTTLE	01/07/2013
1137	NDA/MAL/HDP/1 1241	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	TERBINAFINE TABLETS USP, 250 MG	TERBINAFINE HYDROCHLORIDE	250MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN “ 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/03/2024

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1138	NDA/MAL/HDP/1 1242	FAROMED LIFSCIENCES LLP	METRO PHARMACEUTICALS LIMITED	SITAP 50	SITAGLIPTIN PHOSPHATE MONOHYDRATE	50MG	ADVANCED CHEMICAL INDUSTRIES (ACI) LIMITED7, HAJEEGONJ ROAD, GOODNYL, NARAYANGONJ - 1400	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/03/2024
1139	NDA/MAL/HDP/1 1243	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	ZETIRISE	ALBENDAZOLE	200MG/5ML	SUNRISE INTERNATIONAL LABS LTD PLOT NO. 100, LANE-5, SECTOR II, PHASE-II, IDA, CHERLAPALLY INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X10.0 ML BOTTLE	22/03/2024

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1140	NDA/MAL/HDP/1 1244	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	ESOPRALIN	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40MG	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/03/2024
1141	NDA/MAL/HDP/1 1245	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	VALPIN-200	SODIUM VALPROATE	200MG	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	22/03/2024

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1142	NDA/MAL/HDP/1 1246	SCOTT-EDIL ADVANCE RESEARCH LABORATORIES & EDUCATION LTD.,	ROYAL PHARMA 2011 LIMITED	SCOFIX 400	CEFIXIME TRIHYDRATE	400MG	M/S SCOTT-EDIL ADVANCE RESEARCH LABORATORIES AND EDUCATION LIMITEDHILL-TOP, INDUSTRIAL AREA, BHATOLI KALAN, BADDI, DISTT. SOLAN (HP) - 173205, INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	22/03/2024
1143	NDA/MAL/HDP/1 1248	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICAL S LTD	VIDAGLIN	VILDAGLIPTIN	50 MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/03/2024

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1144	NDA/MAL/HDP/1 1249	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	ARH-L	ARTEMETHER + LUMEFANTRINE	(180 MG + 1080 MG)/ 60ML	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X60.0 ML BOTTLE	22/03/2024
1145	NDA/MAL/HDP/1 125	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	AUROXONE 1000	CEFTRIAZONE	1000MG	AUROBINDO PHARMA LIMITED, FORMULATIONS UNIT-VI- R7AUROBINDO PHARMA LIMITED, FORMULATIONS UNIT-VI SY.NO.329/39 & 329/47 CHITKUL(V) PATANCHERU MANDAL, SANGA REDDY DISTTELANGANA502 307	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2009

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1146	NDA/MAL/HDP/1 1250	AUROCHEM LABORATORIES(I) PVT LTD	SUPER MEDIC LTD	DOBESIL H	CALCIUM DOBESILATE MONOHYDRATE + LIDOCAINE HYDROCHLORIDE + HYDROCORTISON E ACETATE + ZINC OXIDE	0.5 % W/W + 3.0 %W/W + 0.25 % W/W + 5.0 % W/W	AUROCHEM LABORATORIES (I) PVT LTD8, PALGHAR TALUKA INDUSTRIAL CO - OPERATIVE ESTATE LIMITED PALGHAR, DISTRICT - PALGHAR, 401404	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	22/03/2024
1147	NDA/MAL/HDP/1 1252	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TELMICLAR HTZ 40/12.5	TELMISARTAN + HYDROCHLOROT HIAZIDE	40 MG + 12.5 MG	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	16/03/2024

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1148	NDA/MAL/HDP/1 1253	FRESENIUS KABI MANUFACTURING S.A. (PTY) LTD	SURGIPHARM (U) LIMITED	CLINDAMYCIN FRESENIUS 600MG/4ML	CLINDAMYCIN PHOSPHATE	600MG/4ML	FRESENIUS KABI MANUFACTURING SA (PTY) LIMITED6 GIBAUD ROAD, KORSTEN, 6020, PORT ELIZABETH, SOUTH AFRICALABESFAL LABORATORIOS ALMIRO, S.A ZONA INDUSTRIAL DO LAGEDO, 3465-157 SANTIAGO DE BESTEIROS	PORTUGALSOUTH AFRICA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X4.0 ML AMPOULE	22/03/2024
1149	NDA/MAL/HDP/1 1254	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ORIXO 400	OFLOXACIN	400MG	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	16/03/2024

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1150	NDA/MAL/HDP/1 1255	MANKIND PHARM LTD	TATA UGANDA LIMITED	MAHACEF-200	CEFIXIME TRIHYDRATE	200 MG	COPMED PHARMACEUTICALS PVT LTD-UNIT II. ,PLOT 50, GONDPUR INDUSTRIAL AREA, PAONTA, SAHIB, SIRMOUR, HIMACHAL PRADESH- 173025, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	22/03/2024
1151	NDA/MAL/HDP/1 1256	BRAWN LABORATORIES LTD	TATA UGANDA LIMITED	MOXIBRU	MOXIFLOXACIN	0.5% W/V	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML BOTTLE	22/03/2024



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1152	NDA/MAL/HDP/1 1257	BRAWN LABORATORIES LTD	TATA UGANDA LIMITED	BRUCOXIA-90	ETORICOXIB	90MG	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/03/2024
1153	NDA/MAL/HDP/1 1258	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ADERAN HTZ 16/12.5	CANDESARTAN CILEXETIL + HYDROCHLOROT HIAZIDE	16 MG + 12.5 MG	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	16/03/2024

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1154	NDA/MAL/HDP/1 1259	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICAL S LTD)	TATA UGANDA LIMITED	MAGNILEK	GADOPENTETATE DIMEGLUMINE	469MG/ML	UNIQUE PHARMACEUTICAL LABORATORIESPLOT NO.4, PHASE IV, GIDC, INDUSTRIAL AREA, PANOLI- 394 116, DIST: BHARUCH, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL, 1.0X10.0 ML VIAL, 1.0X15.0 ML VIAL	22/03/2024
1155	NDA/MAL/HDP/1 1260	MANKIND PHARM LTD	TATA UGANDA LIMITED	MAHACEF-100	CEFIXIME TRIHYDRATE	100 MG	COPMED PHARMACEUTICALS PVT LTD-UNIT II. ,PLOT 50, GONDPUR INDUSTRIAL AREA, PAONTA, SAHIB, SIRMOUR, HIMACHAL PRADESH- 173025, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	22/03/2024

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1156	NDA/MAL/HDP/1 1261	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	COLIHENZ	CITICOLINE SODIUM	500MG	STANFORD LABORATORIES PRIVATE LIMITED (A SUBSIDIARY COMPANY OF LA RENON HEALTHCARE PRIVATE LIMITED)8, INDUSTRIAL AREA, MEHATPUR - 174315, HIMACHAL PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	16/03/2024
1157	NDA/MAL/HDP/1 1262	AMN LIFE SCIENCE PVT LTD	VITACARE LIMITED	MOXITAM 125	AMOXICILLIN TRIHYDRATE	125MG PER 5ML	AMN LIFE SCIENCE PVT LTD67/P-1, MALAV, AREA- BHILAD, VALSAD- 396105, GUJARAT	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X60.0 ML BOTTLE	22/03/2024

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1158	NDA/MAL/HDP/1 1263	ORCHIDIA PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NORMOPROST	LATANOPROST	50MCG/ML	ORCHIDIA PHARMACEUTICAL INDUSTRIESAL OBOUR CITY INDUSTRIAL ZONE, AREA 14, 15 - PLOT NO. 12011 - CAIRO - EGYPT	EGYPT	OPHTHALMIC DROPS	1.0X1.0X3.0 ML BOTTLE	22/03/2024
1159	NDA/MAL/HDP/1 1264	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	FLAIROF	ROFLUMILAST	250MCG	HETERO LABS LIMITED (UNIT III)...22-110, I.D.A, JEDIMETLA, HYDERABAD-500 055, ANDHRA PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X15.0 TABLET BLISTER	16/03/2024

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1160	NDA/MAL/HDP/1 1265	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	NEUTAS	RECOMBINANT HUMAN GRANULOCYTE COLONY STIMULATING FACTOR	300MCG/0.5ML	INTAS PHARMACEUTICALS LTD (BIOPHARMA DIVISION)PLOT NO. 423/P/A, SARKHEJ- BAVLA HIGHWAY, MORAIYA, TALUKA SANAND, AHMEDABAD- 382213, GUJARAT	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0 ML PRE- FILLED SYRINGE	22/03/2024
1161	NDA/MAL/HDP/1 1266	I-CARE PHARMA LTD	AIVEEN (U) LIMITED	IZ 500	AZITHROMYCIN DIHYDRATE	500MG	CORONA REMEDIES PVT. LTDVILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0 TABLET BLISTER	16/03/2024

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1162	NDA/MAL/HDP/1 1267	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ASTRA PHARMA (U) LIMITED	CACHMAX-200	CEFIXIME TRIHYDRATE	200 MG	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	16/03/2024
1163	NDA/MAL/HDP/1 1268	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	PARACO-DENK 1000/60	PARACETAMOL + CODEINE PHOSPHATE HEMIHYDRATE	1000 MG + 60 MG	BENE-ARZNEIMITTEL GMBHHERTERTICHS TR. 1-3, 81479 MUNCHEN - GERMANY	GERMANY	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY STRIP	16/03/2024

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1164	NDA/MAL/HDP/1 1269	INTAS PHARMACUITICALS LTD	NORVIK ENTERPRISES LIMITED	DOXORUBICIN INJECTION	DOXORUBICIN	2MG/ML	INTAS PHARMACEUTICALS LTD.PLOT NO. 457, 458, & 191/218P,VILLAGE: MATODA, TAL. SANAND, AHMEDABAD, GUJARAT, 382210 INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X25.0 ML VIAL	22/03/2024
1165	NDA/MAL/HDP/1 1270	RUSAN PHARMA LTD.	NORVIK ENTERPRISES LIMITED	ADDNOK-N 2/0.5	BUPRENORPHINE HYDROCHLORIDE + NALOXONE HYDROCHLORIDE	2 MG + 0.5 MG	RUSAN PHARMA LTDKHASRA NO. 122MI, CENTRAL HOPE TOWN, BEHIND PHARMA CITY, SELAQUI, DEHRADUN- 248197, UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY SUBLINGUAL TABLETS	1.0X3.0X10.0 TABLET BLISTER, 1.0X10.0 TABLET BLISTER, 1.0X10.0X10.0 TABLET BLISTER	22/03/2024

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1166	NDA/MAL/HDP/1 1271	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	DOLUTEGRAVIR SODIUM 50 MG, EMTRICITABINE 200 MG AND TENOFVIRAL AFENAMIDE 25 MG	DOLUTEGRAVIR SODIUM + EMTRICITABINE + TENOFVIR ALAFENAMIDE	50 MG + 200 MG + 25 MG	LAURUS LABS LTD (UNIT 2)PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	16/03/2024
1167	NDA/MAL/HDP/1 1273	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	ABACAVIR, DOLUTEGRAVIR AND LAMIVUDINE TABLETS	ABACAVIR SULFATE + DOLUTEGRAVIR SODIUM + LAMIVUDINE	600 MG + 50 MG + 300 MG	LAURUS LABS LTD (UNIT 2)PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE, 1.0X180.0 TABLET BOTTLE, 1.0X90.0 TABLET BOTTLE	16/03/2024



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1168	NDA/MAL/HDP/1 1274	HILTON PHARMA (PVT) LTD	BOOTS PHARMACEUTICAL S LIMITED	DAPA 10MG	DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE	10 MG	HILTON PHARMACEUTICALS (PVT) LIMITED PLOT NO. 13-14, SECTOR 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X14.0 TABLET BLISTER	16/03/2024
1169	NDA/MAL/HDP/1 1275	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	SPIRONOLACTON E	SPIRONOLACTON E	25MG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI- 248197, DEHRADUN (UTTARAKHAND)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/03/2024

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1170	NDA/MAL/HDP/1 1276	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	EFAVIRENZ, LAMIVUDINE AND TENOFVIR DISOPROXIL FUMARATE 400/300/300 MG TABLET	EFAVIRENZ + LAMIVUDINE + TENOFVIR DISOPROXIL FUMARATE	400MG + 300MG + 300MG	CIPLA LIMITED PLOT NO. A-33, A-2 & A- 37/2/2 (UNIT-I), A- 42(UNIT-II), MIDC PATALGANGA, 410220 DISTRICT RAIGAD, MAHARASHTRA CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED (CIPLAQCIL) PLOT 1- 7, 1ST RING ROAD, LUZIRA INDUSTRIAL PARK	UGANDA/INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER, 1.0X90.0 TABLET CONTAINER	16/03/2024
1171	NDA/MAL/HDP/1 1277	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	ANGILOCK 50	LOSARTAN POTASSIUM	50 MG	SQUARE PHARMACEUTICALS LIMITED - DHAKA UNIT KALI AKOIR GAZIPUR	BANGLADESH	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	16/03/2024

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1172	NDA/MAL/HDP/1 1278	AGOG PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	AGOXIN-500	AMOXICILLIN TRIHYDRATE	500MG	MILAN LABORATORIES (INDIA) PVT LTD,63,67,87,35,36, 64, 65 JAWAHAR CO- OP INDUSTRIAL ESTATE KAMOTHE, PANVEL NAVI MUMBAI	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X1.0X20.0 CAPSULE BLISTER	16/03/2024
1173	NDA/MAL/HDP/1 1279	MSN LABORATORIES PRIVATE LIMITED,	GOOD DAY PHARMACY LIMITED	SILOTRIF 8	SILODOSIN	8MG	MSN LABORATORIES LTD. PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, ZIP CODE - 502 325, ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	16/03/2024

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1174	NDA/MAL/HDP/1 128	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	BTC KIT	FLUCONAZOLE + AZITHROMYCIN + SECNIDAZOLE	150MG + 1G + 1G	LINCOLN PHARMACEUTICALS L.T.DTRIMUL ESTATE KHATRAJ 382721 GHANDINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY COMBINATION PACK TABLETS	1.0X4.0 TABLET BLISTER	01/07/2013
1175	NDA/MAL/HDP/1 1280	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BRUGENTA EYE/EAR DROPS	GENTAMICIN SULFATE	0.3%W/V	BRAWN LABORATORIES LTD .13, NIT, INDUSTRIAL AREA, FARIDABAD- 121001, HARYANA	INDIA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE	16/03/2024

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1176	NDA/MAL/HDP/1 1281	WORLD MEDICINE Å°LAÅž SAN. VE TIC. A.Åž.	GOODMAN INTERNATIONAL LTD	SERTOFEN	DEKKETOPROFEN TROMETAMOL	25MG	WORLD MEDICINE ILAC SAN VE TIC A.S.15 TEMMUZ MAHALLESİ, CAMI YOLU CADDESİ, NO: 50 K:4 WM PLAZA, GUNESIL- BAGCILAR/INSTANB UL, TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	16/03/2024
1177	NDA/MAL/HDP/1 1282	WORLD MEDICINE Å°LAÅž SAN. VE TIC. A.Åž.	GOODMAN INTERNATIONAL LTD	CULENTO 4MG	MONTELUKAST SODIUM	4MG	WORLD MEDICINE ILAC SAN VE TIC A.S.15 TEMMUZ MAHALLESİ, CAMI YOLU CADDESİ, NO: 50 K:4 WM PLAZA, GUNESIL- BAGCILAR/INSTANB UL, TURKEY	TURKEY	ORAL SOLID ORDINARY GRANULES	1.0X28.0 SACHET CARTON	16/03/2024

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1178	NDA/MAL/HDP/1 1283	THE SEARLE COMPANY LIMITED	HEALTHCARE LTD.	VAPTOR 10MG	ROSUVASTATIN CALCIUM	10MG	SEARLE PAKISTAN LIMITED,F-319, SITE KARACHI	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	16/03/2024
1179	NDA/MAL/HDP/1 1284	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	MYDEKLA 60	DACLATASVIR DIHYDROCHLORID E	60MG	MYLAN LABORATORIES LTD .F/4 & F/12, MALEGAON MIDC, SINNAR, NASHIK-422 113, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X28.0 TABLET CONTAINER	16/03/2024

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1180	NDA/MAL/HDP/1 1285	JSC BIOCAD, SAINT PETERSBURG	ONCOPHARM (U) LTD	BEVALAST	BEVACIZUMAB	25 MG/ML	JSC BIOCAD NEUDORF, FACILITY 2BLD. 38, CONSTRUCTION 1, SVYAZI ST., STRELNA, SAINT-PETERSBURG, RUSSIA, 198515	RUSSIA	PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES	1.0X1.0X16.0 ML VIAL, 1.0X1.0X4.0 ML VIAL, 1.0X1.0X100.0 MG VIAL, 1.0X1.0X400.0 MG VIAL	22/03/2024
1181	NDA/MAL/HDP/1 1286	JSC BIOCAD	ONCOPHARM (U) LTD	ACELLBIA	RITUXIMAB	10 MG/ML	JSC BIOCAD NEUDORF, FACILITY 2BLD. 38, CONSTRUCTION 1, SVYAZI ST., STRELNA, SAINT-PETERSBURG, RUSSIA, 198515	RUSSIA	PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES	1.0X1.0X50.0 ML VIAL, 1.0X1.0X500.0 MG VIAL	22/03/2024

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1182	NDA/MAL/HDP/1 1287	LABORATÓRIOS BASI	ONCOPHARM (U) LTD	MIDAZOLAM BASI	MIDAZOLAM	15 MG/3 ML	LABORATORIOS BASI INDUSTRIA FARMACEUTICAPAR QUE INDUSTRIAL MANUEL LOURENCO FERREIRA, LOTES 8, 15 E 16, 3450-232 MORTAGUA - PORTUGAL	PORTUGAL	PARENTERAL ORDINARY AMPOULES	1.0X10.0X3.0 ML AMPOULE	22/03/2024
1183	NDA/MAL/HDP/1 1288	MICRO LABS LIMITED	PHARMA VILLE LIMITED	PARACETAMOL BP 500MG TABLET	PARACETAMOL	500MG	MICRO LABS LIMITED, HOSURNO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	22/03/2024



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1184	NDA/MAL/HDP/1 1289	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ADCCLENA 5	LENALIDOMIDE	5MG	MYLAN LABORATORIES LTD PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR - 454775; DIST; DHAR; MADHYA PRADESH;	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X14.0 CAPSULE BLISTER	16/03/2024
1185	NDA/MAL/HDP/1 1290	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ADCCLENA 10	LENALIDOMIDE	10MG	MYLAN LABORATORIES LTD PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR - 454775; DIST; DHAR; MADHYA PRADESH;	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X14.0 CAPSULE BLISTER	16/03/2024

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1186	NDA/MAL/HDP/1 1291	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ADCCLENA 15	LENALIDOMIDE	15MG	MYLAN LABORATORIES LTD PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR - 454775; DIST; DHAR; MADHYA PRADESH;	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X14.0 CAPSULE BLISTER	16/03/2024
1187	NDA/MAL/HDP/1 1293	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	MOFECON 500	MYCOPHENOLAT E MOFETIL	500MG	CONCORD BIOTECH LIMITED 297-298/2P, AT. VALTHERA, TAL - DHOLKA, DIST - AHMEDABAD - 382225, GUJARAT - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X6.0X10.0 TABLET BLISTER	22/03/2024

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1188	NDA/MAL/HDP/1 1294	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	MOFECON C-250	MYCOPHENOLAT E MOFETIL	250 MG	CONCORD BIOTECH LIMITED 297-298/2P, AT. VALTHERA, TAL - DHOLKA, DIST - AHMEDABAD - 382225, GUJARAT - INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X6.0X10.0 CAPSULE BLISTER	22/03/2024
1189	NDA/MAL/HDP/1 1295	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DYGLI 100	SITAGLIPTIN	100MG	BAFNA PHARMACEUTICALS LIMITED UNIT IINO. 147, MADHAVARAM RED HILLS ROAD, GRANTLYON VILLAGE, VADAKARAI POST, CHENNAI, TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/03/2024

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1190	NDA/MAL/HDP/1 1296	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DYGLI-50	SITAGLIPTIN	50MG	BAFNA PHARMACEUTICALS LIMITED UNIT IINO. 147, MADHAVARAM RED HILLS ROAD, GRANTLYON VILLAGE, VADAKARAI POST, CHENNAI, TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/03/2024
1191	NDA/MAL/HDP/1 1297	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	OLMAT-AM	OLMESARTAN MEDOXOMIL + AMLODIPINE BESILATE	40MG + 5MG	MICRO LABS LIMITED, HOSURNO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/03/2024

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1192	NDA/MAL/HDP/1 1298	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	OLMAT-AM	OLMESARTAN MEDOXOMIL + AMLODIPINE BESILATE	20MG + 5MG	MICRO LABS LIMITED, HOSURNO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/03/2024
1193	NDA/MAL/HDP/1 1299	LABORATĂRIOS VITĂRIA, S.A	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TRAUSAN	CITICOLINE SODIUM	100MG/ML	FAES FARMA SAMAXIMO AGUIRRE 14. 48940 LEIOA ĂE SPAIN	SPAIN	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X50.0 ML BOTTLE	22/03/2024

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1194	NDA/MAL/HDP/1 130	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	KLARO-500	CLARITHROMYCIN TABLETS	500MG	LINCOLN PHARMACEUTICALS LIMITED TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER	01/07/2012
1195	NDA/MAL/HDP/1 1309	LABORATORIOS BASI INDUSTRIA FARMACEUTICA S.A	HEAVENCENT THERAPEUTICS LIMITED	AZITHROMYCIN	AZITHROMYCIN	500MG	GUFIC BIOSCIENCES LIMITED (UNIT 2) SURVEY NO. 171, NATIONAL HIGHWAY NO. 8, NEAR GRID, AT & PO: KABILPORE, NAVSARI - 396424, GUJARAT - INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL	28/03/2024

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1196	NDA/MAL/HDP/1 131	FEROZSONS LABORATORIES LTD	HEALTHCARE LTD.	XAVOR 50	LOSARTAN	50MG	FEROZSONS LABORATORIES LTDAMANGARH- NOWSHERA, (KHYBER ☐ PAKHTOONKHWA), PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2014
1197	NDA/MAL/HDP/1 132	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	M-CALZ	CALCIUM CITRATE +MAGNESIUM HYDROXIDE + ZINC SULPHATE + COLECALCIFEROL	1000MG+100MG+ 4MG+200.I.U	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2012

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1198	NDA/MAL/HDP/1 1329	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GLIMERON 4	GLIMEPIRIDE	4MG	AJANTA PHARMA LIMITED-MIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/05/2024
1199	NDA/MAL/HDP/1 1330	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S LIMITED	PREGASAFE M 75	PREGABALIN + METHYLCOBALA MIN	75 MG + 750 MCG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISION-PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	24/05/2024



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1200	NDA/MAL/HDP/1 1331	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S LIMITED	ALMOTAN 12.5	ALMOTRIPTAN MALATE	12.5 MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISION-PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X6.0X1.0 TABLET BLISTER	22/05/2024
1201	NDA/MAL/HDP/1 1332	WORLD MEDICINE İLAÇ SAN. VE TIC. A.Ş.	GOODMAN INTERNATIONAL LTD	PIRETİKOL	PARACETAMOL	250MG/5ML	WORLD MEDICINE ILAC SAN VE TIC A.S.- 15 TEMMUZ MAHALLESİ, CAMI YOLU CADDESİ, NO: 50 K:4 WM PLAZA, GUNESIL- BAGCILAR/INSTANB UL, TURKEY	TURKEY	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	24/05/2024

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1202	NDA/MAL/HDP/1 1333	MERIDIAN ENTERPRISES PRIVATE LIMITED.	VIDA AFRICA LTD	NASO-FLO	SODIUM CHLORIDE	0.9%W/V	MERIDIAN ENTERPRISES PVT. LTD--PLOT NO. 418, G.I.D.C.,KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	NASAL SYSTEMIC DROPS	1.0X1.0X20.0 ML BOTTLE	22/05/2024
1203	NDA/MAL/HDP/1 1334	MERIDIAN ENTERPRISES PRIVATE LIMITED.	VIDA AFRICA LTD	ZORIN ADULT	XYLOMETAZOLINE HYDROCHLORIDE	0.1% W/V	MERIDIAN ENTERPRISES PVT. LTD--PLOT NO. 418, G.I.D.C.,KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	NASAL SYSTEMIC DROPS	1.0X1.0X10.0 ML BOTTLE	24/05/2024

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1204	NDA/MAL/HDP/1 1335	MERIDIAN ENTERPRISES PRIVATE LIMITED.	VIDA AFRICA LTD	ZORIN PAEDIATRIC	XYLOMETAZOLINE HYDROCHLORIDE	0.05% W/V	MERIDIAN ENTERPRISES PVT. LTD--PLOT NO. 418, G.I.D.C., KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	NASAL SYSTEMIC DROPS	1.0X1.0X10.0 ML BOTTLE	22/05/2024
1205	NDA/MAL/HDP/1 1336	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	TOLSIN 0.4	TAMSULOSIN HYDROCHLORIDE	0.4 MG	MICRO LABS LIMITED, HOSUR-NO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	22/05/2024

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1206	NDA/MAL/HDP/1 1337	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROCID	MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE	(250 MG + 250 MG)/5 ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N- 119, N-113 MIDC TARAPUR BOISAR DIST. THANE 401506 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	24/05/2024
1207	NDA/MAL/HDP/1 1338	MIDASCARE PHARMACEUTICAL S PRIVATE LIMITED,	ABACUS PHARMA (AFRICA) LIMITED	RELISPRAY DR	DICLOFENAC DIETHYLAMINE + METHYL SALICYLATE + LEVOMENTHOL	01.16 % W/W + 10.00 % W/W + 5% W/W	MIDAS CARE PHARMACEUTICALS PVT LTD.-B-16 MIDC, WALUJ AURANGABAD 431136, MAHARASHTRA, INDIA	INDIA	TOPICAL EXTERNAL PRESSURISED AEROSOLS	1.0X55.0 G CANNISTER	24/05/2024

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1208	NDA/MAL/HDP/1 1339	ZUVENTUS HEALTHCARE LIMITED	NORVIK ENTERPRISES LIMITED	CORTIMAX 6 MG	DEFLAZACORT	6 MG	M/S ZUVENTUS HEALTHCARE LIMITED (KAMEREY BHASMEY, ELAKA PAKYONG, RANGPO, EAST SIKKIM, 737132 - INDIA)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X6.0 TABLET BLISTER	11/06/2024
1209	NDA/MAL/HDP/1 134	FEROZSONS LABORATORIES LTD	HEALTHCARE LTD.	XAVOR DIU	LOSARTAN AND HYDROCHLORTHI AZIDE	50/12.5MG	FEROZSONS LABORATORIES LTDAMANGARH- NOWSHERA, (KHYBER ☐ PAKHTOONKHWA), PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2013

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1210	NDA/MAL/HDP/1 1340	ZUVENTUS HEALTHCARE LIMITED	NORVIK ENTERPRISES LIMITED	CORTIMAX 12MG	DEFLAZACORT	12 MG	M/S ZUVENTUS HEALTHCARE LIMITED (KAMEREY BHASMEY, ELAKA PAKYONG, RANGPO, EAST SIKKIM, 737132 - INDIA)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X6.0 TABLET BLISTER	11/06/2024
1211	NDA/MAL/HDP/1 1341	PUNISKA HEALTHCARE PRIVATE LIMITED	NORVIK ENTERPRISES LIMITED	AEPISSTEM	LEVETIRACETAM	100 MG/ML	PUNISKA HEALTHCARE PRIVATE LIMITED (SURVEY NO. 168/1/1, PIPAN, SANAND, DISTRICT - AHMEDABAD 380053, GUJARAT - INDIA)	INDIA	PARENTERAL ORDINARY VIALS	1.0X2.0X5.0 ML VIAL	11/06/2024

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1212	NDA/MAL/HDP/1 1342	SHREEJI CARE LIMITED	SHREEJI CARE LIMITED	DICLOFENAC	DICLOFENAC SODIUM	50MG	GLOBELA PHARMA PVT.LTD.-357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	22/05/2024
1213	NDA/MAL/HDP/1 1343	SQUARE PHARMACEUTICAL S LTD	GAMA PHARMACEUTICAL S (U) LIMITED	ANGILOCK 25	LOSARTAN POTASSIUM	25MG	SQUARE PHARMACEUTICALS LIMITED - DHAKA UNIT (KALIAKOIR GAZIPUR)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/06/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1214	NDA/MAL/HDP/1 1344	WOCKHARDT LTD	STAR PHARMACEUTICAL S LTD	ZEDEX COLD	ACETAMINOPHEN + DEXTROMETHOR PHAN HYDROBROMIDE + PHENYLEPHRINE HYDROCHLORIDE	325 MG + 10 MG + 5 MG	SOFTGEL HEALTHCARE PRIVATE LIMITED (20/1, VANDALUR - KELAMBAKKAM ROAD, PUDUPAKKAM VILLAGE, KANCHEEPURAM DISTRICT, TAMIL NADU - 603 103 - INDIA)	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 TABLET BLISTER	01/06/2024
1215	NDA/MAL/HDP/1 1345	WOCKHARDT LTD	STAR PHARMACEUTICAL S LTD	ZEDEX D	ACETAMINOPHEN + DEXTROMETHOR PHAN HYDROBROMIDE + DOXYLAMINE SUCCINATE	325 MG + 10 MG + 6.25 MG	SOFTGEL HEALTHCARE PRIVATE LIMITED (20/1, VANDALUR - KELAMBAKKAM ROAD, PUDUPAKKAM VILLAGE, KANCHEEPURAM DISTRICT, TAMIL NADU - 603 103 - INDIA)	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X25.0X4.0 CAPSULE BLISTER	01/06/2024



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1216	NDA/MAL/HDP/1 1346	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TORSINEX-10	TORSEMIDE	10MG	MICRO LABS LIMITED, HOSUR (NO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024
1217	NDA/MAL/HDP/1 1347	REDDYS PHARMA LIMITED	REDDYS PHARMA LIMITED	REDCEPHIN SL	CEFTRIAZONE SODIUM + SULBACTAM SODIUM	1000 MG + 500 MG	INJECT CARE PARENTERALS PVT LTD (PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.5G VIAL	01/06/2024

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1218	NDA/MAL/HDP/1 1348	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	OTRINAL	XYLOMETAZOLINE HYDROCHLORIDE	0.1%W/V	ABACUS PARENTERAL DRUGS LIMITED (PLOT 114, BLOCK 191, KINGA)	UGANDA	NASAL TOPICAL DROPS	1.0X1.0X10.0 ML VIAL	01/06/2024
1219	NDA/MAL/HDP/1 1349	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	ZINAVIR 750 MG	CEFUROXIME SODIUM	750MG	INJECT CARE PARENTERALS PVT LTD (PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X750MG VIAL + 1.0X1.0X10.0ML WFI IN LDPE BOTTLE	01/06/2024

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1220	NDA/MAL/HDP/1 1350	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	KLOVINAL	METRONIDAZOLE + CLOTRIMAZOLE + LACTOBACILLUS SPORES	500 MG + 100 MG + 150 MILLIONS	BLISS GVS PHARMA LIMITED (10,11 & 12,DEWAN UDYOG NAGAR,ALIYALI,PALG HAR,MAHARASHTRA 401404,INDIA)	INDIA	VAGINAL TABLETS	1.0X1.0X6.0 PESSARY STRIP	01/06/2024
1221	NDA/MAL/HDP/1 1351	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LOTEL	LOTEPREDNOL ETABONATE	0.5%W/W	AJANTA PHARMA LIMITED-MIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	OPHTHALMIC GELS/SOLS	1.0X1.0X5.0 ML BOTTLE	22/05/2024

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1222	NDA/MAL/HDP/1 1352	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BRINZOX	BRINZOLAMIDE	1.0% W/V	AJANTA PHARMA LIMITED-MIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	OPHTHALMIC SUSPENSIONS	1.0X1.0X5.0 ML BOTTLE	22/05/2024
1223	NDA/MAL/HDP/1 1353	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BETOACT	BEPOTASTINE BESILATE	1.5% W/V	AJANTA PHARMA LIMITED-MIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	22/05/2024

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1224	NDA/MAL/HDP/1 1354	ARCELIA LIFE SCIENCES LTD.	NOVOMED HEALTHCARE LIMITED	TRANEXAMIC ACID TABLETS BP 500 MG	TRANEXAMIC ACID	500MG	ASSOCIATED BIOTECH-VILLAGE: KISHANPURA, GUGUMAJRA ROAD, BADDI THE: NALAGARH HIMACHAL PRADESH 174101 - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	22/05/2024
1225	NDA/MAL/HDP/1 1355	EMCURE PHARMACEUTICAL S LTD -	HARLEYS UGANDA LIMITED	MOLENA-200	MOLNUPIRAVIR	200MG	EMCURE PHARMACEUTICALS LIMITED-PLOT NO. P- 2. ITBT PARK, PHASE II, MIDC, HINJWADI PUNE 411057, MHARASHTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X40.0 CAPSULE CONTAINER	22/05/2024

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1226	NDA/MAL/HDP/1 1357	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	DOVPRELA	PRETOMANID	200MG	MYLAN LABORATORIES LIMITED-NO. H-12 & H-13, MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD - 431 136, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X26.0 TABLET CONTAINER	24/05/2024
1227	NDA/MAL/HDP/1 1358	BHARAT SERUMS & VACCINES LTD.	ABACUS PHARMA (AFRICA) LIMITED	EVAFACT	DIENOGEST	2MG	NAARI PHARMA PRIVATE LIMITED- PLOT NO. 14-16 &55- 57, SECTOR-5, IIE, PANTNAGAR, RUDRAPUR-263153, DIST. U.S. NAGAR, UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	24/05/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1228	NDA/MAL/HDP/1 1359	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	HALOSCOT 5	HALOPERIDOL	5MG	M/S SCOTT-EDIL PHARMACIA LTD -56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	22/05/2024
1229	NDA/MAL/HDP/1 136	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOSCAB APPLICATION	BENZYL BENZOATE	25%W/W	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL EMULSIONS	1.0X1.0X100.0 ML BOTTLE	01/07/2013

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1230	NDA/MAL/HDP/1 1360	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	HALOSCOT 10	HALOPERIDOL	10MG	M/S SCOTT-EDIL PHARMACIA LTD -56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	22/05/2024
1231	NDA/MAL/HDP/1 1361	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ETORIB 90	ETORICOXIB	90MG	PINNACLE LIFE SCIENCE PVT LTD- KHASRA NO. 1328- 1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	24/05/2024



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1232	NDA/MAL/HDP/1 1362	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ETORIB 120	ETORICOXIB	120MG	PINNACLE LIFE SCIENCE PVT LTD- KHASRA NO. 1328- 1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	24/05/2024
1233	NDA/MAL/HDP/1 1363	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ETORIB 60	ETORICOXIB	60MG	PINNACLE LIFE SCIENCE PVT LTD- KHASRA NO. 1328- 1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	24/05/2024

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1234	NDA/MAL/HDP/1 1364	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	DESLOSCOT-5	DESLORATADINE	5MG	M/S SCOTT-EDIL PHARMACIA LTD -56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	24/05/2024
1235	NDA/MAL/HDP/1 1365	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	EFAVIRENZ, LAMIVUDINE AND TENOFIVIR DISOPROXIL FUMARATE 400/300/300 MG TABLET	EFAVIRENZ + LAMIVUDINE + TENOFIVIR DISOPROXIL FUMARATE	400MG + 300MG + 300MG	CIPLA LIMITED-PLOT NO. A-42 (UNIT-II), MIDC, PATALGANGA - 410220, DISTRICT: RAIGAD, MAHARASHTRA - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER,1.0X90. 0 TABLET CONTAINER	24/05/2024

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1236	NDA/MAL/HDP/1 1366	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	SCOZINC-20 DT	ZINC SULPHATE MONOHYDRATE	20MG	M/S SCOTT-EDIL PHARMACIA LTD -56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	24/05/2024
1237	NDA/MAL/HDP/1 1367	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	ACLOHERP 200	ACICLOVIR	200 MG	AUROBINDO PHARMA LIMITED, UNIT - XV-PLOT NO. 17A, E BONANGI (V), PARAWADA (M), VISAKHAPATNAM DISTRICT, ANDHRA PRADESH. PIN: 531021	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X5.0 TABLET BLISTER	22/05/2024

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1238	NDA/MAL/HDP/1 1368	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ACLOHERP 400	ACICLOVIR	400MG	AUROBINDO PHARMA LIMITED, UNIT - XV-PLOT NO. 17A, E BONANGI (V), PARAWADA (M), VISAKHAPATNAM DISTRICT, ANDHRA PRADESH. PIN: 531021	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X5.0 TABLET BLISTER	22/05/2024
1239	NDA/MAL/HDP/1 1369	EUGIA PHARMA SPECIALITIES LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TAMFONY 20	TAMOXIFEN CITRATE	20MG	EUGIA PHARMA SPECIALITIES LIMITED-SURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/05/2024

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1240	NDA/MAL/HDP/1 1370	GAMA PHARMACEUTICAL S (U) LIMITED	GAMA PHARMACEUTICAL S (U) LIMITED	GYNO-DAKTAZOL OVULES	MICONAZOLE NITRATE	400MG	JERUSALEM PHARMACEUTICALS CO. LTD-AL-BIREH RAMALLAH INDUSTRIAL ZONE, AL-BIREH NABLUS ROAD, P.O. BOX: 3570 PALESTINE	PALESTINE	VAGINAL SUPPOSITORIES	1.0X1.0X3.0 OVULE BLISTER	22/05/2024
1241	NDA/MAL/HDP/1 1371	NVS KENYA LTD	SURGIPHARM (U) LIMITED	PAGENAX 120 MG/ML	BROLUCIZUMAB	120 MG/ML	NOVARTIS PHARMA STEIN AG STERILE OPERATIONS SOLID OPERATIONS- NOVARTIS PHARMA STEIN AG SCHAFFHAUSERSTRA SSE, 4332 STEIN - SWITZERLAND NOVARTIS PHARMA AG-LICHTSTRASSE 35 - 4056 BASEL, SWITZERLAND	SWITZERLAND	PARENTERAL ORDINARY VIALS	1.0X1.0X1.0 ML VIAL + 1*1 FILTER NEEDLE	22/05/2024

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1242	NDA/MAL/HDP/1 1372	BIOSIMILARS NEWCO LIMITED	KIMSY MEDS LTD	OGIVRI	TRASTUZUMAB	150MG/VIAL	BIOCON BIOLOGICS LIMITED-SPECIAL ECONOMIC ZONE, PLOT NO. 2, 3, 4 & 5, PHASE - IV, BOMMASANDRA- JIGANI LINK ROAD, BOMMASANDRA POST, BENGALURU - 560099, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X15.0 ML VIAL	22/05/2024
1243	NDA/MAL/HDP/1 1373	HEALTH LINK PHARMACY LTD	HEALTH LINK PHARMACY LIMITED	ROYOMOL 500	PARACETAMOL	500 MG	INNOVA CAPTAB PVT. LTD-1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	22/05/2024

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1244	NDA/MAL/HDP/1 1376	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	UNIFEN 10	BACLOFEN	10 MG	UNICHEM LABORATORIES LTD- UNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/05/2024
1245	NDA/MAL/HDP/1 1377	CENTURION LABORATORIES PVT. LTD.	SHREEJI PHARMACEUTICAL S LIMITED	FERROUS SULFATE TABLETS BP 200 MG	FERROUS SULFATE	200MG	CENTURION LABORATORIES PVT LTD (PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA)	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/06/2024

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1246	NDA/MAL/HDP/1 1378	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	UNIFEN 20	BACLOFEN	20MG	UNICHEM LABORATORIES LTD- UNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/05/2024
1247	NDA/MAL/HDP/1 1379	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	DARUNAVIR TABLETS 600 MG	DARUNAVIR	600MG	LAURUS LABS LTD (UNIT 2) (PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH,)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0.10.0 TABLET BLISTER	01/06/2024



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1248	NDA/MAL/HDP/1 138	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGO-CALAMINE	CALAMINE	15%W/W	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	TOPICAL EXTERNAL LOTIONS	1.0X1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2013
1249	NDA/MAL/HDP/1 1381	LES LABORATOIRES SERVIER	HARLEYS UGANDA LIMITED	DAFLON 500MG	DIOSMIN 90% + HESPERIDIN 10%	500MG	SERVIER EGYPT INDUSTRIES LIMITED (SEI) (PLOT NO. 37 1ST INDUSTRIAL ZONE. PLOT NO. 184 - 8 2ND INDUSTRIAL ZONE " 6TH OCTOBER CITY GIZA - EGYPT)	EGYPT	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER	01/06/2024

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1250	NDA/MAL/HDP/1 1382	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	GLIMERON 1	GLIMEPIRIDE	1MG	AJANTA PHARMA LIMITED (MIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM))	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024
1251	NDA/MAL/HDP/1 1383	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	METAPIR 100	TOPIRAMATE	100MG	MICRO LABS LIMITED, HOSUR (NO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024

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1252	NDA/MAL/HDP/1 1385	BETA DRUGS LTD	PHARMACINE UGANDA LIMITED	ADCARB 450MG/45ML	CARBOPLATIN	10 MG/ML	BETA DRUGS LIMITED-KHURUNI- LOHIMAJRA ROAD THE: BADDI, DISTT: SOLAN (H.P) - INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X45.0 ML VIAL	22/05/2024
1253	NDA/MAL/HDP/1 1386	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	METAPIR - 50	TOPIRAMATE	50MG	MICRO LABS LIMITED, HOSUR (NO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024

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1254	NDA/MAL/HDP/1 1389	OMNICALS PHARMA PVT. LTD	GITTOES PHARMACEUTICAL S LIMITED	OMIZINC 20	ZINC SULFATE MONOHYDRATE	20MG	THE ACME LABORATORIES LIMITED-DHULIVITA, DHAMRAI, DHAKA - 1350, BANGLADESH	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X5.0X10 .0 TABLET BLISTER	22/05/2024
1255	NDA/MAL/HDP/1 139	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOVATE	BETAMETHASONE	0.1%W/W	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2012

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1256	NDA/MAL/HDP/1 1390	BHARAT SERUMS & VACCINES LTD.	ABACUS PHARMA (AFRICA) LIMITED	AMPHONEX	AMPHOTERICIN B	50MG	BHARAT SERUM AND VACCINES LIMITED (PLOT NO. K-27 ADDITIONAL M.I.D.C INDIA)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X50.0 MG VIAL	01/06/2024
1257	NDA/MAL/HDP/1 1392	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	TELMICLAR 80	TELMISARTAN	80MG	AJANTA PHARMA LIMITED (MIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM))	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024

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1258	NDA/MAL/HDP/1 1393	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	GLIMERON 3	GLIMEPIRIDE	3MG	AJANTA PHARMA LIMITED (MIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM))	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024
1259	NDA/MAL/HDP/1 1395	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	GLIMERON 2	GLIMEPIRIDE	2MG	AJANTA PHARMA LIMITED (MIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM))	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024

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1260	NDA/MAL/HDP/1 1396	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ESMOLOC 40	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40MG	AJANTA PHARMA LIMITED (PLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT- 392130)	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024
1261	NDA/MAL/HDP/1 1398	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ROSUCHOL -10	ROSUVASTATIN	10MG	AJANTA PHARMA LIMITED (AJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024

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1262	NDA/MAL/HDP/1 1399	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DOLOGAN DENK	PARACETAMOL + IBUPROFEN + CAFFEINE	250 MG + 200 MG + 50 MG	ARTESAN PHARMA GMBH & CO. KG- WENDLANDSTR.1, 29439, LUCHOW	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	24/05/2024
1263	NDA/MAL/HDP/1 140	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOVATE-N	BETAMETHASONE +NEOMYCIN SULPHATE	0.1%W/W+0.5%W/ W	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2013



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1264	NDA/MAL/HDP/1 1400	ZIM LABORATORIES LTD	REDDYS PHARMA LIMITED	CLARZIM 500	CLARITHROMYCIN	500MG	ZIM LABORATORIES LIMITED (B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/06/2024
1265	NDA/MAL/HDP/1 1401	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	ARTESUNATE AMODIAQUINE BILAYER TABLETS 50MG/135MG			MICRO LABS LTD,- PLOT S-155 TO S- 159, VERNA IND. ESTATE, PHASE III, VERNA-GOA-403722	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X25.0X3.0 TABLET BLISTER	22/05/2024

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1266	NDA/MAL/HDP/1 1402	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	ARTESUNATE AMODIAQUINE BILAYER TABLETS 25MG/67.25MG	ARTESUNATE + AMODIAQUINE HYDROCHLORIDE	25MG/67.25MG	MICRO LABS LTD,- PLOT S-155 TO S- 159, VERNA IND. ESTATE, PHASE III, VERNA-GOA-403722	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X25.0X3.0 TABLET BLISTER	22/05/2024
1267	NDA/MAL/HDP/1 1404	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LASTAVIN AM 5/160	AMLODIPINE + VALSARTAN	5 MG + 160 MG	AJANTA PHARMA LIMITED (AJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024

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1268	NDA/MAL/HDP/1 1405	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	ARTESUNATE AMODIAQUINE BILAYER TABLETS 100MG/270MG	ARTESUNATE + AMODIAQUINE HYDROCHLORIDE	100MG + 270MG	MICRO LABS LTD,- PLOT S-155 TO S- 159, VERNA IND. ESTATE, PHASE III, VERNA-GOA-403722	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X25.0X3.0 TABLET BLISTER	22/05/2024
1269	NDA/MAL/HDP/1 1406	MEDICAL UNION PHARMACEUTICAL S.	KARURI PHARMACEUTICAL S LTD.	INSULINAGYPT 70/30 100 IU/ML INJECTION 10 ML	INSULIN HUMAN (RECOMBINANT DNA ORIGIN)	100 IU/ML (70% ISOPHANE INSULINE + 30% REGUILAR INSULIN)	MEDICAL UNION PHARMACEUTICALS, 6TH OCTOBER SITE (2ND INDUSTRIAL ZONE, PLOT NO. 1, STREET NO. 22, GIZA GOVERNORATE - EGYPT)	EGYPT	PARENTERAL ORDINARY VIALS	1.0X1.0X10.0ML VIAL	21/06/2024

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1270	NDA/MAL/HDP/1 1407	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICAL S LIMITED	ITRAPINN	ITRACONALE	100 MG	PINNACLE LIFE SCIENCE PVT LTD (KHASRA NO. 1328- 1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP))	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X4.0 CAPSULE BLISTER	01/06/2024
1271	NDA/MAL/HDP/1 1408	MEDOCHEMIE LTD.	LABOREX UGANDA LIMITED	CELMANTIN 20	ROSUVASTATIN CALCIUM	20MG	MEDOCHEMIE (FACTORY AZ). (2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL)	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024

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1272	NDA/MAL/HDP/1 1409	ZOTA HEALTHCARE LTD.	REDDYS PHARMA LIMITED	ATRONA-10	ATORVASTATIN CALCIUM	10MG	ZOTA HEALTHCARE LIMITED (PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY SATTION, SACHIN - 394230, SURAT, GUJARAT)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.X3.0X10.0 TABLET BLISTER	01/06/2024
1273	NDA/MAL/HDP/1 1410	EMCURE PHARMACEUTICAL S LTD -	HARLEYS UGANDA LIMITED	SEVCAR 400	SEVELAMER CARBONATE	400MG	EMCURE PHARMACEUTICALS LIMITED, (LANE NO.3, PHASE II SIDCO INDUSTRIAL COMPLEX BARI, BRAHMANA JAMMU (J&K) 181133 - INDIA)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET Blister	01/06/2024

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1274	NDA/MAL/HDP/1411	EMCURE PHARMACEUTICALS LTD -	HARLEYS UGANDA LIMITED	SEVCAR 800	SEVELAMER CARBONATE	800MG	EMCURE PHARMACEUTICALS LIMITED, (LANE NO.3, PHASE II SIDCO INDUSTRIAL COMPLEX BARI, BRAHMANA JAMMU (J&K) 181133 - INDIA)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/06/2024
1275	NDA/MAL/HDP/1412	LG CHEM, LTD.	MM PARTNERS LOGISTICS LIMITED	EUPOLIO	INACTIVATED POLIOVIRUS TYPE 1 (SABIN STRAIN) + INACTIVATED POLIOVIRUS TYPE 2 (SABIN STRAIN) + INACTIVATED POLIOVIRUS TYPE 3 (SABIN STRAIN)	5 D-ANTIGEN UNITS + 8 D-ANTIGEN UNITS + 16 D-ANTIGEN UNITS	LG CHEM LIMITED, OSONG PLANT- 151, OSONGSAENGMYEONG-RO, OSONG-EUP, HEUNGDEOK-GU, CHEONGJU-SI, HUNGCHONGBUK-DO (POSTAL CODE: 28162) - REPUBLIC OF KOREA	NORTH KOREA	PARENTERAL ORDINARY VIALS	1.0X10.0X2.5 ML VIAL, 1.0X10.0X0.5 ML VIAL	24/05/2024

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1276	NDA/MAL/HDP/1 1413	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	P-ALAXIN DISPERSIBLE 40/320	DIHYDROARTEMI SININ + PIPERAQUINE PHOSPHATE	40 MG + 320 MG	BLISS GVS PHARMA LTD,-PLOT 10, SURVEY NO. 38/1, DEWAN UDYONG NAGAR ALIYALI VILLAGE TAL PALGHAR DIST. THANE - INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X3.0 TABLET BLISTER	24/05/2024
1277	NDA/MAL/HDP/1 1414	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	NEBSTYLE 5	NEBIVOLOL HYDROCHLORIDE	5MG	AUROBINDO PHARMA LIMITED UNIT 3-PLOT NO. 313, 314, BACHUPALLY, RR DIST. 500090	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/05/2024

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1278	NDA/MAL/HDP/1 1415	NEXT WAVE (INDIA)	REVITAL HEALTH CARE LTD	MUPORIG	MUPIROCIN	2% W/W	NEXT WAVE- RAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X10.0 G TUBE	22/05/2024
1279	NDA/MAL/HDP/1 1416	BIODEAL LABORATORIES LTD PLOT NO.123	ABACUS PHARMA (AFRICA) LIMITED	PODOSAL PAINT	PODOPHYLLUM RESIN	20%W/V	BIODEAL LABOARATORIES LTD (123, LUNGA LUNGA ROAD, INDUSTRIAL AREA, NAIROBI)	KENYA	TOPICAL EXTERNAL LIQUIDS	1.0X1.0X10.0 ML Vial	12/06/2024



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1280	NDA/MAL/HDP/1 1417	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYTEL 80	TELMISARTAN	80MG	EAST AFRICAN (INDIA) OVERSEAS (PLOT NO.1, PHARMACITY SELAQUI DEHRADUN “ 248011 (U.K), INDIA)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024
1281	NDA/MAL/HDP/1 1418	FAROMED LIFSCIENCES LLP	METRO PHARMACEUTICAL S LIMITED	ACORA	TICAGRELOR	90 MG	ADVANCED CHEMICAL INDUSTRIES (ACI) LIMITED (7, HAJEEGONJ ROAD, GOODNYL, NARAYANGONJ - 1400)	BANGLADESH	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0TABLE T BLISTER	21/05/2024

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1282	NDA/MAL/HDP/1419	FAROMED LIFSCIENCES LLP	METRO PHARMACEUTICALS LIMITED	APTIN	VILDAGLIPTIN	50MG	ADVANCED CHEMICAL INDUSTRIES (ACI) LIMITED (7, HAJEENONJ ROAD, GOODNYL, NARAYANGONJ - 1400)	BANGLADESH	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/05/2024
1283	NDA/MAL/HDP/142	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CANDIZOL	CLOTRIMAZOLE	1%W/W	AGOG PHARMA LTD PLOT NO.33, SECTOR II, VASAI, TALUKA INDL CO-OP ESTATE LTD, GAURAI PADA, VASAI(E) DIST. T HANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2013

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1284	NDA/MAL/HDP/1 1420	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ADERAN HTZ 8/12.5	CANDESARTAN CILEXETIL + HYDROCHLOROT HIAZIDE	8 MG + 12.5 MG	AJANTA PHARMA LIMITED (MIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM))	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024
1285	NDA/MAL/HDP/1 1421	INFUGEN PHARMA PVT. LTD.	TATA UGANDA LIMITED	INFUSUNATE	ARTESUNATE	60 MG /VIAL	SANJAR PHARMACEUTICALS LIMITED-SURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X60.0 MG VIAL + 5ML CLEAR GLASS AMPOULE OF 0.9%W/V SODIUM CHLORIDE INJECTION BP + 1ML CLEAR GLASS AMPOULE OF 5.0%W/V SODIUM BICARBONATE INJECTION	22/05/2024

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1286	NDA/MAL/HDP/1 1422	BIOMATRIX HEALTHCARE PVT LTD.-	MEDIWORLD PHARMA AFRICA LTD	CLEOBACT 300	CLINDAMYCIN HYDROCHLORIDE	300 MG	BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	22/05/2024
1287	NDA/MAL/HDP/1 1423	S KANT HEALTHCARE LTD -	ABACUS PHARMA (AFRICA) LIMITED	SKLOBETA	CLOBETASOL PROPIONATE	0.05% W/W	S KANT HEALTHCARE LIMITED (1802 - 1805, G.I.D.C., PHASE III, VAPI - 396195 GUJARAT, INDIA.)	INDIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 TUBE	01/06/2024

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1288	NDA/MAL/HDP/1 1424	SERUM INSTITUTE OF INDIA PVT LTD	NORVIK ENTERPRISES LIMITED	ROTASIL - LIQUID	LIVE ATTENUATED BOVINE - HUMAN ROTAVIRUS REASSORTANT STRATIN [G1, G2, G3, G4 AND G9]	≥ 10 <sup>5.6</sup> FFU /SEROTYPE PER DOSE (2.0 ML)	SERUM INSTITUTE OF INDIA LTD -.PLOT NO. 212/2 HADAPSAR, OFF SOLI POONAWALLA ROAD, PUNE 411028 - INDIA	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X50.0X4.0 ML VIAL	22/05/2024
1289	NDA/MAL/HDP/1 1425	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	SACUVAN 24/26	SACUBITRIL + VALSARTAN	24 MG + 26 MG	HETERO LABS LIMITED (UNIT III)... (22-110, I.D.A, JEEDIMETLA, HYDERABAD-500 055, ANDHRA PRADESH, INDIA)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024

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1290	NDA/MAL/HDP/1 1426	GLAXOSMITHKLINE BIOLOGICALS S.A.	UNITED HEALTHCARE DISTRIBUTORS LTD	MOSQUIRIX	RTS,S (PLASMODIUM FALCIPARUM AND HEPATITIS B ANTIGEN )		GLAXOSMITHKLINE BIOLOGICALS S.A- PARC DE LA NOIRE EPINE, AVENUE FLEMING 20-1300 WAVRE - BELGIUM GLAXOSMITHKLINE BIOLOGICALS-637 RUE DES AULMOIS, 59230 SAINT- AMAND-LES-EAUX	BELGIUM	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X2.0 DOSE VIAL + 1*50*1ML GLASS VIAL OF DILUENT	24/05/2024
1291	NDA/MAL/HDP/1 1427	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	ABACAVIR, DOLUTEGRAVIR AND LAMIVUDINE TABLETS 600MG/50MG/30 0MG	ABACAVIR SULFATE + DOLUTEGRAVIR SODIUM + LAMIVUDINE	600MG + 50MG + 300MG	HETERO LABS LIMITED (UNIT V) (SY. NO. 439, 440, 441 & 458, POLEPALLY VILLAGE, JADCHERLA MANDAL MAHABOBNAGAR DISTRICT, PIN-509 301, TELANGANA, INDIA)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	01/06/2024

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1292	NDA/MAL/HDP/1 1428	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	SACUVAN 49/51	SACUBITRIL + VALSARTAN	49 MG + 51 MG	HETERO LABS LIMITED (UNIT III)... (22-110, I.D.A, JEEDIMETLA, HYDERABAD-500 055, ANDHRA PRADESH, INDIA)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024
1293	NDA/MAL/HDP/1 1429	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	GLINSIP 25	SITAGLIPTIN PHOSPHATE	25MG	M/S. ANNORA PHARMA PRIVATE LIMITED (SY. NO. 261, ANNARAM VILLAGE, GUMMADIDALA MANDAL, SANGAREDDY DISTRICT, TELENGANA STATE Â€" 502313, INDIA)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER	01/06/2024

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1294	NDA/MAL/HDP/1 143	LINCOLN P'CAL LTD	METRO PHARMACEUTICAL S LIMITED	LOSA-H	LOSARTAN + HYDROCHLOROT HIAZIDE	50MG + 12.5MG	LINCOLN PHARMACEUTICALS LIMITEDTRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2012
1295	NDA/MAL/HDP/1 1430	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	GLINSIP 50	SITAGLIPTIN PHOSPHATE	50 MG	M/S. ANNORA PHARMA PRIVATE LIMITED (SY. NO. 261, ANNARAM VILLAGE, GUMMADIDALA MANDAL, SANGAREDDY DISTRICT, TELENGANA STATE Â€" 502313, INDIA)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER	01/06/2024



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1296	NDA/MAL/HDP/1 1432	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CACHMONT-LC TABLET	LEVOCETIRIZINE DIHYDROCHLORID E + MONTELUKAST SODIUM	5 MG + 10 MG	CACHET PHARMACEUTICALS PVT LTD . (VILLAGE THANA, BADDI, TEHSIL-NALAGARH DIST. SOLAN, HIMACHAL PRADESH- 173205)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET Blister	01/06/2024
1297	NDA/MAL/HDP/1 1434	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CACHMONT-LC SYRUP	LEVOCETIRIZINE DIHYDROCHLORID E + MONTELUKAST SODIUM	(2.5 MG + 4 MG )/5 ML	CACHET PHARMACEUTICALS PVT LTD . (VILLAGE THANA, BADDI, TEHSIL-NALAGARH DIST. SOLAN, HIMACHAL PRADESH- 173205)	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60 ML BOTTLE	01/06/2024

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1298	NDA/MAL/HDP/1 1436	SYNOKEM PHARMACEUTICAL S LIMITED	BIOGEN PHARMA LIMITED	LEVOCETRI	LEVOCETIRIZINE DIHYDROCHLORID E	5 MG	SYNOKEM PHARMACEUTICALS LIMITED (SYNOKEM PHARMACEUTICALS LIMITED, PLOT NO. 35-36, SECTOR-6A, IIE, (SIDCUL), RANIPUR (BHEL), HARIDWAR, 249403, (UTTARAKHAND) - INDIA)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS		01/06/2024
1299	NDA/MAL/HDP/1 1437	NEXT WAVE (INDIA)	DAVIMED PHARMA LIMITED	DAVIGRA-50	SILDENAFIL CITRATE	50 MG	NEXT WAVE (RAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P))	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/06/2024

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1300	NDA/MAL/HDP/1 1438	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	DOLOFLAM	ETOFENAMATE	10% W/W	MICRO LABS LIMITED, HOSUR (NO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA)	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X50.0 G TUBE	01/06/2024
1301	NDA/MAL/HDP/1 1439	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	ZOTAMET 500	METFORMIN HYDROCHLORIDE	500MG	ZOTA HEALTHCARE LIMITED (PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY SATTION, SACHIN - 394230, SURAT, GUJARAT)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.X10.0X10.0 TABLET BLISTER	01/06/2024

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1302	NDA/MAL/HDP/1 1440	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	URYDOS-4	SILODOSIN	4 MG	MICRO LABS LIMITED, HOSUR (NO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA)	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X1.0X10.0 TABLET BLISTER	01/06/2024
1303	NDA/MAL/HDP/1 1441	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	URYDOS-8	SILODOSIN	8 MG	MICRO LABS LIMITED, HOSUR (NO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA)	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X1.0X10.0 TABLET BLISTER	01/06/2024

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1304	NDA/MAL/HDP/1 1442	HILTON PHARMA (PVT) LTD	LIFEWAY PHARMACEUTICAL S LTD	SITAGLU 50 MG	SITAGLIPTIN PHOSPHATE	50 MG	HILTON PHARMACEUTICALS (PVT) LIMITED (PLOT NO. 13-14, SECTOR 15, KORANGI INDUSTRIAL AREA, KARACHI-74900)	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/06/2024
1305	NDA/MAL/HDP/1 1443	AL ANDALOUS FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CARDIOTIMIDE 5 MG	TORSEMIDE	5MG	AL ANDALOUS FOR PHARMACEUTICAL INDUSTRIES (PART NO. 7/6 - 6TH INDUSTRIAL AREA - 6TH OCTOBER CITY - GIZA)	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/06/2024

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1306	NDA/MAL/HDP/1 1444	HILTON PHARMA (PVT) LTD	LIFEWAY PHARMACEUTICAL S LTD	SITAGLU 100 MG	SITAGLIPTIN PHOSPHATE	100 MG	HILTON PHARMACEUTICALS (PVT) LIMITED (PLOT NO. 13-14, SECTOR 15, KORANGI INDUSTRIAL AREA, KARACHI-74900)	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/06/2024
1307	NDA/MAL/HDP/1 1445	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	DICLOTRIX	DICLOFENAC SODIUM	50 MG	BIOMATRIX HEALTHCARE PRIVATE LIMITED (SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT)	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/06/2024

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1308	NDA/MAL/HDP/1 1446	INJECTCARE PARENTERALS PVT. LTD	REDDYS PHARMA LIMITED	FORCIL	BENZYL PENICILLIN SODIUM	1,000,000 UNITS (600MG) PER VIAL	INJECT CARE PARENTERALS PVT LTD (PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X60.0ML CONTAINER	01/06/2024
1309	NDA/MAL/HDP/1 1447	FAROMED LIFSCIENCES LLP	METRO PHARMACEUTICAL S LIMITED	SITAP 100	SITAGLIPTIN PHOSPHATE MONOHYDRATE	100MG	ADVANCED CHEMICAL INDUSTRIES (ACI) LIMITED (7, HAJEEGONJ ROAD, GOODNYL, NARAYANGONJ - 1400)	BANGLADESH	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET Blister	21/05/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1310	NDA/MAL/HDP/1 1448	SYNOKEM PHARMACEUTICAL S LIMITED	ROYAL PHARMA 2011 LIMITED	IBURO-200	IBUPROFEN	200MG	SYNOKEM PHARMACEUTICALS LIMITED (SYNOKEM PHARMACEUTICALS LIMITED, PLOT NO. 35-36, SECTOR-6A, IIE, (SIDCUL), RANIPUR (BHEL), HARIDWAR, 249403, (UTTARAKHAND) - INDIA)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/06/2024
1311	NDA/MAL/HDP/1 1449	PT SANBE FARMA	MEDVIN PHARMA LIMITED	PUMPISEL	PANTOPRAZOLE SODIUM	40 MG/VIAL	PT SANBE FARMA UNIT 3. (JL INDUSTRI CIMAREME NO.8 PADALARANG 40533 BANDUNG)	INDONESIA	PARENTERAL ORDINARY DRY VIALS	1.0X40.0 MG VIAL	01/06/2024



## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1312	NDA/MAL/HDP/1 145	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	HILAC	LACTULOSE	68%W/V	HILTON PHARMA (PVT) LTD PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2005
1313	NDA/MAL/HDP/1 1450	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	DICORATE ER 250	DIVALPROEX SODIUM	250MG	SUN PHARMA LABORATORIES LIMITED (6-9, EPIP, KARTHOLI, BARI BRAHMANA, JAMMU - 181133 (JAMMU AND KASHMIR) - INDIA)	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/06/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1314	NDA/MAL/HDP/1 1454	COSMOS LTD.	ASTRA PHARMA (U) LIMITED	HARTEZE 10	RIVAROXABAN	10MG	COSMOS LTD..- RANGWE ROAD OFF, LUNA LUNGA ROAD, INDUSTRIAL AREA - NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	31/05/2024
1315	NDA/MAL/HDP/1 1455	COSMOS LTD.	ASTRA PHARMA (U) LIMITED	HARTEZE 15	RIVAROXABAN	15MG	COSMOS LTD..- RANGWE ROAD OFF, LUNA LUNGA ROAD, INDUSTRIAL AREA - NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	31/05/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1316	NDA/MAL/HDP/1 1456	COSMOS LTD.	ASTRA PHARMA (U) LIMITED	HARTEZE 20	RIVAROXABAN	20MG	COSMOS LTD.- RANGWE ROAD OFF, LUNA LUNGA ROAD, INDUSTRIAL AREA - NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	31/05/2024
1317	NDA/MAL/HDP/1 1457	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICAL S LIMITED	ROXPINN 20	RIVAROXABAN	20 MG	PINNACLE LIFE SCIENCE PVT LTD (KHASRA NO. 1328 - 1330, VILLAGE MANPURA. TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH, 174101 - INDIA)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1318	NDA/MAL/HDP/1 1458	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICAL S LIMITED	PIXAB 5	APIXABAN	5 MG	PINNACLE LIFE SCIENCE PVT LTD (KHASRA NO. 1328 - 1330, VILLAGE MANPURA. TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH, 174101 - INDIA)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024
1319	NDA/MAL/HDP/1 1459	LINCOLN PHARMACEUTICAL S LIMITED	METRO PHARMACEUTICAL S LIMITED	LIDOCAINE & ADRENALINE INJECTION BP	LIDOCAINE HYDROCHLORIDE + ADRENALINE ACID TARTRATE	(21.33 MG + 0.0125 MG)/ML	LINCOLN PARENTERAL LTD . (11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ 382721 TA: KALOL DIST. GANDHINAGAR GUJARAT)	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X30.0ML, 1.0X1.0X50.0ML VIAL	01/06/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1320	NDA/MAL/HDP/1 1460	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ANASOMA 1	ANASTROZOLE	1MG	EUGIA PHARMA SPECIALITIES LIMITED (SURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024
1321	NDA/MAL/HDP/1 1461	BIOMATRIX HEALTHCARE PVT LTD.-	MEDIWORLD PHARMA AFRICA LTD	LOPAGYL	LOPERAMIDE HYDROCHLORIDE	2MG	BIOMATRIX HEALTHCARE PRIVATE LIMITED (SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT)	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0CAPS ULE BLISTER	01/06/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1322	NDA/MAL/HDP/1 1462	LINCOLN PHARMACEUTICAL S LTD.	METRO PHARMACEUTICAL S LIMITED	LINEZOD	LINEZOLID	600 MG	LINCOLN PARENTERAL LTD . (11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ 382721 TA: KALOL DIST. GANDHINAGAR GUJARAT)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/06/2024
1323	NDA/MAL/HDP/1 1463	LINCOLN PHARMACEUTICAL S LTD.	METRO PHARMACEUTICAL S LIMITED	MAJEROL	CARBAMAZEPINE	200 MG	LINCOLN PARENTERAL LTD . (11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ 382721 TA: KALOL DIST. GANDHINAGAR GUJARAT)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/06/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1324	NDA/MAL/HDP/1 1464	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ASTRA PHARMA (U) LIMITED	CACHMAX- DS	CEFIXIME TRIHYDRATE	100MG/5ML	INNOVA CAPTAB PVT. LTD (1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.))	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X60.0ML BOTTLE, 1.0X1.0X100.0ML BOTTLE	01/06/2024
1325	NDA/MAL/HDP/1 1465	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICAL S LIMITED	ROXPINN 10	RIVAROXABAN	10 MG	PINNACLE LIFE SCIENCE PVT LTD (KHASRA NO. 1328 - 1330, VILLAGE MANPURA. TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH, 174101 - INDIA)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1326	NDA/MAL/HDP/1 1466	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ASTRA PHARMA (U) LIMITED	LYSOFLAM	PARACETAMOL + DICLOFENAC POTASSIUM + SERRATIOPEPTID ASE	500 MG + 50 MG + 15 MG	CACHET PHARMACEUTICALS PVT LTD . (VILLAGE THANA, BADDI, TEHSIL-NALAGARH DIST. SOLAN, HIMACHAL PRADESH- 173205)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/06/2024
1327	NDA/MAL/HDP/1 1467	ZUVENTUS HEALTHCARE LIMITED	NORVIK ENTERPRISES LIMITED	GUTCLEAR SYRUP	LACTITOL MONOHYDRATE	10 G/15 ML	PINNACLE LIFE SCIENCE PVT LTD (KHASRA NO. 1328- 1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP))	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/06/2024



## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1328	NDA/MAL/HDP/1 1468	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	NAT D 5000 IU	CHOLECALCIFERO L	5000 IU	MEGA LIFESCIENCES PUBLIC CO. LTD (PLANT 1; 384 MOO 4, SOI 6, BANGPOO INDUSTRIAL ESTATE, PATTANA 3 ROAD, PHRAEKSA, MUEANG, SAMUTPRAKARN 10280 THAILAND)	THAILAND	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X30 CAPSULE CONTAINER, 1.0X60.0 CAPSULE CONTAINER	01/06/2024
1329	NDA/MAL/HDP/1 1470	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	LEDOBOOK 7.5	LENALIDOMIDE	7.5 MG	EUGIA PHARMA SPECIALITIES LIMITED (SURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101)	INDIA	ORAL SOLID RETARD OTHER CAPSULES	1.0X3.0X7.0 CAPSULE BLISTER	01/06/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1330	NDA/MAL/HDP/1 1471	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	LEDOBOOK 20	LENALIDOMIDE	20 MG	EUGIA PHARMA SPECIALITIES LIMITED (SURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101)	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X7.0 CAPSULE BLISTER	01/06/2024
1331	NDA/MAL/HDP/1 1473	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	COROLOR	TICAGRELOR	90 MG	MICRO LABS LIMITED , (92, SIPCOT, HOSUR 635126)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024

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1332	NDA/MAL/HDP/1 1475	EMCURE PHARMACEUTICAL S LTD -	HARLEYS UGANDA LIMITED	JUSTEEZ 50	VILDAGLIPTIN	50MG	EMCURE PHARMACEUTICALS LIMITED, (LANE NO.3, PHASE II SIDCO INDUSTRIAL COMPLEX BARI, BRAHMANA JAMMU (J&K) 181133 - INDIA)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X15.0 TABLET BLISTER	01/06/2024
1333	NDA/MAL/HDP/1 1476	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TELFOCUS -H- 80/12.5	TELMISARTAN + HYDROCHLOROT HIAZIDE	80 MG + 12.5 MG	AUROBINDO PHARMA LTD, UNIT VII (SY. NO. 411/P, 425/P, 434/P, 435/P & 458/P, PLOT NO. S1 (PART), SPECIAL ECONOMIC ZONE (SEZ), TSIIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHRLA MANDAL, MAHABOOB NAGA DISTRICT, PIN CODE: 509302,)	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1334	NDA/MAL/HDP/1 1477	BRAWN LABORATORIES LTD	TATA UGANDA LIMITED	BUCLAPOXIME 200	CEFPODOXIME PROXETIL	200MG	BRAWN LABORATORIES LIMITED (13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/06/2024
1335	NDA/MAL/HDP/1 1478	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TELFOCUS -H- 40/12.5	TELMISARTAN + HYDROCHLOROT HIAZIDE	40 MG + 12.5 MG	AUROBINDO PHARMA LTD, UNIT VII (SY. NO. 411/P, 425/P, 434/P, 435/P & 458/P, PLOT NO. S1 (PART), SPECIAL ECONOMIC ZONE (SEZ), TSIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHRLA MANDAL, MAHABOOB NAGA DISTRICT, PIN CODE: 509302,)	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024

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1336	NDA/MAL/HDP/1 1479	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TELFOCUS -H- 80/25	TELMISARTAN + HYDROCHLOROT HIAZIDE	80 MG + 25 MG	AUROBINDO PHARMA LTD, UNIT VII (SY. NO. 411/P, 425/P, 434/P, 435/P & 458/P, PLOT NO. S1 (PART), SPECIAL ECONOMIC ZONE (SEZ), TSIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHRLA MANDAL, MAHABOOB NAGA DISTRICT, PIN CODE: 509302,)	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024
1337	NDA/MAL/HDP/1 1480	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	MOMESONE	MOMETASONE FUROATE	0.1% W/W	MICRO LABS LIMITED, HOSUR (NO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA)	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	01/06/2024

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1338	NDA/MAL/HDP/1 1481	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	RISPITAS 1	RISPERIDONE	1MG	INTAS PHARMACEUTICALS LIMITED (CAMP ROAD, SELAQUI- 248197, DEHRADUN (UTTARAKHAND))	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/06/2024
1339	NDA/MAL/HDP/1 1482	ARCELIA LIFE SCIENCES LTD.	PLUTO PHARMACEUTICAL S LIMITED	ARCELIAA® CEFIXIME	CEFIXIME	200 MG	ASSOCIATED BIOTECH (VILLAGE: KISHANPURA, GUGUMAJRA ROAD, BADDI THE: NALAGARH HIMACHAL PRADESH 174101 - INDIA)	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0x1.0x10.0 TABLET Blister	01/06/2024

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1340	NDA/MAL/HDP/1 1483	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ZINAXIME 750	CEFUROXIME SODIUM	750 MG	INNOVA CAPTAB PVT. LTD (1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.))	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X750 MG VIAL (10.0ML CLEAR GLASS VIAL)	01/06/2024
1341	NDA/MAL/HDP/1 1484	ACINO AG	LABOREX UGANDA LIMITED	VICORDIA 5 MG	IVABRADINE HYDROCHLORIDE	5MG	PHARMATHEN INTERNATIONAL S.A (INDUSTRIAL PARK SAPES, RODOPI PREFECTURE, BLOCK NO. 5, RODOPI 69300 - GREECE)	GREECE	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/06/2024

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1342	NDA/MAL/HDP/1 1485	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	MAGMEN 625	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500 MG + 125 MG	M/S SCOTT-EDIL ADVANCE RESEARCH LABORATORIES AND EDUCATION LIMITED (HILL-TOP, INDUSTRIAL AREA, BHATOLI KALAN, BADDI, DISTT. SOLAN (HP) - 173205, INDIA)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/06/2024
1343	NDA/MAL/HDP/1 1486	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	MAGMEN-312.5	AMOXICILLIN + CLAVULANATE POTASSIUM	250 MG + 62.5 MG	M/S SCOTT-EDIL ADVANCE RESEARCH LABORATORIES AND EDUCATION LIMITED (HILL-TOP, INDUSTRIAL AREA, BHATOLI KALAN, BADDI, DISTT. SOLAN (HP) - 173205, INDIA)	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X100.0 ML BOTTLE	01/06/2024



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1344	NDA/MAL/HDP/1 1488	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ZINAXIME DS	CEFUROXIME AXETIL	125MG/5ML	INNOVA CAPTAB PVT. LTD (1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.))	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X60.0ML CONTAINER	01/06/2024
1345	NDA/MAL/HDP/1 149	UNIVERSAL CORPORATION LTD	DELMAW ENTERPRISES LIMITED	NEUROBA	GABAPENTIN	300MG	UNIVERSAL CORPORATION LTD..PLOT 13777 CLUB ROAD, PAST KIKUYU	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2015

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1346	NDA/MAL/HDP/1 1490	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	FINRIV	FINASTERIDE	5 MG	EAST AFRICAN (INDIA) OVERSEAS (PLOT NO.1, PHARMACITY SELAQUI DEHRADUN “ 248011 (U.K), INDIA)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X10 G Tube	01/06/2024
1347	NDA/MAL/HDP/1 1491	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	OMESCOT	OMEPRAZOLE SODIUM	40 MG/VIAL	M/S SCOTT-EDIL PHARMACIA LTD (56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X40.0 MG VIAL (10.0ML AMBER GLASS) + 1.0X10.0ML AMPOULE, WFI IN LDPE BOTTLE	01/06/2024

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1348	NDA/MAL/HDP/1 1492	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	COCINE	AMIKACIN SULFATE	500MG/2ML	M/S SCOTT-EDIL PHARMACIA LTD (56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA)	CHINA	PARENTERAL ORDINARY VIALS	1.0X1.0X2.0ML VIAL	01/06/2024
1349	NDA/MAL/HDP/1 1494	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	HYOSCINE BUTYLBROMIDE 20 MG/ML	HYOSCINE BUTYLBROMIDE	20 MG/ML	M/S SCOTT-EDIL PHARMACIA LTD (56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA)	INDIA	PARENTERAL ORDINARY AMPOULES	1X15 ML Bottle, 1X50 ML Bottle	01/06/2024

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1350	NDA/MAL/HDP/1 1496	SWISS PARENTERALS LTD	SHREEJI CARE LIMITED	PHYLLINE	AMINOPHYLLINE	250MG/10ML	SWISS PARENTERALS LIMITED (UNIT-1) (808, 809, 810, KERALA INDUSTRIAL ESTATE, GIDC, NR. BAVLA, AHMEDABAD - 382220, GUJARAT - INDIA)	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X4.0X7.0 TABLET Blister	22/05/2024
1351	NDA/MAL/HDP/1 1497	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	DOLOKIND PLUS	ACECLOFENAC + PARACETAMOL	100 MG + 325 MG	MANKIND PHARMA LIMITED (UNIT - II, VILLAGE KISHANPURA, P.O. JAMNIWALA, TEHSIL PAONTA SAHIB, DISTRICT SIRMOUR - 173025, HIMACHAL PRADESH - INDIA)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/06/2024

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1352	NDA/MAL/HDP/1 1498	AMN LIFE SCIENCE PVT LTD	VITACARE LIMITED	AVAM 156	AMOXICILIN TRIHYDRATE + POTASSIUM CLAVULANATE	(125 MG + 31.25 MG)/5 ML	AMN LIFE SCIENCE PVT LTD (67/P-1, MALAV, AREA- BHILAD, VALSAD- 396105, GUJARAT)	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0x1.0x60.0 ML Container, 1.0x1.0x100.0 ML Container	01/06/2024
1353	NDA/MAL/HDP/1 1499	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	ARMENATE-60	ARTESUNATE	60MG/VIAL	INDASI LIFESCIENCE PRIVATE LIMITED (PLOT NO. 73 TO 77, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN - 396210, INDIA)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL OF 5.0ML VIAL OF 5.0% SODIUM CARBOTE + 2.5ML OF 0.9%W/V SODIUM CHLORIDE	05/06/2024

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1354	NDA/MAL/HDP/1 154	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	BACQURE	IMIPENEM + CILASTATIN	500MG + 500MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED INDUSTRIAL AREA NO.3, A.B. ROAD DEWAS, 455001 (MP), INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X30.0 ML VIAL	01/07/2012
1355	NDA/MAL/HDP/1 158	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	TRAMADOL	TRAMADOL	50MG	TRIVENI FORMULATIONS LTD .PLOT NO. 52, 53,54 ALEAP INDUSTRIAL ESTATE SURAMPALLI VILLAGE GANNAVARAM MANDAL KRISHNA (DT) A.P	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2012

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1356	NDA/MAL/HDP/1 160	DAFRA PHARMA LTD	MULTIPHAR UGANDA LIMITED	DAFRACLAV	AMOXYCILLIN + CLAVULANIC ACID	875MG+125MG	BILIM PHARMACEUTICALS- CERKEZKOY PLANT, 59500 CERKEZKOY, TEKIRDAG	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X2.0X5.0 TABLET BLISTER	01/07/2011
1357	NDA/MAL/HDP/1 163	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	FRUSEMIDE	FUROSEMIDE	40MG	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013

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1358	NDA/MAL/HDP/1 164	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	PIROXICAM	PIROXICAM	20MG	TRIVENI FORMULATIONS LTD .PLOT NO. 52, 53,54 ALEAP INDUSTRIAL ESTATE SURAMPALLI VILLAGE GANNAVARAM MANDAL KRISHNA (DT) A.P	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013
1359	NDA/MAL/HDP/1 166	PANACEA BIOTEC PHARMA LTD	VITACARE LIMITED	DOLZERO	TRAMADOL HYDROCHLORIDE + PARACETAMOL	37.5MG + 325MG	PANACEA BIOTEC PHARMA LIMITEDMALPURI BADDI, DISTRICT SOLAN, HIMACHAL PRADESH-173205 - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013



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1360	NDA/MAL/HDP/1 167	CIRON DRUGS AND PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	METOCLOPRAMID E INJECTION	METOCLOPRAMI DE	5MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD .N- 118,M.I.D.C, TARAPUR,BOISAR, DIST.THANE-401506, MAHARASHTRA,INDI A.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE	01/07/2010
1361	NDA/MAL/HDP/1 168	DAWA LIMITED	SUPER MEDIC LTD	DAWA-CORT CREAM	HYDROCORTISON E	1%W/W	DAWA LTD BABA DOGO ROAD, RUARAKA P.O.BOX 16633-00620, NAIROBI KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2009

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1362	NDA/MAL/HDP/1 169	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	NEBI 5	NEBIVOLOL HYDROCHLORIDE	5MG	ARISTO PHARMACEUTICALS PVT LTD PLOT NO.208 NEW INDUSTRIAL AREA NO.II MANDIDEEP 462046 RAISEN MADHYA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER,1.0X3.0X3. 0X10.0 TABLET BLISTER	01/07/2013
1363	NDA/MAL/HDP/1 172	CIRON DRUGS AND PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE ☒	20MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD .N- 118,M.I.D.C, TARAPUR,BOISAR, DIST.THANE-401506, MAHARASHTRA,INDI A.	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL,1.0X30.0 ML VIAL	01/07/2010

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1364	NDA/MAL/HDP/1 178	HETERO DRUGS LTD	AIVEEN (U) LIMITED	TENOFOVIR	TENOFOVIR DISOPROXIL FUMARATE	300MG	HETERO LABS LTD22- 110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2013
1365	NDA/MAL/HDP/1 179	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	OVITRELLE	CHORIOGONADO TROPIN ALFA	250MCG/0.5ML	MERCK SERONO S.P.A-VIA DELLE MAGNOLIE,15.70026 MODUGNO (BA).ITALY MERCK SERONO SA-1170 AUBONNE(SWITZERL AND)	ITALY, SWITZERLAND	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0 PREFILLED SYRINGE CARTON	01/07/2015

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1366	NDA/MAL/HDP/1 184	DAWA LIMITED	SUPER MEDIC LTD	DACOF MUCOLYTIC	SALBUTAMOL + BROMHEXINE + GUAIPHENESIN + MENTHOL	2.0MG + 4.0MG +100MG + 1.0MG	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2013
1367	NDA/MAL/HDP/1 185	DAWA LIMITED	SUPER MEDIC LTD	DACOF DRY	DIPHENHYDRAMINE + DEXTROMETHORPHAN + MENTHOL	12.5MG + 6.5MG + 1.10MG	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2013

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1368	NDA/MAL/HDP/1 186	DAWA LIMITED	SUPER MEDIC LTD	DACOF EXPECTORANT	DIPHENHYDRAMINE HYDROCHLORIDE + AMMONIUM CHLORIDE + SODIUM CITRATE + MENTHOL	14.0MG + 135.0MG + 57.0MG + 1.10MG	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2013
1369	NDA/MAL/HDP/1 188	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	GMYCIN-80	GENTAMYCIN SULPHATE	80MG/2ML	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X2.0 ML AMPOULE	01/07/2013

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1370	NDA/MAL/HDP/1 189	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	DICLOMAX-75	DICLOFENAC SODIUM	75MG/ML	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X3.0 ML AMPOULE	01/07/2013
1371	NDA/MAL/HDP/1 196	UNIVERSAL CORPORATION LTD	DELMAW ENTERPRISES LIMITED	ACNESOL	TRETINOIN	0.05%W/W	UNIVERSAL CORPORATION LTD..PLOT 13777 CLUB ROAD, PAST KIKUYU	KENYA	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE	01/07/2012

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1372	NDA/MAL/HDP/1 198	THEMIS MEDICARE LTD.	STAR PHARMACEUTICAL S LTD	MALITHER INJECTION	ARTEMETHER	80MG/ML	THEMIS MEDICARE LTD SECTOR 6A ,PLOT NO. 16,17 & 18 IIE,BHEL SIDCUL,HARIDWAR UTTARAKHAND 249403	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE	01/07/2013
1373	NDA/MAL/HDP/1 199	THEMIS MEDICARE LTD	STAR PHARMACEUTICAL S LTD	THEMISET 75	PALONOSETRON HYDROCHLORIDE	0.075MG/1.5ML	THEMIS MEDICARE LIMITESECTOR 6A, PLOT NO. 16 TO18, IIE, BHEL HARIDWA, UTTARAKHAND	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.5 ML VIAL	01/07/2013

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1374	NDA/MAL/HDP/1 201	THEMIS MEDICARE LTD	STAR PHARMACEUTICAL S LTD	THEMISET	PALONOSETRON HYDROCHLORIDE	0.25MG/5ML	THEMIS MEDICARE LIMITEDSECTOR 6A, PLOT NO. 16 TO18, IIE, BHEL HARIDWA, UTTARAKHAND	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.5 ML VIAL	01/07/2013
1375	NDA/MAL/HDP/1 204	THEMIS MEDICARE LTD	STAR PHARMACEUTICAL S LTD	DEXEM INJECTION	DEXMEDETOMIDI NE HYDROCHLORIDE	100	THEMIS MEDICARE LTDSECTOR 6A, PLOT NO. 16 TO18, IIE, BHEL HARIDWA, UTTARAKHAND	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE	01/07/2013



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1376	NDA/MAL/HDP/1 206	THE METHOLATUM CO. LTD	HARLEYS UGANDA LIMITED	DEEP RELIEF	IBUPROFEN + MENTHOL	5%W/W + 3% W/W	THE MENTHOLATUM CO. LTD. 1 REDWOOD AVE PEEL PARK CAMPUS EAST KILBRIDE	UNITED KINGDOM	TOPICAL EXTERNAL OTHER GELS/SOLS	1.0X50.0 G CONTAINER,1.0X15. 0 G CONTAINER,1.0X30. 0 G CONTAINER	01/07/2013
1377	NDA/MAL/HDP/1 208	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	VISCO LIQUID	ALGINIC ACID + MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE + SIMETHICONE	100 MG + 250 MG + 125 MG + 50 MG	ARISTO PHARMACEUTICALS PVT LTD PLOT NO.208 NEW INDUSTRIAL AREA NO.II MANDIDEEP 462046 RAISEN MADHYA PRADESH	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X200.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2011

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1378	NDA/MAL/HDP/1 209	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ARBITEL-80	TELMISARTAN	80MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
1379	NDA/MAL/HDP/1 211	ASTRA ZENECA	MACNAUGHTON LIMITED	BRILINTA	TICAGRELOR	90MG	ASTRA ZENECA ABSE- 151 85 SODERTALJE, SWEDEN (GARTUNAVAGEN & SNACKVIKEN)	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER	01/07/2011

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1380	NDA/MAL/HDP/1 214	FERRER INTERNACIONAL S.A	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NUCLEO C.M.P FORTE	CYTIDINE+URIDINE	5MG+3MG	FERRER INTERNACIONAL, S.AJOAN BUCSALA 1- 9, 08173 SANT CUGAT DEL VALLES, BARCELONA, SPAIN	SPAIN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X15.0 CAPSULE BLISTER	01/07/2013
1381	NDA/MAL/HDP/1 215	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GYNANFORT VAGINAL PESSARY	METRONIDAZOLE +NEOMYCIN SULPHATE+NYSTATIN	500MG+65,000I.U.+ 100,000I.U	BLISS GVS PHARMA LIMITEDNO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	VAGINAL SUPPOSITORIES	1.0X10.0 TABLET BLISTER	01/07/2013

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1382	NDA/MAL/HDP/1 219	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	TORAS-DENK 5	TORASEMIDE	5MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014
1383	NDA/MAL/HDP/1 220	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	LONART	ARTEMETHER + LUMEFANTRINE	180 MG + 1080 MG	BLISS GVS PHARMA LIMITEDNO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BLISTER	01/07/2008

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1384	NDA/MAL/HDP/1 223	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	WHITFIELD'S OINTMENT	BENZOIC ACID + SALICYLIC ACID	6%W/W + 3%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X25.0 G TUBE	01/07/1997
1385	NDA/MAL/HDP/1 226	AFRICURE PHARMACEUTICAL S (INDIA) LTD	ROYAL PHARMA 2011 LIMITED	SALBUTAMOL	SALBUTAMOL	4MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9- 12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER,10.0X1 0.0 TABLET BLISTER	01/07/2005

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1386	NDA/MAL/HDP/1 234	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	BISACODYL TABLETS BP	BISACODYL	5MG	MACLEODS PHARMACEUTICALS LTD.PLOT NO. 25-27 SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN (UT) - 396210, INDIA.	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2007
1387	NDA/MAL/HDP/1 242	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	TOPHEN-100	PHENYTOIN	100MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2013

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1388	NDA/MAL/HDP/1 244	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICAL S LTD	FLEXILOR SR	LORNOXICAM	16MG	GLENMARK PHARMACEUTICALS LTD .VILLAGE KISHANPURA, BADDI- NALAGARH ROAD, TEHSIL BADDI, DISTRICT SOLAN HP 173205	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
1389	NDA/MAL/HDP/1 245	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICAL S LTD	FLEXILOR P8	LORNOXICAM + PARACETAMOL	8MG + 500MG	GLENMARK PHARMACEUTICALS LTD .VILLAGE KISHANPURA, BADDI- NALAGARH ROAD, TEHSIL BADDI, DISTRICT SOLAN HP 173205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014

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1390	NDA/MAL/HDP/1 247	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	PROCIP	CYPROHEPTADIN E	4MG	AGOG PHARMA LTD.PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X5.0X10.0 TABLET BLISTER	01/07/2012
1391	NDA/MAL/HDP/1 252	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	ZOY	SILDENAFIL	50MG	TORQUE PHAMACEAUTICALS PVT LTDVILL ISSAPUR P.O DAPPAR INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2013



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1392	NDA/MAL/HDP/1 254	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSATRIM TABLETS	CO-TRIMOXAZOLE	480MG	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10 0.0 TABLET CONTAINER	01/07/1998
1393	NDA/MAL/HDP/1 255	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	NIFELAT RETARD	NIFEDIPINE	20MG	CIPLA LTDMIDC PATALGANGA 410 220 DIST. RAIGAD	INDIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997

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1394	NDA/MAL/HDP/1 259	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	CARDOZ- 6.25	CARVEDILOL	6.25MG	IPCA LABORATORIES LTD PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2013
1395	NDA/MAL/HDP/1 261	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	CARDOZ-12.5	CARVEDILOL	12.5MG	IPCA LABORATORIES LTD PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2013

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1396	NDA/MAL/HDP/1 264	CENTAUR PHARMACEUTICAL S PRIVATE LIMITED	GITTOES PHARMACEUTICAL S LIMITED	OCUCYCLINE EYE OINTMENT	TETRACYCLINE HYDROCHLORIDE	1%W/W	CENTAUR PHARMACEUTICALS PVT LTD -PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE,1.0X3.5 G TUBE	01/07/2000
1397	NDA/MAL/HDP/1 265	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	COMBIPLEX	VITAMIN B1 + VITAMIN B2 + NICOTINAMIDE + VITAMIN B6	1.0 MG + 1.0 MG + 15 MG + 0.5 MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2008

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1398	NDA/MAL/HDP/1 275	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	NIFELAT 10 F.C TABLETS	NIFEDIPINE	10MG	REMEDICA LIMITED AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997
1399	NDA/MAL/HDP/1 278	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP	DIHYDROARTEME SININ + PIPERAQUINE PHOSPHATE	40MG +320MG	GUILIN PHARMACEUTICAL CO LTDNO.43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X9.0 TABLET BLISTER,1.0X8.0 TABLET BLISTER,1.0X25.0X1 .0X9.0 TABLET BLISTER	01/07/2013

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1400	NDA/MAL/HDP/1 282	ZEE PHARMACEUTICAL S LTD	ZEE PHARMACEUTICAL S LIMITED	LOSABERG	LOSARTAN POTASSIUM	50MG	THE MADRAS PHARMACEUTICALS.. NO. 137B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI 600096	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
1401	NDA/MAL/HDP/1 285	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANFUR-750	CEFUROXIME	750MG	SANCE LABORATORIES PRIVATE LTDPB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X750.0 MG VIAL	01/07/2012

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1402	NDA/MAL/HDP/1 287	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANIX- DS 100	CEFIXIME	100MG/5ML	SANCE LABORATORIES PVT LTDVI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2014
1403	NDA/MAL/HDP/1 290	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANIX 400 CAP	CEFIXIME	400MG	SANCE LABORATORIES PVT LTDVI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X10.0 CAPSULE BLISTER	01/07/2013

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1404	NDA/MAL/HDP/1 291	BAYER SCHERING PHARMA	SURGIPHARM (U) LIMITED	ULTRAVIST-300	IOPROMIDE	300MG/ML	BAYER PHARMA A.GMULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL,1.0X100.0 ML VIAL	01/07/2012
1405	NDA/MAL/HDP/1 293	ZEE PHARMACEUTICAL S LTD	ZEE PHARMACEUTICAL S LIMITED	ZEEGRA - 100	SILDENAFIL CITRATE	100MG	THE MADRAS PHARMACEUTICALS.. NO. 137B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI 600096	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0 TABLET BLISTER	01/07/2016

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1406	NDA/MAL/HDP/1 294	BAYER SCHERING PHARMA	SURGIPHARM (U) LIMITED	ULTRAVIST 370	IOPROMIDE	370MG/ML	BAYER PHARMA A.GMULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	PARENTERAL ORDINARY VIALS	1.0X100.0 ML VIAL,1.0X50.0 ML VIAL	01/07/2012
1407	NDA/MAL/HDP/1 295	SHAIGAN PHARMACEUTICAL S (PVT) LTD	HARLEYS UGANDA LIMITED	ZEPAR	ALBENDAZOLE	200MG	SHAIGAN PHARMACEUTICALS (PVT) LTD14TH KM, ADYALA ROAD, RAWALPINDI- PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	01/07/1997



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1408	NDA/MAL/HDP/1 299	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANAXONE PLUS- 1000	CEFTRIAZONE+SU LBACTAM	1000MG+500MG	SANCE LABORATORIES PRIVATE LTDPB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.5 G VIAL,1.0X50.0X1.0 VIAL CARTON	01/07/2012
1409	NDA/MAL/HDP/1 302	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	HIPEN CAPSULES	AMOXYCILLIN	250MG	SPARSH BIO-TECH PVT. LIMITEDPLOT NO. 1;SURVEY NO. 242/243/244,LAKHA BAVAD,JAMNAGAR- 361 006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1997

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1410	NDA/MAL/HDP/1 303	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	FIBRAL	FINOFIBRATE	200MG	MICRO LABS LTD ..57, SIPCOT INDUSTRIAL COMPLEX, HOSUR- 635126, TAMIIL NADU	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER,1.0X10.0X1 0.0 CAPSULE BLISTER	01/07/2013
1411	NDA/MAL/HDP/1 304	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DIAPRIDE PLUS 2	GLIMEPIRIDE+ METFORMIN	2MG + 500MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2012

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1412	NDA/MAL/HDP/1 307	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ARBITEL 40	TELMISARTAN	40MG	MICRO LABS LTD ..57, SIPCOT INDUSTRIAL COMPLEX, HOSUR- 635126, TAMIIL NADU	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
1413	NDA/MAL/HDP/1 312	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	SLIPIZEM- 2.5	DIAZEPAM	2.5MG	BLISS GVS PHARMA LIMITEDNO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	RECTAL SYSTEMIC PAEDIATRIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY BLISTER	01/07/2007

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1414	NDA/MAL/HDP/1 319	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	ZESTAVAL 200 F.C TABLETS	ALBENDAZOLE	200MG	REMEDICA LTD HARNON STREET, LIMASSOL INDUSTRIAL ESTATE, 3056 LIMASSOL	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	50.0X2.0 TABLET BLISTER,1.0X2.0 TABLET BLISTER	01/07/1997
1415	NDA/MAL/HDP/1 324	MACK BROWN PHARMACEUTICAL S PVT LIMITED	SHURIK LTD	TOOTH HEAL	MULTI INGREDIENT	MULTI INGREDIENT	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X18.0 ML BOTTLE	01/07/2005

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1416	NDA/MAL/HDP/1 328	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ENGERIX-B VACCINE	HEPATITIS B SURFACE ANTIGEN	20MCG/ML	GLAXOSMITHKLINE BOIOLOGICALS.A RUE DE L'INSTITUT 89 B- 1330 RIXENSART	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X10.0X1.0 ML VIAL (1 DOSE),1.0X25.0X1.0 ML VIAL (1 DOSE)	01/07/1997
1417	NDA/MAL/HDP/1 331	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	BETADERM N OINTMENT	BETAMETHASONE VALERATE + NEOMYCIN	0.1%W/W + 0.5%W/W	ATCO LABORATORIES PVT LTDB-18,S.I.T.E KARACHI 75700, PAKISTAN	PAKISTAN	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE,1.0X5.0 G TUBE	01/07/1997

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1418	NDA/MAL/HDP/1 335	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	PREGATAS	PREGABALIN	75MG	INTAS PHARMACEUTICALS LTDCAMP ROAD SELAQUI DEHRADUN	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2012
1419	NDA/MAL/HDP/1 337	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	FOURTS B	THIAMINE +RIBOFLAVIN + PYRIDOXINE + NICOTINAMIDE + FOLIC ACID + ASCORBIC ACID + COLECALCIFEROL + ACETYL CYSTEINE + GLYCINE + GLUTAMIC ACID + CHROMIUM + VANADIUM + ZINC + SELENIUM	10MG + 10MG + 3MG + 50MG + 1MG + 75MG + 400IU + 25MG +25MG +MG +200MCG + 100MCG + 55MG +100MCG	FOURRTS INDIA LABORATORIES PVT. LIMITEDVANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2016

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1420	NDA/MAL/HDP/1 338	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	GRISEBEN 500	GRISEOFULVIN	500 MG	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
1421	NDA/MAL/HDP/1 341	AUROLAB	SWASTIK PHARMACEUTICAL LTD	G-FLOX	GATIFLOXACIN SESQUIHYDRATE	0.3%W/V	AUROLABNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA	INDIA	OPHTHALMIC LIQUIDS	1.0X5.0 ML VIAL	01/07/2016

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1422	NDA/MAL/HDP/1 345	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SWICH-200	CEFPODOXIME	200MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2010
1423	NDA/MAL/HDP/1 347	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	ORNILOX	ORNIDAZOLE + OFLOXACIN	500MG + 200MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2010



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1424	NDA/MAL/HDP/1 348	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	VALPARIN CHRONO 500	SODIUM VALPROATE (CONTROLLED RELEASE)	500MG	TORRENT PHARMACEUTICAL LTD AHMEDABAD- MEHSANA HIGHWAY, TALUKA- KADI, DIST. MEHSANA , INDRAD-382721	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2009
1425	NDA/MAL/HDP/1 353	MEDLEY PHARMACEUTICALS LTD	EUROPA HEALTHCARE (U) LTD	KITPYLO - C	LANSOPRAZOLE + TINIDAZOLE + CLARITHROMYCIN	30MG +500MG + 250MG	MEDLEY PHARMACEUTICALS LTD, PLOT 18 & 19 SURVEY NO 378/7 & 379/ 2&3 ZARI CAUSEWAY ROAD KACHIGAM	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X7.0X1.0X6.0 TABLET BLISTER (BLISTER CONTAINS 2 CAPSULES AND 4 TABLETS)	01/07/2015

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1426	NDA/MAL/HDP/1 359	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	DIFENAC-100 SR	DICLOFENAC SODIUM	100MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD PLOT M 444B STRETCHER ROAD NTINDA	UGANDA	ORAL SOLID RETARD CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/2016
1427	NDA/MAL/HDP/1 361	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	FALCI CARE	ARTESUNATE	120MG	SWISS PARENTERALS LTD 809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X30.0 MG VIAL + 1*5ML OF 0.9%W/V NACL AMPOULE + 1*1ML OF 5%W/V NAHCO3 AMPOULE	01/07/2016

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1428	NDA/MAL/HDP/1 362	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	BACTOCLAV-1000	AMOXICILLIN + CLAVULANATE	875 MG + 125 MG	MICRO LABS LIMITED PLOT 16 VEERASANDRA IND. AREA, ANEKAL TALUK, BANGALORE INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X6.0 TABLET STRIP	01/07/2013
1429	NDA/MAL/HDP/1 367	DAWA LIMITED	SUPER MEDIC LTD	ACEPAR	ACECLOFENAC + PARACETAMOL	100 MG + 500 MG	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2013

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1430	NDA/MAL/HDP/1 368	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	D5	GLUCOSE	5%W/V	ABACUS PARENTERAL DRUGS LIMITEDBLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE,1.0X250.0 ML BOTTLE	01/07/2010
1431	NDA/MAL/HDP/1 369	MEDIPHARM (EA) LTD	MEDIPHARM INDUSTRIES (E.A) LTD	ORALYTE CO- PACK ORANGE FLAVOUR	DT ZINC-20 + ORAL REHYDRATION SALTS (ORS)	20G	MEDIPHARM INDUSTRIES( EA) LTD PLOT 65 KAKAJJO ROAD BWEYOGERERE P.O.BOX 6218,KAMPALA,UGA NDA MEDICAMEN BIOTECH LTD,,SP- 1192 A&B PHASE IV INDUSTRIAL AREA BHIWADI 301019 DIST. ALWAR (RAJASTHAN) - INDIA AGOG PHARMA LTD PLOT	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X2.0X20.8 G SACHET + 1.0 *10.0 TABLET BLISTER	01/07/2016

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1432	NDA/MAL/HDP/1 370	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	STERILIZED WATER FOR INJECTION	WATER FOR INJECTION	NEUTRAL	ABACUS PARENTERAL DRUGS LIMITEDBLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY AMPOULES	1.0X5.0 ML AMPOULE,1.0X10.0 ML AMPOULE,1.0X7.5 ML AMPOULE	01/07/2010
1433	NDA/MAL/HDP/1 372	AXA PARENTERALS LTD	VITACARE LIMITED	RL	LACTIC ACID + SODIUM HYDROXIDE + SODIUM CHLORIDE + POTASSIUM CHLORIDE + CALCIUM CHLORIDE	(0.24 + 0.115 + 0.6 + 0.04 + 0.027)G/100ML	AXA PARENTERALS LTDKISHNPUR, JAMALPUR ROORKEE- 247677	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2014

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1434	NDA/MAL/HDP/1 377	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	SUPER AMP	WATER FOR INJECTION	N/A	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTDVILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0 ML AMPOULE	01/07/2014
1435	NDA/MAL/HDP/1 380	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	HYCORT CREAM	HYDROCORTISON E	1%W/W	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X30.0 G TUBE	01/07/1997

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1436	NDA/MAL/HDP/1 382	HOVID BERHAD	UNITED HEALTHCARE DISTRIBUTORS LTD	INOX CAPSULES	ITRACONAZOLE	100MG	HOVID BHDLOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1.0X7.0X4.0 CAPSULE BLISTER	01/07/2012
1437	NDA/MAL/HDP/1 383	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	KETOFEN GEL	KETOPROFEN	2.5%W/W	HOVID BHD (IPOH SITE)121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G CONTAINER	01/07/2013

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1438	NDA/MAL/HDP/1384	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LAMIVUDINE AND ZIDOVUDINE TABLETS	LAMIVUDINE + ZIDOVUDINE	30MG + 60MG	CIPLA LTD.- PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2013
1439	NDA/MAL/HDP/1387	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	LAN-30	LANSOPRAZOLE	30MG	INTAS PHARMACEUTICALS LTDCAMP ROAD SELAQUI DEHRADUN	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X5.0X10.0 CAPSULE STRIP	01/07/2004



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1440	NDA/MAL/HDP/1 390	ASTRA ZENECA	MACNAUGHTON LIMITED	CRESTOR	ROSUVASTATIN CALCIUM	5MG	IPR PHARMACEUTICALS INC, LOT 17 INDUSTRIAL PARK PUERTO RICO, SAN ISIDRO, PUERTO RICO	PUERTO RICO	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2010
1441	NDA/MAL/HDP/1 392	ASTRA ZENECA	MACNAUGHTON LIMITED	ZOLADEX	GOSERELIN	3.6MG	ASTRA ZENECA UK LIMITEDASTRAZENECA UK LIMITED SILK ROAD BUSINESS PARK, MACCLES FIELD, CHESHIRE SK 10 2NA,	UNITED KINGDOM	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0 PREFILLED SYRINGE CARTON	01/07/1997

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1442	NDA/MAL/HDP/1 393	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANFUR	CEFUROXIME	500MG	SANCE LABORATORIES PRIVATE LTDPB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2016
1443	NDA/MAL/HDP/1 394	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANPIME -1000	CEFEPIME	1000MG	SANCE LABORATORIES PRIVATE LTDPB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X15.0 ML VIAL	01/07/2010

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1444	NDA/MAL/HDP/1 395	ASTRA ZENECA AB	MACNAUGHTON LIMITED	NEXIUM 40MG IV	ESOMEPRAZOLE	40MG/5ML	ASTRA ZENECA- KVARNBERGAGATAN 12, SE-151 SODERTALJE	SWEDEN	PARENTERAL ORDINARY VIALS	1.0X1.0X5.0 ML VIAL,1.0X10.0X5.0 ML VIAL	01/07/2010
1445	NDA/MAL/HDP/1 397	ASTRA ZENECA	MACNAUGHTON LIMITED	PLENDIL	FELODIPINE	10MG	ASTRAZENECA SWEDEN OPERATIONSASTRAZ ENECA SWEDEN OPERATIONS SE-151 85 SODERTALJE ASTRAZENECA PHARMACEUTICAL CO LTD.NO. 2 HUANGSHAN ROAD, WUXI, 214028, JIANGSU	CHINA SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2001

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1446	NDA/MAL/HDP/1 400	MEGA LIFSCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	PANFOR SR 500	METFORMIN HYDROCHLORIDE	500MG	INVENTIA HEALTHCARE LIMITEDF-1 - F-1/1 - F75/1, ADDITIONAL AMBERNATH MIDC, AMBERNATH EAST 421506, DIST. THANE, MAHARASHTRA - INDIA	INDIA	ORAL SOLID RETARD TABLETS	1.0X5.0X20.0 TABLET BLISTER	01/07/2015
1447	NDA/MAL/HDP/1 402	MEGA LIFSCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	PANFOR SR 1000	METFORMIN HYDROCHLORIDE	1000MG	INVENTIA HEALTHCARE LIMITEDF-1 - F-1/1 - F75/1, ADDITIONAL AMBERNATH MIDC, AMBERNATH EAST 421506, DIST. THANE, MAHARASHTRA - INDIA	INDIA	ORAL SOLID RETARD TABLETS	1.0X5.0X20.0 TABLET BLISTER	01/07/2015

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1448	NDA/MAL/HDP/1 406	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	CEBAY DRY SYRUP	CEFIXIME TRIHYDRATE	50MG/5ML	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2014
1449	NDA/MAL/HDP/1 409	PHARMACTIV FZCO	JEET PHARMACEUTICAL S LIMITED	ROMYCIN	AZITHROMYCIN	200MG/5ML	NABIQASIM INDUSTRIES (PVT) LTD-17/24,KORANGI INDUSTRIAL AREA, KORANGI, KARACHI- PAKISTAN.	PAKISTAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X15.0 ML BOTTLE	01/07/2007

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1450	NDA/MAL/HDP/1 411	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	CIPIUM	CHLORPHENIRAM INE	4MG	LEBEN LAB PVT LTD L4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X20.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2011
1451	NDA/MAL/HDP/1 413	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	PODINE MOUTH WASH	POVIDONE IODINE	0.1%W/V	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL TOPICAL LIQUIDS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE	01/07/2014

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1452	NDA/MAL/HDP/1414	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	DICLORAN SR TABLETS	DICLOFENAC SODIUM	100MG	UNIQUE PHARMACEUTICAL LABS LIMITED. .215-216, 216-219, 304-308, GIDC PANOLI 394116-GUJARAT	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1X10X10 TABLET BLISTER	01/07/2016
1453	NDA/MAL/HDP/1417	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	MILICAL TABLETS	CALCIUM CITRATE + VITAMIN D3	1000MG +200 I.U	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2001

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1454	NDA/MAL/HDP/1 418	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	AMINOPHYLLINE TABLETS	AMINOPHYLLINE	100MG	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10. 0X10.0 TABLET BLISTER	01/07/2011
1455	NDA/MAL/HDP/1 419	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SINOPRIL 10	LISINOPRIL	10MG	GLOBAL NAPI PHARMACEUTICALS - 2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER, 1.0X3.0X10 .0 TABLET BLISTER	01/07/2005



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1456	NDA/MAL/HDP/1422	SHAIGAN PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	STAMIN	CETIRIZINE DIHYDROCHLORIDE	10MG	SHAIGAN PHARMACEUTICALS (PVT) LTD14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2005
1457	NDA/MAL/HDP/1427	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	TENA-50	ATENOLOL	50MG	AGOG PHARMA LTD PLOT NO.33, SECTOR II, VASAI, TALUKA INDL CO-OP ESTATE LTD, GAURAI PADA, VASAI(E) DIST. T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER, 1.0X28.0 TABLET BLISTER, 1.0X10.0X10.0 TABLET BLISTER	01/07/2011

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1458	NDA/MAL/HDP/1 431	INTAS PHARMACUITICALS LTD	NORVIK ENTERPRISES LIMITED	TORTAS 10	TORSEMIDE	10MG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI- 248197,DEHRADUN UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
1459	NDA/MAL/HDP/1 433	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	NORISTERAT	NORETHISTERON E ENANTATE	200MG	BAYER PHARMA A.GMULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	PARENTERAL ORDINARY VIALS	1.0 ML PRE- FILLED SYRINGE,1.0X100.0 X1.0 ML VIAL	01/07/1997

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1460	NDA/MAL/HDP/1 436	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CONCOR 10	BISOPROLOL HEMIFUMARATE	10MG	WINTHROP PHARMACEUTICALS( PTY) LTD,315 WATLOO ROAD,WATLOO,PRET ORIA,SOUTHAFRICA (FPP SECONDARY PACKAGING,FPP RELEASE/QC TESTING SITE) MERCK KGAA250 FRANKFRUTER STRASSE 250-64293 DARMSTADT	GERMANY SOUTH AFRICA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014
1461	NDA/MAL/HDP/1 441	AXA PARENTERALS LTD	VITACARE LIMITED	SODIUM CHLORIDE	SODIUM CHLORIDE	0.9%W/V	AXA PARENTERALS LTDKISHNPUR, JAMALPUR ROORKEE- 247677	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2014

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1462	NDA/MAL/HDP/1445	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	AXONE 1000	CEFTRIAZONE SODIUM	1000MG	CADILA PHARMACEUTICALS LIMITED 1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL	01/07/2003
1463	NDA/MAL/HDP/1446	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	VITAMIN B COMPLEX	VITAMINS B1 + B2 + B6 + NIACINAMIDE	0.5 MG + 0.5MG + 7.5MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2015

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1464	NDA/MAL/HDP/1447	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VITONA PLUS	VITAMINS + MINERALS	MULTI-INGREDIENT	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X6.0 CAPSULE BLISTER	01/07/2014
1465	NDA/MAL/HDP/1449	SHAIGAN PHARMACEUTICALS (PVT) LTD	HARLEYS UGANDA LIMITED	ZEPAR SUSPENSION	ALBENDAZOLE	200MG/5ML	SHAIGAN PHARMACEUTICALS (PVT) LTD14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	01/07/2000

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1466	NDA/MAL/HDP/1 450	GLAXOSMITHKLINE LIMITED LIKONI	UNITED HEALTHCARE DISTRIBUTORS LTD	VOLTAREN EMULGEL 1%	DICLOFENAC DIETHYLAMMONI UM	1%W/V	GSK CONSUMER HEALTH SAGSK CONSUMER HEALTH SA, ROUTE DE L'ETRAZ, NYON, 1260, SWITZERLAND	SWITZERLAND	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE,1.0X50.0 G TUBE	01/07/1997
1467	NDA/MAL/HDP/1 451	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN INJECTION	DICLOFENAC	25MG/ML	NOVARTIS PHARMA STEIN AGSCHAFFHARVSERT RASSE CH-4332 STEIN SWITZERLAND.	SWITZERLAND	PARENTERAL ORDINARY AMPOULES	1.0X3.0 ML AMPOULE	01/07/1997

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1468	NDA/MAL/HDP/1 454	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	PAINEX	PARACETAMOL + ASPIRIN + CAFFEINE	500MG + 400MG + 50 MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X25.0X4.0 TABLET STRIP	01/07/2003
1469	NDA/MAL/HDP/1 456	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	SUCRAFIL O GEL	SUCRALFATE + OXETACAINE	10MG + 0.2MG	FOURRTS INDIA LABORATORIES PVT. LIMITED VANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE, 1.0X200.0 ML BOTTLE	01/07/2013

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1470	NDA/MAL/HDP/1 457	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICAL S LIMITED	DYSEN FORTE	SECNIDAZOLE	1000MG	NABIQASIM INDUSTRIES (PVT) LIMITED17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	01/07/2006
1471	NDA/MAL/HDP/1 458	STRIDES PHARMA SCIENCE LIMITED	DELMAW ENTERPRISES LIMITED	CLAVICIN INJECTION	AMOXICILLIN + POTASSIUM CLAVULANATE	1.2G	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.2 G VIAL	01/07/2013



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1472	NDA/MAL/HDP/1 460	VENUS REMEDIES LTD	REDDYS PHARMA LIMITED	PARIN E	ENOXAPARIN	80MG	VENUS REMEDIES LTD -UNIT II HILL TOP INDUSTRIAL ESTATE JHARMAJRI EPIP PHASE I BHATOLI KALAN BADDI (H.P)	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X10.0X2.0X0.8 ML PRE- FILLED SYRINGE	01/07/2009
1473	NDA/MAL/HDP/1 463	ARISTO PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	ARISTOZYME LIQUID	DIASTASE+PEPSIN	50MG+10MG	ARISTO PHARMACEUTICALS PVT. LIMITEDPLOT NO. 208, NEW INDUSTRIAL AREA NO. II, MANDIDEEP- 462046, DIST. - RAISEN, MADHYA PRADESH, INDIA.	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X200.0 ML BOTTLE	01/07/2015

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1474	NDA/MAL/HDP/1 465	NORVATIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTFAST 50MG	DICLOFENAC POTASSIUM	50MG	MIPHARM S.P.A VIA BERNARDO QUARANTA, 12- 20141, MILANO ITALY.	ITALY	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X3.0 SACHET CARTON,9.0X1.0X3. 0X3.0 SACHET CARTON	01/07/2014
1475	NDA/MAL/HDP/1 468	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	OCID 20	OMEPRAZOLE	20MG	S KANT HEALTHCARE LTD- PLOT NO. 1802- 1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT. EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID RETARD CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	01/07/1998

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1476	NDA/MAL/HDP/1 469	VOGEN LABORATORIES LTD	BUFFALO HEALTH CARE LTD	DURAMOX 125	AMOXICILLIN	125MG/5ML	VOGEN LABORATORIES LTD70, M.HERACLEOUS STR. AYIOS ATHANASIOS INDUSTRIAL AREA, LIMASSOL, CYPRUS	CYPRUS	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2007
1477	NDA/MAL/HDP/1 474	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGODIC GEL	DICLOFENAC DIETHYLAMINE	1%W/W	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/2016

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1478	NDA/MAL/HDP/1476	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	SEPTOL	SILVER SULFADIAZINE + CHLORHEXIDINE GLUCONATE	1%W/W + 0.20W/W	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2016
1479	NDA/MAL/HDP/1478	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	KAMAGRA	SILDENAFIL	50MG	AJANTA PHARMA LIMITED PAITHAN MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASHTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2001

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1480	NDA/MAL/HDP/1 482	SANOPI PASTEUR	LABOREX UGANDA LIMITED	STAMARIL PASTEUR	YELLOW FEVER VIRUS 17D-204 STRAIN(LIVE ATTENUATED)	NLT 1000 I.U	SANOPI PASTEUR1541 AVENUE MARCEL MERIEUX, 69280 MARCY, LETOILE SANOPI PASTEUR S.A2,AVENUE PONT PASTEUR 69007 LYON- FRANCE(BUSINESS ADDRESS)	FRANCE	PARENTERAL ORDINARY VIALS	1.0X1.0 DOSE VIAL + 0.5ML OF SOLVENT IN PRE- FILLED SYRINGE,1.0X10.0X 10.0 DOSE VIAL + 1*10*10 DOSE AMPOULE OF NS	01/07/1997
1481	NDA/MAL/HDP/1 485	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DICLOFEN 25	DICLOFENAC	25MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTDP.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL- RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY BLISTER	01/07/2011

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1482	NDA/MAL/HDP/1 486	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AMPIMAX-1	AMPICILLIN	1G	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X1.0 G VIAL	01/07/2011
1483	NDA/MAL/HDP/1 488	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DICLO-DENK 100 RECTAL	DICLOFENAC SODIUM	100MG	HAUPT PHARMA WULFING GMBH.BETHELNER LANDSTR. 18, 31028 GRONAU	GERMANY	RECTAL SYSTEMIC ADULT SUPPOSITORIES	10.0X1.0X2.0X5.0 SUPPOSITORY STRIP,1.0X5.0 SUPPOSITORY STRIP	01/07/2000

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1484	NDA/MAL/HDP/1 492	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DICLO-DENK 75 INJECTION	DICLOFENAC SODIUM	25MG/ML	HAUPT PHARMA WULFING GMBH;- BETHELNER LANDSTR. 18, 31028 GRONAUILLIURE, GERMANY.	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X10.0X3.0 ML AMPOULE	01/07/1998
1485	NDA/MAL/HDP/1 493	AUROBINDO PHARMA LTD UNIT VII	GITTOES PHARMACEUTICAL S LIMITED	KOACT 1000	AMOXICILLIN/CLA VULANATE POTASSIUM	875MG/125MG	AUROBINDO PHARMA LIMITED, UNIT III SURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJIRI (DISTRICT) - 500090 TELENGANA (STATE)	INDIA	ORAL SOLID RETARD TABLETS	1X4 TABLET BLISTER	01/07/2007

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1486	NDA/MAL/HDP/1 494	FERRER INTERNACIONAL S.A	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	PEITEL 0.25%	PREDNICARBATE	0.25%W/W	FERRER INTERNACIONAL, S.AJOAN BUCSALA 1- 9, 08173 SANT CUGAT DEL VALLES, BARCELONA, SPAIN	SPAIN	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	01/07/2013
1487	NDA/MAL/HDP/1 497	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LAEOVATE CREAM	BETAMETHASONE VALERATE	0.1%W/W	LABORATORY & ALLIED LTD-PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	01/07/1997



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1488	NDA/MAL/HDP/1 499	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	PROMETHAZINE	PROMETHAZINE HYDROCHLORIDE	25MG/ML	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	CHINA INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE	01/07/2005
1489	NDA/MAL/HDP/1 500	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	ATRIPLA	EFAVIRENZ+EMTR ICITABINE + TENOFVIR	600MG +200MG+300MG	PATHEON INCMISSISSAUGA, ON L5N 7K9 CANADA	CANADA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2008

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1490	NDA/MAL/HDP/1 503	MEDICAL UNION PHARMACUTICALS	KARURI PHARMACEUTICALS LTD.	SEDIPROCT CREAM	HYDROCORTISON E+CINCHOCAINE	0.5%W/W + 0.5%W/W	MEDICAL UNION PHARMA .COABU- SULTAN ISMAILIA EGYPT	EGYPT	TOPICAL EXTERNAL OTHER CREAMS	1.0X20.0 G TUBE	01/07/2003
1491	NDA/MAL/HDP/1 505	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	SERETIDE EVOHALER	SALMETEROL/ FLUTICASONE PROPIONATE	25/50 MCG	GLAXO WELLCOME PRODUCTIONZONE INDUSTRIELLE NO.2 23 RUE LAVOISER 27000 EVREUX	FRANCE	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X1.0 CANNISTER CARTON	01/07/2007

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1492	NDA/MAL/HDP/1508	DAWA LIMITED-	SUPER MEDIC LTD	WOMNIL	ALBENDAZOLE	200MG/5ML	DAWAPLOT 7879, BABA DOGO ROAD RUARAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	01/07/2009
1493	NDA/MAL/HDP/1514	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	VERMOX	MEBENDAZOLE	100MG	SPECPHARM HOLDINGS 15TH ROAD HALFWAY HOUSE JOHNSON & JOHNSON (PTY) LTD241 MAIN ROAD, RETREAT, 7945, CAPE TOWN	SOUTH AFRICA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X6.0 TABLET BLISTER	01/07/1997

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1494	NDA/MAL/HDP/1 516	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	URGENDOL P	TRAMADOL/ PARACETAMOL	37.5MG/ 325MG	WIN MEDICARE PVT LIMITEDMEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2011
1495	NDA/MAL/HDP/1 523	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMPIREN	AMPICILLIN	125MG/5ML	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2007

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1496	NDA/MAL/HDP/1 524	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMOXIREN	AMOXICILLIN TRIHYDRATE	125 MG / 5 ML	RENE INDUSTRIES LIMITED PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2008
1497	NDA/MAL/HDP/1 526	FERRER INTERNACIONAL S.A	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	GAMALATE B6	MAGNESIUM GLUTAMATE HYDROBROMIDE + AMINOBUTYRIC ACID + AMINO HYDROXYBUTYRIC ACID + VITAMIN B6	75MG + 75MG + 37MG + 37MG	FERRER INTERNATIONAL, S.A.C/JOAN BUSCALLA, 1- 9.08173 SANT CUGAT DEL VALLES, BARCELONA	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2015

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1498	NDA/MAL/HDP/1 527	MICRO LABS LTD	LABOREX UGANDA LIMITED	BACTOCLAV	AMOXICILLIN + CLAVULANATE POTASSIUM	200MG + 28.5MG/ 5ML	MICRO LABS LIMITED.PLOT 16, VEERASANDRA IND. AREA,ANEKAL TALUK, BANGALORE INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X100.0 ML BOTTLE	01/07/2012
1499	NDA/MAL/HDP/1 528	MICRO LABS LTD	LABOREX UGANDA LIMITED	BACTOCLAV-625	AMOXYCILLIN + CLAVULANATE POTASSIUM	500 MG + 125 MG	MICRO LABS LIMITED PLOT 16 VEERASANDRA IND. AREA,ANEKAL TALUK,BANGALORE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X6.0 TABLET BLISTER,1.0X2.0X10 .0 TABLET BLISTER	01/07/2007

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1500	NDA/MAL/HDP/1 529	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	PROVIRON	MESTEROLONE	25MG	BAYER WEIMAR GMBH & CO. KGDOBEREINERSTRA SSE 20 D-99427 WEIMAR, GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/1997
1501	NDA/MAL/HDP/1 532	BF BIOSCIENCES LTD	HARLEYS UGANDA LIMITED	NOVAPRESSIN	TERLIPRESSIN	1MG/VIAL	BF BIOSCIENCES LTD. -RAIWIND, PAKISTAN	PAKISTAN	PARENTERAL ORDINARY VIALS	1.0X1.0 MG VIAL	01/07/2014

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1502	NDA/MAL/HDP/1 533	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	5D	GLUCOSE	50G/L	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTDVILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE,1.0X250.0 ML BOTTLE	01/07/2007
1503	NDA/MAL/HDP/1 535	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	FORTIWIN-4	FORTIFIED PROCAINE PENICILLIN SODIUM	4 M.U	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA INJECT CARE PARENTERALS PVT LTD PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195	CHINA INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X4.0 MU VIAL,1.0X100.0X4.0 MU VIAL,1.0X10.0X4.0 MU VIAL	01/07/2011



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1504	NDA/MAL/HDP/1 537	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYZOLE	ALBENDAZOLE	200MG	ELYS CHEMICAL INDUSTRIES LIMITED- ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X20.0X2.0 TABLET BLISTER	01/07/2005
1505	NDA/MAL/HDP/1 538	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYZOLE SUSPENSION	ALBENDAZOLE	200MG	ELYS CHEMICAL INDUSTRIES LIMITED- ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	01/07/2003

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1506	NDA/MAL/HDP/1544	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	PROMETHAZINE HYDROCHLORIDE B.P	PROMETHAZINE HCL	25MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER	01/07/2004
1507	NDA/MAL/HDP/1546	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	LANPRO	LANSOPRAZOLE	30MG	UNICHEM LABORATORIES LTD UNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205 UNICHEM LABORATORIES LTD PLOT NO. 15,16,17,17A & 18, PILERNE INDUSTRIAL ESTATE, PILERNE, BARDEZ, GOA-403511	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X2.0X10.0 CAPSULE BLISTER	01/07/1999

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1508	NDA/MAL/HDP/1 551	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	CALOSHELL-500	CALCIUM CARBONATE + VITAMIN D3	1250MG + 250IU	EMCURE PHARMACEUTICALS LTDLANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2004
1509	NDA/MAL/HDP/1 553	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	VIFEX	SALBUTAMOL + BROMHEXINE + GUAIFENESIN	1MG/5ML+2MG/5 ML+50MG/5ML	EMCURE PHARMACEUTICALS LTDLANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2004

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1510	NDA/MAL/HDP/1554	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL CETIRIZINE	CETIRIZINE DIHYDROCHLORIDE	5MG/5ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2010
1511	NDA/MAL/HDP/1555	GALENTIC PHARMA LTD	VITACARE LIMITED	GALSCRUB	CHLORHEXIDINE	4%W/W	GALENTIC PHARMA PVT. LIMITED R-673, TTC MIDC, RUBALE, THANE BELAPUR NAVI MUMBAI 400 701 INDIA	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X500.0 ML BOTTLE	01/07/2008

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1512	NDA/MAL/HDP/1 557	GLAXOSMITHKLINE	UNITED HEALTHCARE DISTRIBUTORS LTD	SYNFLORIX VACCINE	PNEUMOCOCCAL POLYSACCHARIDE SEROTYPES (1,5,6B,7F,9V,14,2 3F) + (4,18C,19F) + PROTEIN D+TETANUS TOXOID+DIPHTHER IA TOXOID CARRIER PROTEINS AND ALUMINIUM PHOSPHATE	1MCG+3MCG+13M CG+8MCG+5MCG+ 0.5MG	GLAXOSMITHKLINE BOIOLOGICALSS.A RUE DE L'INSTITUT 89 B- 1330 RIXENSART	BELGIUM	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X0.5 ML PRE- FILLED SYRINGE (1 DOSE),1.0X100.0X0. 5 ML VIAL (1 DOSE)	01/07/2010
1513	NDA/MAL/HDP/1 563	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	AMOXIL	AMOXYCILLIN	125MG/5ML	GLAXO WELLCOME PRODUCTION.ZONE INDUSTRIELLE DE LA PEYENNIERE 53100 MAYENNE, FRANCE	FRANCE	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

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1514	NDA/MAL/HDP/1 566	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	VITAVIT	MULTI- INGREDIENT	MULTI- INGREDIENT	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	NULL	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2009
1515	NDA/MAL/HDP/1 569	ABBVIE (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	KALETRA	LOPINAVIR+RITO NAVIR	80MG + 20MG	AESICA PHARMACEUTICALS SRL QUEENBOROUGH KENT ME 11 5EL, UNITED KINGDOM	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X5.0X1.0X60.0 ML BOTTLE	01/07/2007

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1516	NDA/MAL/HDP/1571	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	RHOCLONE	MONOCLONAL ANTI-D IMMUNOGLOBULIN	300MCG	BHARAT SERUMS AND VACCINES LIMITED,PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X2.0 ML VIAL (1 DOSE VIAL)	01/07/2013
1517	NDA/MAL/HDP/1572	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS LTD	ROSUVAS 20	ROSUVASTATIN	20MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2011

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1518	NDA/MAL/HDP/1574	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	AMTAS-5	AMLODIPINE	5MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	2.0X2.0X7.0 TABLET BLISTER,10.0X10.0 TABLET BLISTER	01/07/2003
1519	NDA/MAL/HDP/1579	PT SANBE FARMA	MEDVIN PHARMA LIMITED	PLASMINEX	TRANEXAMIC ACID	100MG/ML	PT SANBE FARMA JI INDIRINO.8 KOMPLEKS INDUSTRI CIMAREME PADALARANG BANDUNG	INDONESIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X5.0 ML AMPOULE	01/07/2011



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1520	NDA/MAL/HDP/1 581	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	PANTOTAB	PANTOPRAZOLE	40MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2006
1521	NDA/MAL/HDP/1 582	LINCON PHARMCUETICALS LIMITED	METRO PHARMACEUTICALS LIMITED	CEEPRO-500	CIPROFLOXACIN	500MG	LINCOLN PHARMACEUTICALS LTD-TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

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1522	NDA/MAL/HDP/1 584	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	UCLOX	CLOXACILLIN SODIUM	500MG	UNI MEDICOLABS. 21 22 PHARMACY SELAQUI DEHRADUN 248197	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL	01/07/2015
1523	NDA/MAL/HDP/1 585	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	UDIHEP FORTE	URSODEOXYCHOL IC ACID	300MG	WIN-MEDICARE PRIVATE LIMITEDMEERUT- MUZAFFARNAGAR ROAD, MODIPURAM 250110 UTTAR PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2010

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1524	NDA/MAL/HDP/1 588	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	TOZAAR-H	LOSARTAN POTASSIUM + HYDROCHLOROT HIAZIDE	50MG + 12.5MG	TORRENT PHARMACEUTICALS LIMITED AHMEDABAD- MEHSANA HIGHWAY, TAL. KADI, DIST. MEHSANA, INDRAD 382 721, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP,1.0X4.0X7.0 TABLET BLISTER	01/07/2005
1525	NDA/MAL/HDP/1 589	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	CENTACID SUSPENSION	MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE+SIME THICONE	40MG+200MG+25 0MG/5ML	CENTAUR PHARMACEUTICALS PVT LTD PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE,1.0X170.0 ML BOTTLE	01/07/1997

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1526	NDA/MAL/HDP/1 591	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	CENTIPAR ELIXIR	PIPERAZINE CITRATE	750ML/5ML	CENTAUR PHARMACEUTICALS PVT LTD PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X30.0 ML BOTTLE	01/07/1997
1527	NDA/MAL/HDP/1 598	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOCIM 400	CIMETIDINE	400MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

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1528	NDA/MAL/HDP/1 605	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	ASPIRIN TABLETS	ACETYL SALICYLIC ACID	300MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER	01/07/2001
1529	NDA/MAL/HDP/1 615	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	APCALIS SX	TADALAFIL	20MG	AJANTA PHARMA LIMITED PAITHAN MANUFACT URING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X2.0 TABLET BLISTER	01/07/2005

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1530	NDA/MAL/HDP/1 616	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	CEZIN	CETIRIZINE	5MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X30.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2011
1531	NDA/MAL/HDP/1 627	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	CANDID-V GEL	CLOTRIMAZOLE	2%W/W	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	VAGINAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/2004

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1532	NDA/MAL/HDP/1 629	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	CARVETAS 12.5	CARVEDILOL	12.5MG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI- 248197, DEHRADUN (UTTARAKHAND)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
1533	NDA/MAL/HDP/1 631	AUROBINDOM PHARMA LIMITED	GITTOES PHARMACEUTICAL S LIMITED	NEVIRAPINE ORAL SUSPENSION	NEVIRAPINE	50MG/5ML	AUROBINDO PHARMA LTD, UNIT III SURVEY NO. 313, 314 BACHUPALLY (VILLAGE) QUTHUBULLAPUR (MANDAL) RR DISTRICT HYDERABAD ANDHRA PRADESH 500090	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X240.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2007

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1534	NDA/MAL/HDP/1 635	CADILA PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S LTD.	ORITAXIM 1000MG INJECTION	CEFOTAXIME SODIUM	1GM	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 G VIAL	01/07/1997
1535	NDA/MAL/HDP/1 636	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	VIGAMOX	MOXIFLOXACIN	5MG/ML	S.A.ALCON COUVREUR N.VRIJKSWEWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2013



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1536	NDA/MAL/HDP/1 638	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FLADAZOLE	SECNIDAZOLE	500MG	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	01/07/2005
1537	NDA/MAL/HDP/1 639	GLAXO SMITHLINE LIMITED	UNITED HEALTHCARE DISTRIBUTORS LTD	PANADOL EXTRA WITH OPTIZORB	PARACETAMOL + CAFFEINE	500MG + 65MG	GRANULES INDIA LIMITEDSY. NO. 160/A, 161/E, 162 & 174/A GAGILLAPUR VILLAGE, DUNDIGAL- GANDIMAISAMMA MANDAL, MEDCHAL - MALKHAJGIRI DISTRICT - 500043 TELENGANA	IRELAND INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER,1.0X100.0 TABLET CARTON	01/07/2003

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1538	NDA/MAL/HDP/1 641	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	UNIENZYME C MPS	NICOTINAMIDE+SIMETHICONE+PAPAN+FUNGAL DIASTASE+CHARCOAL	25MG+50MG+30MG+20MG+75MG	UNICHEM LABORATORIES LIMITEDC-31,32 & D-10, INDUSTRIAL AREA, MEERUT ROAD, GHAZIABAD, U.P.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2004
1539	NDA/MAL/HDP/1 646	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	BETROZOLE TABLETS	METRONIDAZOLE +DILOXANIDE	200MG+250MG	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BLISTER	01/07/2002

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1540	NDA/MAL/HDP/1 650	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	TEGRETOL CR 200	CARBAMAZEPINE	200MG	NOVARTIS FARMA S.P.A.-VIA PROVINCIALE SCHITO 131, 80058 TORRE ANNUNZIATA, ITALY	ITALY	ORAL SOLID RETARD TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2006
1541	NDA/MAL/HDP/1 651	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	MEGATRIM SUSPENSION	CO-TRIMOXAZOLE	240MG/5ML	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED VANDALUR ROAD	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	, 1X60 ML BOTTLE	01/07/1997

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1542	NDA/MAL/HDP/1 652	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	VALPARIN CHRONO 300	SODIUM VALPROATE	300MG	TORRENT PHARMACEUTICAL LTD AHMEDABAD- MEHSANA HIGHWAY, TALUKA- KADI, DIST. MEHSANA , INDRAD-382721	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2009
1543	NDA/MAL/HDP/1 656	AIVEEN (U) LIMITED	AIVEEN (U) LIMITED	AZIGYL-500	AZITHROMYCIN	500MG	MEDICO REMEDIES PVT LIMITED 8 & 9 DEWAN & SONS, UDYOG NAGAR PALGAR, DISTRICT THANE MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER, 1.0X3.0 TABLET BLISTER	01/07/2015

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1544	NDA/MAL/HDP/1 660	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOCIM-200	CIMEDITINE	200MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10 0.0X10.0 TABLET STRIP	01/07/2005
1545	NDA/MAL/HDP/1 661	ABBVIE (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	ALUVIA 100/25	LOPINAVIR/ RITONAVIR	100MG/25MG	ABBVIE DEUTSCHLAND GMBH & CO. KG.KNOLLSTASSE 50, D-67061, LUDWIGSHAFEN, GERMANY.	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2007

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1546	NDA/MAL/HDP/1 663	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	ALCID-PINK	ALUMINIUM HYDROXIDE/MAG NESIUM TRISILICATE	400MG+400MG/50 ML	TORQUE PHARMACEUTICALS PVT LTDISAAPUR P.O DAPPAR 140056 INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X400.0 ML BOTTLE,1.0X160.0 ML BOTTLE	01/07/2003
1547	NDA/MAL/HDP/1 665	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOXIN CAPSULES	AMOXICILLIN TRIHYDRATE	250MG	MILAN LABORATORIES (INDIA ) PVT LTD PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTDNO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSH OP 406 AND 407)	INDIA CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER,1.0X10. 0X10.0 CAPSULE BLISTER	01/07/1998

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1548	NDA/MAL/HDP/1 675	MERCK SHARP & DOHME BV	SURGIPHARM (U) LIMITED	GARDASIL	QUADRIVALENT HUMAN PAPILLOMAVIRUS RECOMBINANT VACCINE (TYPES 6, 11, 16, 18)	(20MCG+40MCG+4 0MCG+20MCG)/0. 5ML	MERK & CO. INCSUMNEYTOWN PIKE, P.O BOX 4, WEST POINT, PENNSYLVANIA, U.S. 19486, USA	UNITED STATES	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X0.5 ML PRE- FILLED SYRINGE (1 DOSE),1.0X10.0X0.5 ML VIAL (1 DOSE)	01/07/2007
1549	NDA/MAL/HDP/1 676	KOPRAN LIMITED	TATA UGANDA LIMITED	CLOXIN-250	CLOXACILLIN	250MG	KOPRAN LTDVILLAGE SAVROLI TAL KHARAPUR DIST RAIGAD 410 202	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CONTAINER,1.0X10 00.0 CAPSULE CONTAINER,1.0X10. 0X10.0 CAPSULE BLISTER	01/07/1997

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1550	NDA/MAL/HDP/1 678	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	HYDROCORTISON E SODIUM SUCCINATE	HYDROCORTISON E SODIUM SUCCINATE	100MG/VIAL	INDASI LIFESCIENCE PRIVATE LIMITED PLOT NO. 73 TO 77, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN - 396210, INDIA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X100.0 MG VIAL	01/07/2007
1551	NDA/MAL/HDP/1 679	LEBEN LABORATORIES PVT. LTD	MALIX PHARMA (U) LIMITED	CIPROLEB	CIPROFLOXACIN	500MG	LEBEN LABORATORIES PVT. LTD. PLOT NO. L-4, PHASE -III, M.I.D.C, AKOLA, 444104, MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007



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1552	NDA/MAL/HDP/1 680	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	H-CORT	HYDROCORTISON E	0.1%W/W	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997
1553	NDA/MAL/HDP/1 682	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICAL S LIMITED	TOFLOX-200	OFLOXACIN	200MG	LINCOLN PHARMACEUTICAL LIMITED TRIMAL ESTATE KHATRAJ KOLOL, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER, 1.0X10.0X1 .0X10.0 TABLET BLISTER	01/07/2005

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1554	NDA/MAL/HDP/1 689	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	OMESK	OMEPRAZOLE	20MG	S.KANT HEALTHCARE LTD PLOT 1802, 1805, GIDC PHASE III VAPI 39179, GUJARAT	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	01/07/2010
1555	NDA/MAL/HDP/1 690	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	FINALLERG	CETIRIZINE DIHYDROCHLORID E	1MG/ML	PHARMA INTERNATIONAL COMPANY MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2004

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1556	NDA/MAL/HDP/1 692	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFODOX 50MG/5ML SUSPENSION	CEFPODOXIME PROXETIL	50MG/5ML	PHARMA INTERNATIONAL CO.,AL-QASTAL AREA, AIRPORT ROAD, 11941, AMMAN	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X50.0 ML BOTTLE	01/07/2007
1557	NDA/MAL/HDP/1 693	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	OPTIMAL (0.05%) CREAM	TRETINOIN USP	0.5MG/1G	PHARMA INTERNATIONAL COMPANY .MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN	JORDAN	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	01/07/2005

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1558	NDA/MAL/HDP/1 697	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	FINALLERG	CETIRIZINE DIHYDROCHLORID E	10MG	PHARMA INTERNATIONAL COMPANYMAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2005
1559	NDA/MAL/HDP/1 698	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	AZICIP 500	AZITHROMYCIN	500MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED (CIPLAQCIL)PLOT 1- 7, 1ST RING ROAD, LUZIRA INDUSTRIAL PARK CIPLA LTD.VERNA IND. ESTATE GOA 403 722 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X1.0X3.0 TABLET BLISTER	01/07/2009

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1560	NDA/MAL/HDP/1 701	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FORMIN	METFORMIN HYDROCHLORIDE	500MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
1561	NDA/MAL/HDP/1 702	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	DELOR	CLOBETASOL PROPIONATE	0.05%W/W	PHARMA INTERNATIONAL COMPANYMAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	TOPICAL EXTERNAL OINTMENTS	1.0X25.0 G TUBE	01/07/2005

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1562	NDA/MAL/HDP/1704	DAFRA PHARMA LTD	MULTIPHAR UGANDA LIMITED	DAFRACLAV	AMOXYCILLIN + POTASSIUM CLAVULANATE	500MG + 125MG	BILIM ILAC SAN. VE. TIC. A.S.CERKEZKOY ORGANIZE SANAYI BOLGESI, KARAAGAC, MH. 5. SK. NO. 6, KAPAKLI - TEKIRDAG 59510	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X5.0 TABLET BLISTER	01/07/2011
1563	NDA/MAL/HDP/1707	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	FEBRICOL TABLETS	PARACETAMOL / PSEUDOEPHEDRINE / CHLORPHENIRAMINE	500MG / 30MG / 2MG	XEPA-SOUL PATTINSON (MALAYSIA) SDN BLD 1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X2.0X10.0 TABLET BLISTER	01/07/1997

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1564	NDA/MAL/HDP/1708	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	DENTAMOL	ACETAMINOPHEN	500MG	LABORATORY & ALLIED LTD PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/1997
1565	NDA/MAL/HDP/1709	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	LUCIN CREAM	HYDROCORTISON E	1%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE, 1.0X15.0 G TUBE, 1.0X5.0 G TUBE	01/07/1997

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1566	NDA/MAL/HDP/1711	KOPRAN LIMITED	TATA UGANDA LIMITED	AMYN-250	AMOXYCILLIN	250MG	KOPRAN LIMITED VILLAGE-SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER, 1.0X1000.0 CAPSULE CONTAINER	01/07/1997
1567	NDA/MAL/HDP/1713	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	LUMITER	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	OXALIS LABS VILLAGE THEDA P.O LODHIMAJRA, THESIL BADDI DISTRICT SOLAN HIMACHAL PRADESH MACLEODS PHARMACEUTICALS LIMITED, UNIT II PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN - 396210 (UT) - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X8.0 TABLET BLISTER, 1.0X1.0X6.0 TABLET BLISTER, 1.0X1.0X24.0 TABLET BLISTER, 1.0X30.0X12.0 TABLET BLISTER, 1.0X1.0X12.0 TABLET BLISTER, 1.0X30.0X18.0 TABLET BLISTER, 1.0X1.0X18.0 TABLET BLISTER, 1.0X30.0X6.0 TABLET BLISTER, 1.0X30.0X2.0 TABLET	01/07/2007



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1568	NDA/MAL/HDP/1715	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	MUCOLYN SYRUP	AMMONIUM CHLORIDE+CHLORPHENIRAMINE+DEXTROMETHORPHAN+BROMHEXINE	50MG+2MG+5MG+4MG	BETA HEALTHCARE INTERNATIONAL LTD -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	01/07/2011
1569	NDA/MAL/HDP/1723	USV PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GROVIT MULTIVITAMIN DROPS	MULTI-INGREDIENT	MULTI-INGREDIENT	SAKAR HEALTHCARE PVT LTDSAKAR HEALTHCARE PVT LTD, BLOCK NO 10-13, M.N. DESA	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X15.0 ML BOTTLE	01/07/2000

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1570	NDA/MAL/HDP/1724	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	AVAMYS NASAL SPRAY	FLUTICASONE FUROATE	27.5MCG/ACTUATION	GLAXO OPERATIONS UK LTD--HARMIRE ROAD, BARNARD CASTLE, DURHAM DL128 DT UK	UNITED KINGDOM	NASAL TOPICAL SPRAYS WITHOUT GAS	1.0X120.0 METERED DOSE CANNISTER	01/07/2009
1571	NDA/MAL/HDP/1725	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	MYCORIL CREAM 1%	CLOTRIMAZOLE	1%W/W	REMEDICA LIMITED LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2000

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1572	NDA/MAL/HDP/1 728	ARISTO PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	DELISPRIN 75MG	ASPIRIN	75MG	ARISTO PHARMACEUTICALS PVT LTD PLOT NO 208 NEW INDUSTRIAL GREEN NO2 MANDIDEED 462046	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP,1.0X10.0X14. 0 TABLET STRIP	01/07/2007
1573	NDA/MAL/HDP/1 730	COSMOS LTD	ASTRA PHARMA (U) LIMITED	ZITHROX	AZITHROMYCIN	500MG	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER	01/07/2008

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1574	NDA/MAL/HDP/1 731	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	MEDIVEN-S OINTMENT	BETAMETHASONE VALERATE + SALICYLIC ACID	0.05%W/W + 3%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997
1575	NDA/MAL/HDP/1 732	MICRO LABS LTD	LABOREX UGANDA LIMITED	CEFEX-250	CEPHALEXIN	250MG	MICROLABS LIMITEDPLOT NO. 121-124, KIADB, BOMMASANDRA , - JIGNI LINK ROAD, ANEKUL TALUK,BANGALORE, KARNATAKA, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1999

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1576	NDA/MAL/HDP/1 734	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMOMINT	COMPOUND MAGNESIUM TRISILICATE	500MG	TIL HEALTH CAREPLOT 100, WEST, R- 5, SOUTH; SRICITY SEZ, CHERIVI, IRUHUL AM, PSOT, SATYAVED U MANDAL, CHITTOOR DISTRICT-ANDRA PRADESH-517588, INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	10.0 TABLET CONTAINER, 250.0 TABLET CONTAINER, 500.0 TABLET CONTAINER, 100.0 TABLET CONTAINER, 1000.0 TABLET CONTAINER	01/07/1997
1577	NDA/MAL/HDP/1 736	MEDOCHÉMIE LTD	LABOREX UGANDA LIMITED	KLERIMED	CLARITHROMYCIN	500MG	MEDOCHÉMIE (FACTORY AZ).-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2009

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1578	NDA/MAL/HDP/1 739	MEDOCHÉMIE LTD	LABOREX UGANDA LIMITED	MELOX	MELOXICAM	15MG	MEDOCHÉMIE LTD PHARMACEUTICAL INDUSTRY-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2009
1579	NDA/MAL/HDP/1 741	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEOPRED-P	PREDNISOLONE ACETATE + NEOMYCIN SULPHATE+ POLYMYXIN-B	5MG/ML +5MG/ML + 1M I.U/ML	AMMAN PHARMACEUTICALS INDUSTRIES -.KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005

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1580	NDA/MAL/HDP/1 743	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	DAPRIL	LISINOPRIL DIHYDRATE	10MG	MEDOCHEMIE (FACTORY AZ).-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2009
1581	NDA/MAL/HDP/1 745	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APIGEN	GENTAMYCIN SULPHATE	0.3%W/V	AMMAN PHARMACEUTICALS INDUSTRIES- AMMAN PHARMACEUTICAL INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005

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1582	NDA/MAL/HDP/1 747	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	PRESARTAN H 50	LOSARTAN POTASSIUM + HYDROCHLOROT HIAZIDE	50MG + 12.5MG	IPCA LABORATORIES LTD PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2008
1583	NDA/MAL/HDP/1 748	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AZ-500	AZITHROMYCIN	500MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0 CAPSULE BLISTER	01/07/2011



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1584	NDA/MAL/HDP/1750	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APIFLOX	NORFLOXACIN	0.3%W/V	AMMAN PHARMACEUTICALS INDUSTRIES-AMMAN PHARMACEUTICAL INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005
1585	NDA/MAL/HDP/1751	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OPTIFUCIN	FUSIDIC ACID	1%W/V	AMMAN PHARMACEUTICALS INDUSTRIES -.KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X5.0 ML AMPOULE	01/07/2005

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1586	NDA/MAL/HDP/1754	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APIMOL	TIMOLOL MALEATE	0.5%W/V	AMMAN PHARMACEUTICALS INDUSTRIES -.KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X5.0 ML VIAL	01/07/2005
1587	NDA/MAL/HDP/1756	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APICROM 2%	SODIUM CROMOGLYCATE	2%W/V	AMMAN PHARMACEUTICALS INDUSTRIES -.KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005

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1588	NDA/MAL/HDP/1 758	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APICORT	PREDNISOLONE ACETATE	0.12%W/V	AMMAN PHARMACEUTICALS INDUSTRIES -.KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005
1589	NDA/MAL/HDP/1 760	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEODEX	NEOMYCIN +DEXAMETHASO NE	0.5%W/V + 0.1%W/V	AMMAN PHARMACEUTICALS INDUSTRIES- AMMAN PHARMACEUTICAL INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OTIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005

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1590	NDA/MAL/HDP/1761	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ATAZOR-R	ATAZANAVIR + RITONAVIR	300 MG + 100 MG	EMCURE PHARMACEUTICALS LTD .PLOT NO. P-2 IT-BT PARK PHASE II MIDC HINJWADI PUNE 411057	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2014
1591	NDA/MAL/HDP/1762	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APITROPIN	ATROPINE	1%W/V	AMMAN PHARMACEUTICALS INDUSTRIES .-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005

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1592	NDA/MAL/HDP/1763	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	ASPIRIN TABLETS BP	ACETYL SALICYLIC ACID	300MG	LABORATORY & ALLIED LTD.PLOT 209/10349 OFF MOMBASA RD NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X20.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER	01/07/1997
1593	NDA/MAL/HDP/1764	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	FRESH BURST LISTERINE	ALCOHOL + THYMOL	95 % W/V + 12 MG	JOHNSON&JOHNSON PTY LTD..241 MAIN ROAD RETREAT 794	SOUTH AFRICA	ORAL LIQUID ORDINARY LIQUIDS	1.0X250.0 ML CONTAINER,1.0X500.0 ML CONTAINER	01/07/2006

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1594	NDA/MAL/HDP/1 766	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	COLDEASE CAPSULES	PARACETAMOL+C AFFEINE CITRATE+CHLORP HENIRAMINE MALEATE+PSEUD OEPHEDRINE HYDROCHLORIDE	400MG+30MG+4M G+30MG	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2005
1595	NDA/MAL/HDP/1 769	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ENGERIX-B VACCINE	HEPATITIS B SURFACE ANTIGEN	10MCG/ML	GLAXOSMITHKLINE BOIOLOGICALSS.A RUE DE L'INSTITUT 89 B- 1330 RIXENSART	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X10.0X0.5 ML VIAL (1 DOSE),1.0X25.0X0.5 ML VIAL (1 DOSE)	01/07/1997

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1596	NDA/MAL/HDP/1772	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS LTD	GESTID TABLETS	COMPOUND MAGNESIUM TRISILICATE	385MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED, INDUSTRIAL AREA NO.3, A.B.ROAD DEWAS,455001 MADHYA PRADESH INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X4.0 TABLET BLISTER	01/07/2000
1597	NDA/MAL/HDP/1773	MICRO LABS LTD	LABOREX UGANDA LIMITED	LEVOBACT 500	LEVOFLOXACIN HEMIHYDRATE	500MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X20.0X5.0 TABLET BLISTER, 1.0X1.0X10.0 TABLET BLISTER	01/07/2005

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1598	NDA/MAL/HDP/1 777	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	NUZAC 20	FLUOXETINE	20MG	CIPLA LTD PLOT NO. L-139, VERNA, GOA 403 722 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2003
1599	NDA/MAL/HDP/1 779	BROOKES PHARMACEUTICAL LABORATORIES L	HARLEYS UGANDA LIMITED	PYODINE SOLUTION	POVIDONE IODINE	10.0G/100ML	BROOKES PHARMACEUTICALS LABORATORIES (PAKISTAN) LTD PLOT 58 SECTOR 15 KORANGI INDUSTRIAL AREA, KARACHI-PAKISTAN	PAKISTAN	TOPICAL EXTERNAL LIQUIDS	1.0X60.0 ML BOTTLE, 1.0X450.0 ML BOTTLE, 1.0X500.0 ML BOTTLE	01/07/1999



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1600	NDA/MAL/HDP/1 780	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENETRIM SUSPENSION	CO-TRIMOXAZOLE	240MG/5ML	RENE INDUSTRIES LIMITEDPLOT 680 KAMULI KIREKA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE	01/07/2000
1601	NDA/MAL/HDP/1 781	ASTRAZENECA	MACNAUGHTON LIMITED	ARIMIDEX	ANASTROZOLE	1MG	ASTRAZENECA PHARMACEUTICALS LPNEWARK, DELAWARE	UNITED STATES	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2000

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1602	NDA/MAL/HDP/1782	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CO-METHER	ARTEMETHER + LUMEFANTRINE	PER 5ML: 15MG + 90MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X30.0 ML BOTTLE	01/07/2010
1603	NDA/MAL/HDP/1783	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LAEOVATE OINTMENT	BETAMETHASONE VALERATE	0.1%W/W	LABORATORY & ALLIED LTD-PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X15.0 G TUBE	01/07/1997

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1604	NDA/MAL/HDP/1784	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	AZICURE-500	AZITHROMYCIN	500MG	MACLEODS PHARMACEUTICALS LIMITED (BLOCK -N1)VILLAGE THEDA, P.O. LODHI MAJRA,TEHSIL BADDI, HIMACHAL PRADESH - 174101,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER	01/07/2005
1605	NDA/MAL/HDP/1785	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	ACTION TABLETS	ACETYL SALICYLATE + CAFFEINE + PARACETAMOL	600MG+50MG+300MG	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X200.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER,1.0X110.0 TABLET STRIP,1.0X12.0 TABLET BLISTER	01/07/1997

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1606	NDA/MAL/HDP/1786	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGONAC TABLETS (THANE)	DICLOFENAC	50MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X1000.0 TABLET CONTAINER, 10.0X10.0 TABLET BLISTER	01/07/2001
1607	NDA/MAL/HDP/1790	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNITRIM TABLET	CO-TRIMOXAZOLE	480MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER, 1.0X250.0 TABLET CONTAINER, 1.0X100.0 TABLET CONTAINER	01/07/1997

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1608	NDA/MAL/HDP/1792	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	LIPODAR	ATORVASTATIN	20MG	DAR AL DAWANA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
1609	NDA/MAL/HDP/1795	KOPRAN LIMITED	TATA UGANDA LIMITED	AMPIK-250	AMPICILLIN	250MG	KOPRAN LIMITED VILLAGE-SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER, 1.0X1000.0 CAPSULE CONTAINER	01/07/1997

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1610	NDA/MAL/HDP/1796	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ZAHA 250	AZITHROMYCIN	250 MG	AJANTA PHARMA LIMITED PLOT NO.Z/103/A, DAHEJ SEZ PART 11, DISTRICT: BHARUCH, GUJARAT-392130 AJANTA PHARMA LIMITED PAITHAN MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASHTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER, 1.0X10.0X1.0X6.0 TABLET BLISTER	01/07/2006
1611	NDA/MAL/HDP/1797	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD	TATA UGANDA LIMITED	AMPICILLIN+CLOxacillin	AMPICILLIN + CLOxacillin	250 MG + 250 MG	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD #14, II PHASE PIA, BANGALORE 560058	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X500.0 MG VIAL	01/07/2010

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1612	NDA/MAL/HDP/1799	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	SECZOL DS	SECNIDAZOLE	1GM	INTAS PHARMACEUTICALS LTD PLOT 457/458, SARKHEJ BAVLA HIGHWAY MATODA 382 210 TAL: SANAND, AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	01/07/2001
1613	NDA/MAL/HDP/1800	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AMLONG-10	AMLODIPINE	10MG	MICRO LABS LTD 92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	01/07/2009

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1614	NDA/MAL/HDP/1 801	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	LABESTEN PESSARIES	CLOTRIMAZOLE	100MG	LABORATORY & ALLIED LTD.--PLOT 209/10349 OFF MOMBASA RD NAIROBI	KENYA	VAGINAL TABLETS	1.0X1.0X6.0 PESSARY STRIP	01/07/1997
1615	NDA/MAL/HDP/1 803	ASTRA ZENECA AB	MACNAUGHTON LIMITED	NEXIUM 40MG	ESOMEPRAZOLE	40MG	ASTRAZENECA AB.GARTUNA & SNACKVIKEN STOCKHOLM	SWEDEN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X7.0 TABLET BLISTER,1.0X14.0 TABLET CARTON,1.0X28.0 TABLET CARTON	01/07/2001



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1616	NDA/MAL/HDP/1807	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	AMPICLOX NEONATAL DROPS	AMPICILLIN + CLOXACILLIN	60 MG / 0.6 ML + 30 MG / 0.6 ML	MEDREICH STERILAB LTD12TH MILE, OLD MADRAS ROAD, VIRGONAGOR, BANGALORE 560049, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X8.0 ML BOTTLE	01/07/1997
1617	NDA/MAL/HDP/1809	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOVIT-6	PYRIDOXINE	25MG	AGOG PHARMA LTDPLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER	01/07/2004

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1618	NDA/MAL/HDP/1810	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOTRI	TRIFLUOPERAZINE	5MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2010
1619	NDA/MAL/HDP/1811	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	DUOVIR TABLETS	ZIDOVUDINE+ LAMIVUDINE	300MG + 150MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED - PLOT 1-7 1ST RING ROAD, LUZIRA, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X6.0X10.0 TABLET BLISTER,1.0X60.0 TABLET BOTTLE	01/07/2001

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1620	NDA/MAL/HDP/1 812	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REQUIN TABLETS	QUININE SULPHATE	300MG	RENE INDUSTRIES LIMITED PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10. 0X10.0 TABLET BLISTER	01/07/2001
1621	NDA/MAL/HDP/1 813	DAWA LIMITED	SUPER MEDIC LTD	MOXAFORTE	AMOXICILLIN + FLUCLOXACILLIN	125 MG + 125MG	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2014

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1622	NDA/MAL/HDP/1 815	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	SUPIROCIN OINTMENT	MUPIROCIN	2%W/W	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL OTHER OINTMENTS	1.0X15.0 G TUBE,1.0X5.0 G TUBE	01/07/2003
1623	NDA/MAL/HDP/1 816	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	DRESS UP CREAM	NEOMYCIN SULPHATE	0.5%W/W	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	01/07/1998

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1624	NDA/MAL/HDP/1 820	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	AZICIN-250	AZITHROMYCIN	250MG	EAST AFRICAN (INDIA) OVERSEAS- PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	01/07/2009
1625	NDA/MAL/HDP/1 821	BLUE CROSS LABORATORIES LTD	STAR PHARMACEUTICAL S LTD	MEFTAL 500 TABLETS	MEFENAMIC ACID	500MG	BLUE CROSS LABORATORIES LTDL- 17, VERNA INDUSTRIAL ESTATE,VERNA GOA- 403722	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/1997

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1626	NDA/MAL/HDP/1 822	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	EPHEDRINE	EPHEDRINE HYDROCHLORIDE	30MG	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2005
1627	NDA/MAL/HDP/1 825	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	COLDEASE SYRUP	PARACETAMOL+C HLORPHENIRAMI NE MALEATE+PSEUD OEPHEDRINE HYDROCHLORIDE	120MG+2MG+15M G	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2005

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1628	NDA/MAL/HDP/1 827	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	ALBASOL SUSPENSION	ALBENDAZOLE	200MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	01/07/2006
1629	NDA/MAL/HDP/1 840	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	OVA-MIT	CLOMIPHENE	50MG	REMEDICA LIMITED AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2011

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1630	NDA/MAL/HDP/1 841	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	FUNGNIL CREAM	CLOTRIMAZOLE	1%W/W	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2000
1631	NDA/MAL/HDP/1 842	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	SUGAQUIN TABLETS	CHLOROQUINE PHOSPHATE	250MG	KAMPALA PHARMACEUTICALS INDUSTIESPLOT NO M44B STRETCHER ROAD INTINDA	UGANDA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2002



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1632	NDA/MAL/HDP/1 843	USV PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ECORIN-75	ASPIRIN	75MG	REMEDEX PHARMAB- 249/250 PEENYA INDUSTRIAL ESTATE BANGALORE 560 058	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
1633	NDA/MAL/HDP/1 844	GUILIN PHARMACEUTICAL S CO.LTD	TRIDEM PHARMA UGANDA LIMITED	SULFAMETHOXAZ OLE / TRIMETHOPRIM	SULFAMETHOXAZ OLE / TRIMETHOPRIM	800MG /160MG	GUILIN PHARMACEUTICAL CO.LTD.NO.43 QUILIDIAN ROAD GUILIN 541002, GUANGXI, CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2011

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1634	NDA/MAL/HDP/1 846	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	ANTAGIT DS GEL ORANGE FLAVOUR	ALUMINIUM HYDROXIDE + MAGNESIUM + SIMETHICONE	400MG + 400MG + 50MG	LEBEN LABORATORIES PVT. LTD.PLOT NO. L-4, PHASE –III, M.I.D.C, AKOLA, 444104, MAHARASHTRA, INDIA.	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X170.0 ML BOTTLE	01/07/2013
1635	NDA/MAL/HDP/1 848	LABORATORY&ALLI ED LTD	HARLEYS UGANDA LIMITED	PARATAL	PARACETAMOL	500MG	LABORATORY & ALLIED LTD-PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/1997

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1636	NDA/MAL/HDP/1 849	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	CIFIN	CIPROFLOXACIN	0.2%W/V	ABACUS PARENTERAL DRUGS LTD PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE,  MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2011
1637	NDA/MAL/HDP/1 850	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	ALZOL TABLETS	ALBENDAZOLE	400MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER, 1.0X10 00.0 TABLET CONTAINER	01/07/2010

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1638	NDA/MAL/HDP/1 851	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	CAPSIFENAC GEL	CAPSAICIN + DICLOFENAC + LEVOMENTHOL + METHYL SALICYLATE	0.438 G + 0.335 G + 0.135 G + 0.918 G	STEDMAN PHARMACEUTICALS PVT LIMITED NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	TOPICAL EXTERNAL EMULSION GELS	1.0X1.0X20.0 G TUBE, 1.0X1.0X10.0 G TUBE	01/07/2011
1639	NDA/MAL/HDP/1 852	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICAL S LTD	VERCEF ORAL SUSPENSION	CEFACLOR	125MG/5ML	SUN PHARMACEUTICAL INDUSTRIES LIMITED INDUSTRIAL AREA 3, A.B. ROAD, DEWAS 455001, MADHYA PRADESH, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

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1640	NDA/MAL/HDP/1 853	ORGANON SOUTH AFRICA (PTY) LTD	SURGIPHARM (U) LIMITED	AERIUS ORAL SOLUTION	DES Loratadine	0.5MG/ML	SCHERING-PLOUGH LABO N.V-- INDUSTRIE PARK 30, ZONE A 2220 HEIST- OP-DEN-BERG	BELGIUM	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE,1.0X150.0 ML BOTTLE	01/07/2007
1641	NDA/MAL/HDP/1 854	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	FUROSEMIDE INJECTION	FUROSEMIDE	10MG/ML	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE,1.0X100. 0X2.0 ML AMPOULE	01/07/2004

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1642	NDA/MAL/HDP/1 856	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PROPRANOLOL TABLETS B.P. 40MG	PROPRANOLOL HYDROCHLORIDE	40MG	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1998
1643	NDA/MAL/HDP/1 861	GUILIN PHARMACEUTICAL S CO LTD	TRIDEM PHARMA UGANDA LIMITED	SULFAMETHOXAZ OLE / TRIMETHOPRIM	SULFAMETHOXAZ OLE / TRIMETHOPRIM	400MG /80MG	GUILIN PHARMACEUTICAL CO.LTD.NO.43 QUILIDIAN ROAD GUILIN 541002, GUANGXI, CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2011

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1644	NDA/MAL/HDP/1 863	AMOUN PHARMACEUTICAL S COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ORACURE GEL	LIDOCAINE HCL+CETYL PYRIDINUM CHLORIDE	2 GM+0.1 GM	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	EGYPT	ORAL TOPICAL GELS AND SOLS	1.0X15.0 G TUBE	01/07/2004
1645	NDA/MAL/HDP/1 864	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	PATANOL	OLOPATADINE HYDROCHLORIDE	0.1%W/V	ALCON COUVREUR NVRJKSWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML VIAL	01/07/2009

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1646	NDA/MAL/HDP/1 877	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	MINT-O-COOL	DRIED ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE	120MG + 250MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER, 1.0X10 00.0 TABLET CONTAINER	01/07/2007
1647	NDA/MAL/HDP/1 879	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPENIV	PHENOXYMETHYL PENICILLIN	250MG	SPARSH BIO-TECH LTD PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10. 0X10.0 TABLET BLISTER	01/07/2004



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1648	NDA/MAL/HDP/1 880	SPARSH BIO-TECH PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMCLOX	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	SPARSH BIO-TECH LTD PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER,1.0X10 0.0X10.0 CAPSULE BLISTER	01/07/2004
1649	NDA/MAL/HDP/1 881	SPARSH BIO-TECH PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMOX	AMOXYCILLIN	250MG	SPARSH BIO-TECH PVT. LIMITED PLOT NO. 1; SURVEY NO. 242/243/244, LAKHA BAVAD, JAMNAGAR- 361 006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0X10.0 CAPSULE BLISTER,1.0X1.0X10 00.0 CAPSULE CONTAINER,1.0X10. 0X10.0 CAPSULE BLISTER	01/07/2004

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1650	NDA/MAL/HDP/1 882	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMCIL	AMPICILLIN	250MG	SPARSH BIO-TECH LTD PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER,1.0X10. 0X10.0 CAPSULE BLISTER	01/07/2004
1651	NDA/MAL/HDP/1 887	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMADOL	PARACETAMOL	500MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X10.0 TABLET BLISTER,100.0 TABLET CONTAINER,250.0 TABLET CONTAINER,500.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1997

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1652	NDA/MAL/HDP/1 889	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM PRED SOL	PREDNISOLONE	5MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X50 0.0 TABLET CONTAINER,1.0X25 0.0 TABLET CONTAINER,1.0X10 0.0 TABLET CARTON,1.0X10.0 TABLET CARTON	01/07/1997
1653	NDA/MAL/HDP/1 891	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	LEVOMAC 500	LEVOFLOXACIN	500MG	MACLEODS PHARMACEUTICALS LTD PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X20.0X5.0 TABLET BLISTER	01/07/2005

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1654	NDA/MAL/HDP/1 892	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	LEVOMAC 250	LEVOFLOXACIN	250MG	MACLEODS PHARMACEUTICALS LTD PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X20.0X5.0 TABLET BLISTER	01/07/2012
1655	NDA/MAL/HDP/1 894	KOPRAN LIMITED	TATA UGANDA LIMITED	TRIM-480	CO-TRIMOXAZOLE	480MG	KOPRAN LIMITEDVILLAGE- SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997

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1656	NDA/MAL/HDP/1 895	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	TRIMAGO (PAEDIATRIC)	CO-TRIMOXAZOLE	100MG/20MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10 0.0X10.0 TABLET BLISTER	01/07/2007
1657	NDA/MAL/HDP/1 898	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	ZAPACID - 30	LANSOPRAZOLE	30MG	WIN MEDICARE PVT LIMITED MEERUT, MUZAFFARNAGER ROAD, MODIPURAM - 250110, UTTAR PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	3.0X10.0 CAPSULE BLISTER	01/07/2001

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1658	NDA/MAL/HDP/1900	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOM 20	OMEPRAZOLE	20MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER,1.0X10.0X10.0 CAPSULE STRIP	01/07/2007
1659	NDA/MAL/HDP/1901	AJANTA PHARMA LTD 31-0	ABACUS PHARMA (AFRICA) LIMITED	IBUMOL	IBUPROFEN + PARACETAMOL	100MG + 162.5 MG /5ML	AJANTA PHARMA LIMITED 31-0 MIDC INDUSTRIAL AREA CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA STATE	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2013

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1660	NDA/MAL/HDP/1 902	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMODIUM	LOPERAMIDE HYDROCHLORIDE	2MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1997
1661	NDA/MAL/HDP/1 911	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CODEINE PHOSPHATE TABLETS BP 30	CODEINE PHOSPHATE	30MG	COSMOS LIMITED RANGWA ROAD, OFF LUNGA LUNGA ROAD, INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1998

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1662	NDA/MAL/HDP/1 912	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	D-WORM	ALBENDAZOLE	200MG	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	01/07/2008
1663	NDA/MAL/HDP/1 914	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	CHLORPHENIRAM INE	CHLORPHENIRAM INE	4MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2003



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1664	NDA/MAL/HDP/1 919	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	CANDIDERM CREAM	BECLOMETASONE /CLOTRIMAZOLE/ GENTAMYCIN	0.025%W/W+1%W /W+0.1%W/W	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE,1.0X15.0 G TUBE	01/07/1999
1665	NDA/MAL/HDP/1 922	IPCA LABORATORIES	MEDVIN PHARMA LIMITED	AZIFAST-500	AZITHROMYCIN	500MG	IPCA LABORATORIES LTD,PLOT NO. T-139 SEJAVTA, RATLAM- 457 002 (M.P.) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X3.0 TABLET BLISTER	01/07/2007

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1666	NDA/MAL/HDP/1924	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	AMPICILLIN SODIUM	AMPICILLIN SODIUM	500MG	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTDNO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSH OP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X500.0 MG VIAL	01/07/2013
1667	NDA/MAL/HDP/1927	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	INTAPLEX TABLET	VITAMIN B COMPOUND	N/A	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER	01/07/1997

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1668	NDA/MAL/HDP/1 928	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	NEUTRAFLUX	ALGINIC ACID + MAGNESIUM HYDROXIDE +ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE + SIMETHICONE	200MG + 250MG +250MG +250MG + 125MG	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2013
1669	NDA/MAL/HDP/1 931	ASTRAZENECA	MACNAUGHTON LIMITED	ZOLADEX LA	GOSERELIN ACETATE	10.8MG	ASTRA ZENECA UK LIMITEDASTRAZENECA UK LIMITED SILK ROAD BUSINESS PARK, MACCLES FIELD,CHESHIRE SK 10 2NA,	UNITED KINGDOM	PARENTERAL RETARD PRE- FILLED SYRINGES	1.0X10.8 MG IMPLANT	01/07/2010

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1670	NDA/MAL/HDP/1 932	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	CANDISTAT CREAM	CLOTRIMAZOLE	1%W/W	ELYS CHEMICAL INDUSTRIES LIMITED- ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	KENYA	ORAL TOPICAL CREAMS	1.0X20.0 G TUBE	01/07/2001
1671	NDA/MAL/HDP/1 934	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENECHLOR SUSPENSION	CHLORAMPHENIC OL	125MG/5ML	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2001

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1672	NDA/MAL/HDP/1 937	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	EFAVIRENZ	EFAVIRENZ	600MG	AUROBINDO PHARMA LIMITED (UNIT III) AURO HOUSE, 313, BUCHUPALLY, QUTHUBULLAPAR(M , RR DISTRICT HYDERABAD- 500090, ANDHERA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2005
1673	NDA/MAL/HDP/1 938	YURIA-PHARM LTD	PHARMA VILLE LIMITED	INFULGAN	PARACETAMOL	10MG/ML	YURIA-PHARM LLC MANUFACTURING SITE NO. 1108, KOBZARSKA STREET, CHERKASY, 18030	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE,1.0X20.0 ML BOTTLE	01/07/2013

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1674	NDA/MAL/HDP/1941	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	RABELOX IV	RABEPRAZOLE	20MG/VIAL	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL	01/07/2005
1675	NDA/MAL/HDP/1942	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	AMCLOREN	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CONTAINER	01/07/2009

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1676	NDA/MAL/HDP/1 943	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	NITROCONTIN 2.6	NITROGLYCERIN (CONTROLLED RELEASE)	2.6MG	MODI MUNDIPHARMA (PVT) LTDMEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID RETARD TABLETS	1.0X25.0 TABLET CONTAINER	01/07/2009
1677	NDA/MAL/HDP/1 946	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	SOLUDOL TABLETS	DICLOFENAC SODIUM	50MG	WIN MEDICARE PVT LIMITEDMEERUT, MUZAFFARNAGER ROAD, MODIPURAM - 250110, UTTAR PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	10.0X10.0 TABLET STRIP	01/07/1998

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1678	NDA/MAL/HDP/1 948	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	ZITHROMAX	AZITHROMYCIN DIHYDRATE	500MG	HAUPT PHARMA LATINA S.R.L LATINA- SS 156KM 47,600- 04100,BORGO SAN,MICHELE	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER,1.0X2.0 TABLET BLISTER	01/07/1998
1679	NDA/MAL/HDP/1 949	MACLEODS PHARMACEUTICAL S LTDS LTD	VITACARE LIMITED	TRENAXA 500	TRANEXAMIC ACID	500MG	MACLEODS PHARMACEUTICALS PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X6.0 TABLET BLISTER	01/07/2011



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1680	NDA/MAL/HDP/1 951	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	CLOPI 75	CLOPIDOGREL	75MG	MACLEODS PHARMACEUTICALS PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA MACLEODS PHARMACEUTICALS LIMITED, UNIT VIVILLAGE THEDA, KHARUNI LODHI MAJRA RD, TEHSIL BADDI N2, DISTRICT SOLAN, HIMACHAL	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	01/07/2006
1681	NDA/MAL/HDP/1 956	MILAN LABORATORIES LTD	GITTOES PHARMACEUTICAL S LIMITED	MILOXY	AMOXYCILLIN	250MG	MILAN LABORATORIES (INDIA) PVT LTD PLOT NOS 63, 67 & 87, JAWAHAR CO-OP. INDUSTRIAL ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/2006

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1682	NDA/MAL/HDP/1 958	MILAN LABORATORIES LTD	GITTOES PHARMACEUTICAL S LIMITED	MILOXY	AMOXYCILLIN	125MG/5ML	MILAN LABORATORIES (INDIA) PVT LTD PLOT NOS 63, 67 & 87, JAWAHAR CO-OP. INDUSTRIAL ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2005
1683	NDA/MAL/HDP/1 959	MILAN LABORATORIES PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	BETRIM 480	CO-TRIMOXAZOLE	480MG	MILAN LABORATORIES (INDIA) PVT LTD PLOT NOS 63, 67 & 87, JAWAHAR CO-OP. INDUSTRIAL ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10. 0X10.0 TABLET BLISTER	01/07/2005

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1684	NDA/MAL/HDP/1 960	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	DIFENAC	DICLOFENAC SODIUM	50MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD PLOT NO. M444B, STRETCHER ROAD, NTINDA, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2003
1685	NDA/MAL/HDP/1 966	MACK BROWN PHARMACEUTICAL S PVT LIMITED	SHURIK LTD	PARACIN	PARACETAMOL	500MG	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2005

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1686	NDA/MAL/HDP/1 969	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN SR 75MG	DICLOFENAC SODIUM	75MG	NOVARTIS PHARMA SPA, TORRE ANNUNZIATA ITALY- NA	ITALY	ORAL SOLID RETARD TABLETS	1.0X30.0 TABLET CONTAINER	01/07/1997
1687	NDA/MAL/HDP/1 970	MACK BROWN PHARMACEUTICAL S PVT LIMITED	SHURIK LTD	CETRAMAC	CETIRIZINE	10MG	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

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1688	NDA/MAL/HDP/1 971	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOMPICLOX ORAL SUSPENSION	AMPICILLIN + CLOXACILLIN	125 MG/5ML + 125 MG/5ML	MILAN LABORATORIES (INDIA ) PVT LTD PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTR A-410209,INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1998
1689	NDA/MAL/HDP/1 974	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	CEFROTIL	CEFUROXIME AXETIL	500MG	SAKAR HEALTH CARE PVT, LTDBLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ- BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2013

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1690	NDA/MAL/HDP/1 975	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	BET-CODERM N	BETAMETHASONE + NEOMYCIN	0.1 W/W + 0.5 W/W	LINCOLN PHARMACEUTICALS LTD10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI, KHATRAJ-382721, GHANDINAGAR ARAT, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2007
1691	NDA/MAL/HDP/1 977	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	LOSAR-H	LOSARTAN + HYDROCHLOROT HIAZIDE	50MG + 12.5MG	UNICHEM LABORATORIES LIMITEDUNICHEM LABORATORIES LIMITED. UNIT II, VILLAGE BHATAULI KALAN, BADDI, DIST. SOLAN PIN CODE 173 205, HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011

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1692	NDA/MAL/HDP/1 984	ELI-LILLY (SUISSE) SA	LABOREX UGANDA LIMITED	CIALIS	TADALAFIL	20MG	LILLY SA, AVDA DE LA INDUSTRIALILLY SA, AVDA DE LA INDUSTRIA, 30 28108 ALCOBENDAS - MADRID	SPAIN	ORAL SOLID ORDINARY TABLETS	2.0X2.0 TABLET BLISTER	01/07/2004
1693	NDA/MAL/HDP/1 987	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	FOMYCETIN	CHLORAMPHENIC OL	250MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDAL UR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X10. 0X10.0 CAPSULE BLISTER	01/07/1997

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1694	NDA/MAL/HDP/1 989	FERRER INTERNACIONAL S.A	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DERMOFIX	SERTACONAZOLE NITRATE	2%W/W	FERRER INTERNATIONAL, S.A.C/JOAN BUSCALLA, 1- 9.08173 SANT CUGAT DEL VALLES, BARCELONA	SPAIN	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2014
1695	NDA/MAL/HDP/1 990	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TAGERA FORTE	SECNIDAZOLE	1G	UNICHEM LABORATORIES LTDUNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205 UNICHEM LABORATORIES LTD-- C31 & 32 INDUSTRIAL AREA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X2.0 TABLET BLISTER	01/07/2005



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1696	NDA/MAL/HDP/1997	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	TENA-100	ATENOLOL	100MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER,1.0X2.0X14.0 TABLET BLISTER,1.0X1000.0 TABLET JAR (WITH STATEMENT "FOR HOSPITAL USE ONLY".)	01/07/2011
1697	NDA/MAL/HDP/1999	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	CARBATOL 200	CARBAMAZEPINE	200MG	TORRENT PHARMACEUTICALS LTD INDRAD-382721, TAL KADI, AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,2.0X5.0X10.0 TABLET BLISTER	01/07/2000

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1698	NDA/MAL/HDP/2000	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	CALCIGARD RETARD	NIFEDIPINE(SR)	20MG	TORRENT PHARMACEUTICALS LTD INDRAD-382721, TAL KADI, AHMEDABAD, INDIA	INDIA	ORAL SOLID RETARD TABLETS	1.0X2.0X5.0X10.0 TABLET BLISTER	01/07/2000
1699	NDA/MAL/HDP/2004	MEDLEY PHARMACEUTICALS LTD	EUROPA HEALTHCARE (U) LTD	R.B.TONE	FERROUS GLUCONATE + VITAMIN C + VITAMIN B12 + VITAMIN B1 + VITAMIN B2 + VITAMIN B6 + CALCIUM PANTOTHENATE + VITAMIN B3 + FOLIC ACID + DIBASIC CA PO4 + ZINC SULPHATE	200MG + 38MG + 4MCG + 3MG + 2.5MG + 1MG + 2.5MG + 1MG + 2.5MG + 23MG + 0.5MG + 100MG + 33MG	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X15.0 CAPSULE BLISTER	01/07/2008

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1700	NDA/MAL/HDP/2005	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	KAMAGRA-100	SILDENAFIL CITRATE	100MG	AJANTA PHARMA LIMITED PLOT NO.Z/103/A, DAHEJ SEZ PART 11, DISTRICT: BHARUCH, GUJARAT-392130 AJANTA PHARMA LIMITED PAITHAN MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASHTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2005
1701	NDA/MAL/HDP/2008	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	CANDID -B-CREAM	CLOTRIMAZOLE + BECLOMETASONE DIPROPIONATE CREAM	1%W/W + 0.025%W/W	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39, D	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2004

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1702	NDA/MAL/HDP/2009	COSMOS LTD	ASTRA PHARMA (U) LIMITED	ZITHROX	AZITHROMYCIN	200MG/5ML	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X15.0 ML BOTTLE,1.0X30.0 ML BOTTLE	01/07/2010
1703	NDA/MAL/HDP/2012	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS LTD	CANDID -B- LOTION	CLOTRIMAZOLE + BECLOMETHASONE DIPROPIONATE	1%W/V + 0.025%W/V	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL LOTIONS	1.0X15.0 ML BOTTLE	01/07/2004

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1704	NDA/MAL/HDP/2 014	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	CANI-MAKS	CLOTRIMAZOLE	1%W/W	S KANT HEALTHCARE LTD1802-1805 GIDC OHASE II VAPS- 396195, GUJARAT, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	01/07/2009
1705	NDA/MAL/HDP/2 016	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICAL S LTD	CANDID CREAM	CLOTRIMAZOLE	1%W/W	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2000

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1706	NDA/MAL/HDP/2018	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	ORAXIN SYRUP	CYPROHEPTADINE+TRICHOLINE CITRATE	2MG+275MG	CENTAUR PHARMACEUTICALS LTD,-KARASWADA MAPUSA GOA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/1997
1707	NDA/MAL/HDP/2019	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOHAL	HALOPERIDOL	10MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2011

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1708	NDA/MAL/HDP/2020	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	QUINE	QUININE SULPHATE	300MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X500.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER,1.0X250.0 TABLET CONTAINER	01/07/1997
1709	NDA/MAL/HDP/2022	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	TORACTIN	CYPROHEPTADINE	2MG/5ML	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1997

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1710	NDA/MAL/HDP/2024	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	NEXPRO - 40	ESOMEPRAZOLE MAGNESIUM TABLET	40MG	TORRENT PHARMACEUTICALS LTDINDRAD-382 721, DIST.MEHSANA,INDIA.A.AT:VILL.MANAKPUR,TEH.NALAGARH,DIST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2004
1711	NDA/MAL/HDP/2025	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	FERRO-B COMPLEX SYRUP	MULTI-INGREDIENT	MULTI-INGREDIENT	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/1997



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1712	NDA/MAL/HDP/2026	BROOKES PHARMACEUTICAL LABORATORIES L	HARLEYS UGANDA LIMITED	CORAM 10MG	AMLODIPINE BESYLATE	10MG	BROOKES PHARMACEUTICALS LABORATORIES (PAKISTAN) LTD PLOT 58 SECTOR 15 KORANGI INDUSTRIAL AREA, KARACHI-PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER, 1.0X10.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	01/07/2009
1713	NDA/MAL/HDP/2027	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CO-ANGINET 160/12.5MG	VALSARTAN + HYDROCHLOROT HIAZIDE	160MG + 12.5MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTDP.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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1714	NDA/MAL/HDP/2029	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	CHLORAMPHENIC OL PALMITATE	CHLORAMPHENIC OL PALMITATE	125MG/5ML	MEDICAMEN BIOTECH LTDSP-1192, A &B, PHASE -IV, INDUSTRIAL AREA BHIWADI -301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2014
1715	NDA/MAL/HDP/2033	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ANGIZAAR-50	LOSARTAN POTASSIUM	50MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2009

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1716	NDA/MAL/HDP/2035	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	NEOSIDAR	SULPHADOXINE + PYRIMETHAMINE	500MG + 25MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X25.0X3.0 TABLET BLISTER,1.0X50.0X3.0 TABLET BLISTER	01/07/2004
1717	NDA/MAL/HDP/2036	ELI-LILLY (SUISSE) SA	LABOREX UGANDA LIMITED	HUMULIN REGULAR	HUMAN INSULIN	100IU	LILLY FRANCE SAFRANCE ELI LILLY & COMPANY LILLY TECHNOLOGY CENTER, 1555 S HARDING, INDIANAPOLIS, INDIANA, 46221	FRANCE UNITED STATES OF AMERICA	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE	01/07/1998

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1718	NDA/MAL/HDP/2040	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN 20/120	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	AJANTA PHARMA LIMITED PLOT NO.Z/103/A, DAHEJ SEZ PART 11, DISTRICT: BHARUCH, GUJARAT-392130 AJANTA PHARMA LIMITED PAITHAN MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASHTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0X12.0 TABLET BLISTER, 1.0X3.0X8.0 TABLET BLISTER, 1.0X30.0X24.0 TABLET BLISTER, 1.0X30.0X18.0 TABLET BLISTER, 1.0X30.0X12.0 TABLET BLISTER, 1.0X1.0X6.0 TABLET BLISTER, 1.0X1.0X12.0 TABLET BLISTER, 1.0X1.0X24.0 TABLET	01/07/2006
1719	NDA/MAL/HDP/2042	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	BURN CURE	SILVER SULFADIAZINE	1%W/W	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR-401210, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997

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1720	NDA/MAL/HDP/2 046	COSMOS LTD	ASTRA PHARMA (U) LIMITED	LORHISTINA	LORATADINE	10MG	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2005
1721	NDA/MAL/HDP/2 047	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	RITONAVIR	RITONAVIR	100MG	MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET CONTAINER,1.0X30. 0 TABLET BOTTLE	01/07/2011

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1722	NDA/MAL/HDP/2053	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ASOMEX-5	AMLODIPINE BESILATE	5MG	EMCURE PHARMACEUTICALS LTD LANE NO.3 PHASE II,SIDCO INDUSTRIAL COMPLEX,BARI-BRAHMANA JAMMU 181 133, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2005
1723	NDA/MAL/HDP/2055	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	ARTESUN	ARTESUNATE	120MG	GUILIN PHARMACEUTICAL CO. LTD.NO. 43 QILIDIAN ROAD, GUILIN 541004	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X120.0 MG VIAL + 1 *2 ML AMPOULE OF 5% SODIUM BICARBONATE SOLUTION + 1*10 ML AMPOULE OF 0.9% SODIUM CHLORIDE	01/07/2011

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1724	NDA/MAL/HDP/2 056	WOCKHARDT LTD	STAR PHARMACEUTICAL S LTD	BRO-ZEDEX	TERBUTALINE SULPHATE +BROMHEXINE HYDROCHLORIDE +GUAIPHENESIN+ MENTHOL	1.25MG+ 4 MG+50 MG+2.5 MG/5 ML	NAXPAR PHARMA PRIVATE LIMITED182, VILLAGE GURUMAJRA, TEHSIL NALAGARH, BADDI, DIST. SOLAN (H.P), 174101 INDIA.	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997
1725	NDA/MAL/HDP/2 058	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	QUININE SULPHATE	QUININE SULPHATE	300MG	MACLEODS PHARMACEUTICALS PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2006

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1726	NDA/MAL/HDP/2061	RENE PHARMACY(R) LTD..	RENE PHARMACY LTD	ADSOCARB TABLETS	ACTIVATED CHARCOAL	250MG	CYANO PHARMA(P)115-C IND ESTATE POLOGROUND, INDORE 452015	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER	01/07/1997
1727	NDA/MAL/HDP/2062	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED		DEXTROMETHORPHAN HYDROBROMIDE BP + CHLORPHENIRAMINE MALEATE BP + AMMONIUM CHLORIDE BP + PSEUDOEPHEDRINE HYDROCHLORIDE BP	(5MG + 2MG + 50MG + 10MG)/5ML	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO LR 209/6534 MOGADISHU ROAD	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	01/07/2006



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1728	NDA/MAL/HDP/2 063	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	MICROGYNON FE	LEVONORGESTRE L/ ETHINYLESTRADI OL.	0.15MG / 0.03MG	BAYER PHARMA A.GMULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X28.0 TABLET BLISTER	01/07/1997
1729	NDA/MAL/HDP/2 066	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	METHOTREXATE	METHOTREXATE	2.5MG	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

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1730	NDA/MAL/HDP/2 067	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	ZYNCET	CETIRIZINE DIHYDROCHLORID E	10MG	UNICHEM LABORATORIES LIMITED UNIT IIVILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X5.0X10.0 TABLET BLISTER	01/07/1999
1731	NDA/MAL/HDP/2 068	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	DOMADOL	TRAMADOL HYDROCHLORIDE	50MG	UNICHEM LABORATORIES LIMITED UNIT IIVILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1999

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1732	NDA/MAL/HDP/2 069	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	SK DERM	BETAMETHASONE + CLOTRIMOXAZOL E + GENTAMYCIN	0.05%W/W + 1%W/W + 0.1%W/W	S KANT HEALTHCARE LTD PLOT NO. 1802- 1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE, 1.0X30.0 G TUBE, 1.0X100.0 G TUBE, 1.0X100.0 G TUBE	01/07/2010
1733	NDA/MAL/HDP/2 070	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	MIRENA	LEVONORGESTRE L	52MG	BAYER OY PANSIONATE 47 20210 TURKU FINLAND	FINLAND	PARENTERAL RETARD IMPLANTS	1.0X1.0 IMPLANT CARTON	01/07/2009

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1734	NDA/MAL/HDP/2071	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	CEFAMOR DRY SYRUP	CEFALEXIN	125MG/5ML	CADILA PHARMACEUTICALS LIMITED 1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2000
1735	NDA/MAL/HDP/2074	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOXIN ORAL SUSPENSION	AMOXYCILLIN TRIHYDRATE	125MG/5ML	MILAN LABORATORIES (INDIA ) PVT LTD PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1998

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1736	NDA/MAL/HDP/2075	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPRED	PREDNISOLONE	5MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 10.0X10.0 TABLET BLISTER	01/07/2006
1737	NDA/MAL/HDP/2076	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOMIDE	FUROSEMIDE	40MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X1000.0 TABLET CONTAINER, 1.0X100.0X10.0 TABLET BLISTER	01/07/2006

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1738	NDA/MAL/HDP/2077	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	AMBRODIL	AMBROXOL HYDROCHLORIDE	30MG/5ML	ARISTO PHARMACEUTICALS PVT. LIMITED PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2007
1739	NDA/MAL/HDP/2083	BIOLOGICAL E. LTD	GITTOES PHARMACEUTICALS LIMITED	BEVAC	PURIFIED HEPATITIS B SURFACE ANTIGEN	20MCG	BIOLOGICAL E LTD PLOT NO.1, S.P BIOTECHNOLOGY PARK, PHASE II KOLTHAR (V), SHAMEERPET(M), RANGA REDDY(DIST), ANDHRA PRADESH, INDIA 500078	INDIA	PARENTERAL ORDINARY VIALS	1.0X35.0X1.0 ML VIAL (1 DOSE VIAL),1.0X24.0X10.0 ML VIAL (10 DOSE VIAL)	01/07/2015

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1740	NDA/MAL/HDP/2 087	ABBVIE (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	NORVIR	RITONAVIR	100MG	ABBVIE DEUTSCHLAND GMBH & CO. KG.KNOLLSTASSE 50, D-67061, LUDWIGSHAFEN, GERMANY.	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2013
1741	NDA/MAL/HDP/2 089	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DIABETMIN XR 500MG	METFORMIN HCL EXTENDED RELEASE	500MG	HOVID BHDLOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013

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1742	NDA/MAL/HDP/2090	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	CIPROREN	CIPROFLOXACIN	500MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
1743	NDA/MAL/HDP/2091	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	CAMSTON	CLOTRIMAZOLE	1%W/W	KPI ( KAMPALA PHARMACEUTICAL INDUSTRIES LTD PLOT M444 B STRETCHER ROAD NTINDA	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2001



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1744	NDA/MAL/HDP/2093	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	TRIGAN-D TABLET	PARACETAMOL + DICYCLOMINE	500MG + 20MG	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET STRIP	01/07/1999
1745	NDA/MAL/HDP/2094	MICRO LABS LTD	LABOREX UGANDA LIMITED	LEVOBACT-750	LEVOFLOXACIN HEMIHYDRATE	750MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2010

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1746	NDA/MAL/HDP/2095	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOMOL	PARACETAMOL	100MG	AGOG PHARMA LTD PLOT NO.33, SECTOR II, VASAI, TALUKA INDL CO-OP ESTATE LTD, GAURAI PADA, VASAI(E) DIST. T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2010
1747	NDA/MAL/HDP/2098	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGO QUININE	QUININE SULPHATE	300MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER	01/07/2006

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1748	NDA/MAL/HDP/2099	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	HYDROCORTISON E 1% CREAM	HYDROCORTISON E	1%W/W	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1998
1749	NDA/MAL/HDP/2100	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ORALCON - F	LEVONORGESTREL & ETHINYLESTRADIOL+ FERROUS FUMARATE	0.15MG + 0.03MG + 75MG	MYLAN LABORATORIES LIMITED..PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, AHMEDABAD, GUJARAT, INDIA 382213 MYLAN LABORATORIES LIMITED.-PLOT NO. 1606-1609	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X28.0 TABLET BLISTER	01/07/2007

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1750	NDA/MAL/HDP/2 101	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CARDISPRIN	ACETYL SALICYLIC ACID	75MG	COSMOS LIMITEDRANGWE ROAD, OFF LUNGA ROAD - INDUSTRIAL AREA NAROB	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2010
1751	NDA/MAL/HDP/2 104	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LAMIVUDINE/NEV IRAPINE /ZIDOVUDINE DISPERSIBLE TABLETS	LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE	30MG + 50MG + 60MG	MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2009

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1752	NDA/MAL/HDP/2 108	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYMOX CAPSULES 250MG	AMOXYCILLIN	250MG	ELYS CHEMICAL INDUSTRIES LTDROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/1997
1753	NDA/MAL/HDP/2 111	HETERO LABS LTD	AIVEEN (U) LIMITED	LOPINAVIR / RITONAVIR	LOPINAVIR / RITONAVIR	200MG /50MG	HETERO LABS LTD22- 110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH HETERO LABS LTD. UNIT (V) .S.NO.439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET CONTAINER	01/07/2011

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1754	NDA/MAL/HDP/2 112	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LOPINAVIR + RITONAVIR	LOPINAVIR + RITONAVIR	200MG + 50MG	MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET CONTAINER	01/07/2008
1755	NDA/MAL/HDP/2 116	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	AMLOVAS-10	AMLODIPINE BESILATE	10MG	MACLEODS PHARMACEUTICALS LTD .PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET STRIP	01/07/2005

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1756	NDA/MAL/HDP/2 120	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MEGAPIME	CEFEPIME	1G	SANCE LABORATORIES PVT LTDVI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL	01/07/2011
1757	NDA/MAL/HDP/2 124	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYMOX	AMOXYCILLIN	125MG/5ML	ELYS CHEMICAL INDUSTRIES LTDROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

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1758	NDA/MAL/HDP/2 125	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	BECLATE 100	BECLOMETASONE	100MCG/DOSE	CIPLA LTD.- PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	NASAL SYSTEMIC METERED-DOSE LIQUIDS	1.0X200.0 METERED DOSE CANNISTER	01/07/2009
1759	NDA/MAL/HDP/2 128	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	TRANSAMIN INJECTION 500MG	TRANEXAMIC ACID	500MG/5ML	HILTON PHARMA (PVT) LTD PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X10.0X5.0 ML AMPOULE	01/07/2005



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1760	NDA/MAL/HDP/2 129	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	CLAVODAR	AMOXICILLIN/CLA VULANIC ACID	500MG/125MG	DAR AL DAWANA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2011
1761	NDA/MAL/HDP/2 132	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	LOPINAVIR/ RITONAVIR	LOPINAVIR/ RITONAVIR	200MG/ 50MG	AUROBINDO PHARMA LTDUNIT III- SURVEY NO.313,BACHUPALL Y VILLAGE,QUTHUBUL LAPUR MANDAL R.R DISTRICT(A.P),INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET CONTAINER	01/07/2010

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1762	NDA/MAL/HDP/2 133	NOVO NORDISK	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ACTRAPID	HUMAN INSULIN	100 I.U./ML	NOVO NORDISK PRODUCTION SAS45 AVENUE D'ORLEANS, 28000 CHARTRES, FRANCE NOVO NORDISK PHARMANOVO ALLE	DENMARK FRANCE	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL	01/07/1997
1763	NDA/MAL/HDP/2 136	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	SEDIPROCT SUPOSITORY	HYDROCORTISON E+ CINCHOCAINE+ ESCULOSIDE+ FRAMYCETIN	5MG + 5MG +10MG +10MG	MEDICAL UNION PHARMA .COABU- SULTAN ISMAILIA EGYPT	EGYPT	TOPICAL EXTERNAL SUPPOSITORIES	1.0X6.0 SUPPOSITORY STRIP	01/07/2003

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1764	NDA/MAL/HDP/2 140	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	AVIRANZ	EFAVIRENZ	600MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2006
1765	NDA/MAL/HDP/2 141	CENTAUR PHARMACEUTICAL S PRIVATE LIMITED	GITTOES PHARMACEUTICAL S LIMITED	INFLAZONE	MULTIINGREDIEN T	N/A	CENTAUR PHARMACEUTICALS PVT LTD -PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE	01/07/2005

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1766	NDA/MAL/HDP/2 143	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	GRISEOFIL	GRISEOFULVIN	500MG	FOURRTS INDIA LABORATORIES PVT. LIMITEDVANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1X10X10 TABLET BLISTER	01/07/2005
1767	NDA/MAL/HDP/2 144	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPICOTIL	TENOXICAM	20MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY VIALS	1.0X3.0 VIAL CARTON + 1*3*2ML WFI AMPOULE	01/07/2014

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1768	NDA/MAL/HDP/2 145	FOURRTS (INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	METFIL 500	METFORMIN	500MG	FOURRTS INDIA LABORATORIES PVT. LIMITEDVANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER	01/07/2005
1769	NDA/MAL/HDP/2 147	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	DICLOFEN -50	DICLOFENAC	50MG	FOURRTS INDIA LABORATORIES PVT. LIMITEDVANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2006

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1770	NDA/MAL/HDP/2 149	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	PRIMOLUT DEPOT	HYDROXYPROGES TERONE HEXANOATE	250MG	BAYER PHARMA A.GMULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE	01/07/1997
1771	NDA/MAL/HDP/2 150	ELI-LILLY (SUISSE) SA	LABOREX UGANDA LIMITED	HUMULIN MIXTURE	HUMAN INSULIN	70/30 I.U	LILLY EGYPT S.A.E. & ELI LILLY AND COMPANY LILLY TECHNOLOGY CENTRE INDIANAPOLIS,INDIA NA 46285 USA	UNITED STATES	PARENTERAL ORDINARY S C VIALS	1.0X4.0 ML VIAL,1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE	01/07/1997

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1772	NDA/MAL/HDP/2 151	USV PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GLYCOMET 850	METFORMIN	850MG	FREDUN PHARMACEUTICALS LIMITED--14,15,16 ZORABIAN INDUSTRIAL COMPLEX PALAGHAR (EAST), DIST THANE 401 404 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2000
1773	NDA/MAL/HDP/2 154	ABACUS PHARMA (AFRICA) LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GLYNASE	GLIPIZIDE	5MG	FREDUN PHARMACEUTICALS LIMITED--14,15,16 ZORABIAN INDUSTRIAL COMPLEX PALAGHAR (EAST), DIST THANE 401 404 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2000

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1774	NDA/MAL/HDP/2 155	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	DOXFIL	DOXYCYCLINE	100MG	FOURRTS INDIA LABORATORIES PVT. LIMITEDVANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2005
1775	NDA/MAL/HDP/2 160	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	ACEM-500	CLARITHROMYCIN	500MG	EMCURE PHARMACEUTICALS LTDLANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2005



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1776	NDA/MAL/HDP/2 161	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CYCLOVAX CREAM	ACICLOVIR	5%W/W	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE	01/07/1997
1777	NDA/MAL/HDP/2 170	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	ALSARTAN-AM	LOSARTAN + AMLODIPINE	50MG + 5MG	ARISTO PHARMACEUTICALS PVT. LIMITEDPLOT NO. 208, NEW INDUSTRIAL AREA NO. II, MANDIDEEP- 462046, DIST. - RAISEN, MADHYA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER	01/07/2011

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1778	NDA/MAL/HDP/2 173	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICAL S LTD	GLEVO-500	LEVOFLOXACIN	500MG	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X5.0 TABLET BLISTER	01/07/2003
1779	NDA/MAL/HDP/2 176	INTAS PHARMACUITICALS LTD	NORVIK ENTERPRISES LIMITED	RISPITAS-2	RISPERIDONE	2MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2011

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1780	NDA/MAL/HDP/2 178	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL CEFUROXIME-250	CEFUROXIME AXETIL	250MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/2008
1781	NDA/MAL/HDP/2 181	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM PHEN	PHENOXYMETHYL PENICILLIN	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	100.0 TABLET CONTAINER,1000.0 TABLET CONTAINER,500.0 TABLET CONTAINER,250.0 TABLET CONTAINER	01/07/1997

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1782	NDA/MAL/HDP/2 185	GLAXOSMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ROTARIX	LIVE ATTENUATED RIX4414 STRAIN OF HUMAN ROTAVIRUS OF THE G1P[8] TYPE	NOT LESS THAN 10 <sup>6</sup> CCID <sub>50</sub> OF THE RIX4414 STRAIN	GLAXOSMITHKLINE BOIOLOGICALSS.A RUE DE L'INSTITUT 89 B- 1330 RIXENSART	BELGIUM	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.5 ML TUBE (1 DOSE),1.0X50.0X1.5 ML TUBE (1 DOSE),1.0X7.5 ML TUBE (5-DOSE) FOR GAVI/UNICEF SUPPLY ONLY	01/07/2009
1783	NDA/MAL/HDP/2 186	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL DIPHENHYDRAMINE PAEDIATRIC SYRUP	DIPHENHYDRAMINE HYDROCHLORIDE + AMMONIUM CHLORIDE	7MG+67.5MG/5ML	KOTRA PHARMA- BHD 1, JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA, MALAYSIA	MALAYSIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2008

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1784	NDA/MAL/HDP/2 189	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL BETAMETHASONE	BETAMETHASONE	0.1%W/W	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X5.0 G TUBE	01/07/2008
1785	NDA/MAL/HDP/2 191	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	KLOXY	CLOXACILLIN	250MG	LABORATORY & ALLIED LTD.--PLOT 209/10349 OFF MOMBASA RD NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X10. 0X10.0 CAPSULE BLISTER	01/07/1997

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1786	NDA/MAL/HDP/2 195	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	EUDERM CREAM	UREA	10%W/W	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X45.0 G TUBE	01/07/1997
1787	NDA/MAL/HDP/2 197	LABORATORY&ALLI ED LTD	HARLEYS UGANDA LIMITED	WHITFIELD'S OINTMENT	BENZOIC ACID + SALICYLIC ACID	6%W/W + 3%W/W	LABORATORY & ALLIED LTD PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE	01/07/1997

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1788	NDA/MAL/HDP/2 199	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	EUTHYROX 50MCG	LEVOTHYROXINE SODIUM	50MCG	MERCK KGAA - FRANKFRUTER STRASSE 250, D- 64293,DARMSTADT- GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X4.0X25.0 TABLET BLISTER,1.0X1.0X30 .0 TABLET BLISTER	01/07/2013
1789	NDA/MAL/HDP/2 201	SHAIGAN PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	CLYCIN	CLINDAMYCIN PHOSPHATE	10MG/ML	SHAIGAN PHARMACEUTICALS (PVT) LTD14TH KM, ADYALA ROAD, RAWALPINDI- PAKISTAN	PAKISTAN	TOPICAL EXTERNAL LOTIONS	1.0X30.0 ML BOTTLE	01/07/2008

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1790	NDA/MAL/HDP/2 208	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL CEPHALEXIN	CEPHALEXIN MONOHYDRATE	500MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2010
1791	NDA/MAL/HDP/2 211	GALENTIC PHARMA (PVT)LTD	VITACARE LIMITED	BENZYL BENZOATE	BENZYL BENZOATE	25%W/W	GALENTIC PHARMA PVT. LIMITEDR-673, TTC MIDC, RUBALE, THANE BELAPURNAVI MUMBAI 400 701 INDIA	INDIA	TOPICAL EXTERNAL EMULSIONS	1.0X200.0 ML BOTTLE,1.0X100.0 ML BOTTLE,1.0X1000.0 ML BOTTLE	01/07/2005



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1792	NDA/MAL/HDP/2 212	DENK PHARMA	BENLE CONSULT LIMITED	CIPRO-DENK 500	CIPROFLOXACIN	500MG	ALLPHARMED PHARBIL ARZNEIMITTEL GMBH12 D377081	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2005
1793	NDA/MAL/HDP/2 214	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	GENTAMICIN INJECTION	GENTAMICIN SULPHATE	40MG/ML	SCOTT-EDIL PHARMACIA LTD (UNIT I)56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X2.0 ML AMPOULE	01/07/2007

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1794	NDA/MAL/HDP/2 216	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	METOCLOPRAMID E	METOCLOPRAMI DE	5MG/ML	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE	01/07/2005
1795	NDA/MAL/HDP/2 219	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	PRIMOLUT N	NORETHISTERON E	5MG	BAYER WEIMAR GMBH & CO. KGDOBEREINERSTRA SSE 20 D-99427 WEIMAR, GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X30.0 TABLET CONTAINER,1.0X2.0 X15.0 TABLET BLISTER	01/07/1997

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1796	NDA/MAL/HDP/2 223	ROYAL PHARMA	ROYAL PHARMA 2011 LIMITED	BENZATHINE PENICILLIN INJECTION	BENZATHINE PENICILLIN	2400000 I.U	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTDNO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSH OP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1X2.4 MU VIAL	01/07/2002
1797	NDA/MAL/HDP/2 224	VOGEN LABORATORIES LTD	BUFFALO HEALTH CARE LTD	DURAMOX 500	AMOXICILLIN	500MG	VOGEN LABORATORIES LTD70, M.HERACLEOUS STR. AYIOS ATHANASIOS INDUSTRIAL AREA, LIMASSOL, CYPRUS	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER,1.0X10.0X1 0.0 CAPSULE BLISTER	01/07/2013

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1798	NDA/MAL/HDP/2 226	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	HEPA-MERZ GRANULES	L-ORNITHINE-L- ASPARTATE	3G/5G	WIN-MEDICARE PRIVATE LIMITEDMEERUT- MUZAFFARNAGAR ROAD, MODIPURAM 250110 UTTAR PRADESH	INDIA	ORAL LIQUID ORDINARY OTHER POWDERS/GRANU LES	1.0X10.0X5.0 G SACHET	01/07/2004
1799	NDA/MAL/HDP/2 231	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	PIRITEX WITH CODEINE	MULTI- INGREDIENT	MULTI- INGREDIENT	MEDIPHARM INDUSTRIES( EA) LTD PLOT 65 KAKAJJO ROAD BWEYOGERERE P.O.BOX 6218,KAMPALA,UGA NDA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997

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1800	NDA/MAL/HDP/2 232	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNICAST	MONTELUKAST	10MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTDP.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL- RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
1801	NDA/MAL/HDP/2 233	ASTRAZENECA	MACNAUGHTON LIMITED	PULMICORT NEBULISER	BUDESONIDE	0.25MG/ML	ASTRA ZENECA SWEDEN OPERATIONS LIQUID PRODUCTION KVARNBERGAGATAN LZ SE-151- 85,SWEDEN	SWEDEN	LUNG ADMINISTRATION LIQUID FOR INHALATION	1.0X4.0X5.0X2.0 ML VIAL	01/07/2011

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1802	NDA/MAL/HDP/2 235	WOCKHARDT LTD	ABACUS PHARMA (AFRICA) LIMITED	WOSULIN-N	INSULIN HUMAN(RECOMB INANT DNA ORIGIN)	100IU/ML	WOCKHARDTWOCK HARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X3.0 ML VIAL,1.0X10.0 ML VIAL	01/07/2006
1803	NDA/MAL/HDP/2 236	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	TEGRETOL 200	CARBAMAZEPINE	200MG	NOVARTIS FARMA S.P.A.-VIA PROVINCIALE SCHITO 131, 80058 TORRE ANNUNZIATA, ITALY	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/1997

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1804	NDA/MAL/HDP/2 237	WOCKHARDT LTD	ABACUS PHARMA (AFRICA) LIMITED	WOSULIN-30/70	INSULIN HUMAN(RECOMB INANT DNA ORIGIN)	100I.U/ML	WOCKHARDT LIMITED - WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL,1.0X3.0 ML VIAL	01/07/2006
1805	NDA/MAL/HDP/2 239	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	TEGRETOL SYRUP	CARBAMAZEPINE	20MG/ML	DELPHARMA HUNINGUE S.A.S-26, RUE DE LA CHAPELLE, 68330 HUNINGUE, FRANCE	FRANCE	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X250.0 ML BOTTLE	01/07/2006

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1806	NDA/MAL/HDP/2 242	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CYCLOVAX 200 TABLETS	ACYCLOVIR	200MG	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/1997
1807	NDA/MAL/HDP/2 243	AFRICURE PHARMACEUTICAL S (INDIA) PRIVATE LIMITED	AFRICURE PHARMACEUTICAL S U LIMITED	SIMDOL TABLETS	PARACETAMOL	500MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITEDPLOT 9- 12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997



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1808	NDA/MAL/HDP/2 245	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	X-PEL	MEBENDAZOLE	100MG	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2008
1809	NDA/MAL/HDP/2 248	GALENTIC PHARMA (PVT)LTD	VITACARE LIMITED	TETRACYCLINE OPHTHALMIC	TETRACYCLINE	1%W/W	GALENTIC PHARMA PVT. LIMITEDR-673, TTC MIDC, RUBALE, THANE, INDIA	INDIA	OPHTHALMIC OINTMENTS	1.0X3.5 G TUBE,1.0X5.0 G TUBE	01/07/2004

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1810	NDA/MAL/HDP/2 249	WOCKHARDT LTD	ABACUS PHARMA (AFRICA) LIMITED	WOSULIN-R	INSULIN	100ML	WOCKHARDT LIMITED - WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X3.0 ML VIAL,1.0X10.0 ML VIAL	01/07/2006
1811	NDA/MAL/HDP/2 252	JOHNSON&JOHNS ON PTY LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	VERMOX	MEBENDAZOLE	500MG	SPECPHARM HOLDINGS 15TH ROAD HALFWAY HOUSE JOHNSON & JOHNSON (PTY) LTD241 MAIN ROAD, RETREAT, 7945, CAPE TOWN	SOUTH AFRICA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0 TABLET BLISTER	01/07/2000

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1812	NDA/MAL/HDP/2 254	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	BURN CUR CREAM	ACRIFLAVINE/THY MOL	N/A	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/1998
1813	NDA/MAL/HDP/2 256	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	AUGMENTIN 457MG/5ML	AMOXICILLIN + CLAVULANIC ACID	400 MG + 57 MG / 5 ML	GLAXO WELLCOME PRODUCTIONZI DE LA PEYENNIERE, 53100, MAYENNE	FRANCE	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X70.0 ML BOTTLE	01/07/2010

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1814	NDA/MAL/HDP/2 258	MYLAN LABORATORIES LIMITED (OTL)	KIMSY MEDS LTD	TENOFOVIR DISOPROXIL + LAMIVUDINE + EFAVIRENZ	TENOFOVIR DISOPROXIL + LAMIVUDINE + EFAVIRENZ	300MG/300MG/60 OMG	QUESTA CARE LIMITED PLOT NO 209/7184 HOMABAY RD TERMINUS GATE NO-19, INDUSTRIAL AREA NAIROBI, KENYA. MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD - PLOT NO. H.12 & H.	INDIA KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET BOTTLE,1.0X1.0X30 .0 TABLET BOTTLE	01/07/2009
1815	NDA/MAL/HDP/2 263	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	CELEMIN 10 PLUS	AMINO ACIDS/ELECTROLY TES	10%W/V+10%W/V	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X500.0 ML BOTTLE	01/07/2001

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1816	NDA/MAL/HDP/2 265	HETERO DRUGS LTD	AIVEEN (U) LIMITED	TENOFOVIR/ LAMIVUDINE	TENOFOVIR DISOPROXIL FUMARATE + LAMIVUDINE	300MG + 300MG	HETERO LABS LTD22- 110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH HETERO LABS LTD (UNIT- V)SY.NO.438,439,44 0 & 458 APIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2010
1817	NDA/MAL/HDP/2 267	MYLAN LABORATORIES LIMITED (OTL)	KIMSY MEDS LTD	TENOFOVIR DISOPROXIL FUMARATE + LAMIVUDINE	TENOFOVIR DISOPROXIL FUMARATE + LAMIVUDINE	300MG+300MG	QUESTA CARE LIMITEDPLOT NO 209/7184 HOMABAY RD TERMINUS GATE NO-19, INDUSTRIAL AREA NAIROBI, KENYA. MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD - PLOT NO. H-12 & H-	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2007

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1818	NDA/MAL/HDP/2 269	DAWA LIMITED	SUPER MEDIC LTD	DAWAMOX	AMOXYCILLIN TRIHYDRATE	125MG/5ML	DAWA PHARMACEUTICALS LIMITEDPLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997
1819	NDA/MAL/HDP/2 271	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	ARTEMETHER 20MG/LUMEFANT RINE 120MG	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	IPCA LABORATORIES LTD PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X3.0X6.0 TABLET BLISTER,1.0X30.0X1 8.0 TABLET BLISTER,1.0X30.0X2 4.0 TABLET BLISTER,1.0X10.0X1 .0X6.0 TABLET BLISTER,1.0X10.0X2 .0X6.0 TABLET BLISTER,1.0X30.0X1 2.0 TABLET BLISTER,1.0X30.0X4 .0X6.0 TABLET BLISTER,1.0X30.0X3 0X6.0 TABLET	01/07/2010

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1820	NDA/MAL/HDP/272	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	CLARANTA -500	CLARITHROMYCIN	500MG	AJANTA PHARMA LTD .B-4//5/6, MIDC INDUSTRIALAREA, PAITHAN-431 128, AURANGBAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X2.0X10.0 TABLET BLISTER	01/07/2005
1821	NDA/MAL/HDP/280	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	BETADROP-N	BETAMETHASONE + NEOMYCIN	0.1 %W/V + 0.5 %W/V	REMINGTON PHARMACEUTICAL INDUS. PVT LTD, 117 ALLAM	PAKISTAN	OPHTHALMIC DROPS	1.0X7.5 ML VIAL	01/07/1999

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1822	NDA/MAL/HDP/2 281	PHARMACTIV FZCO	JEET PHARMACEUTICAL S LIMITED	LUMFORT	LORATADINE	10MG	NABIQASIM INDUSTRIES (PVT) LIMITED17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007
1823	NDA/MAL/HDP/2 282	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	PROPAN	PROPRANOLOL	40MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2011



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1824	NDA/MAL/HDP/2 287	GLAXO WELLCOME (KENYA) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZINNAT	CEFUROXIME AXETIL	250MG	GLAXOSMITHKLINE UK LTD HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER, 1.0X50.0 TABLET CARTON	01/07/1997
1825	NDA/MAL/HDP/2 290	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LAMIVUDINE + ZIDOVUDINE	LAMIVUDINE + ZIDOVUDINE	150MG + 300MG	MYLAN LABORATORIES LTD- F-4, F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD - H-12 & H-13, MIDC, WALUJ, AURANGABA D- 431136 MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2008

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1826	NDA/MAL/HDP/2 293	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TIOCON	TIOCONAZOLE	1%W/W	GLOBAL NAPI PHARMACEUTICALS - 2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	EGYPT	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2005
1827	NDA/MAL/HDP/2 295	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	ROZITTA 10	ROSUVASTATIN CALCIUM	10MG	DAR AI DAWANA UR PLANT,AMMAN,JOR DAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013

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1828	NDA/MAL/HDP/297	DAWA LIMITED	SUPER MEDIC LTD	SABULIN SYRUP	SALBUTAMOL SULPHATE	2MG/5ML	DAWA LIMITED BABA DOGO RWARAKA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	01/07/2008
1829	NDA/MAL/HDP/298	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S LIMITED	SAFELEVO 500	LEVOFLOXACIN	500MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER, 1.0X1.0X10 .0 TABLET BLISTER	01/07/2013

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1830	NDA/MAL/HDP/2 299	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	ROZITTA 20	ROSUVASTATIN CALCIUM	20MG	DAR AI DAWANA UR PLANT,AMMAN,JOR DAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013
1831	NDA/MAL/HDP/2 303	MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZIAK 5/6.25	BISOPROLOL + HYDROCHLOROT HIAZIDE	5 MG + 6.25 MG	MERCK KGAAFRANKFURTER STRASSE 250 64271 DARMSTADT GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014

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1832	NDA/MAL/HDP/2 304	MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZIAK 10/6.25	BISOPROLOL + HYDROCHLOROT HIAZIDE	10 MG + 6.25 MG	MERCK KGAAFRANKFURTER STRASSE 250 64271 DARMSTADT GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014
1833	NDA/MAL/HDP/2 305	MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZIAK 2.5/6.25	BISOPROLOL + HYDROCHLOROT HIAZIDE	2.5 MG + 6.25 MG	MERCK KGAAFRANKFURTER STRASSE 250 64271 DARMSTADT GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014

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1834	NDA/MAL/HDP/2 306	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	MICROLUT	LEVONORGESTRE L	0.03MG	BAYER PHARMA A.GMULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X35.0 TABLET BLISTER	01/07/2010
1835	NDA/MAL/HDP/2 312	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CLAVOMID 625	AMOXICILLIN + CLAVULANIC ACID	500 MG + 125 MG	REMEDICA LIMITED AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	2.0X10.0 TABLET BLISTER	01/07/2006

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1836	NDA/MAL/HDP/2 313	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CLAVOMID 375	AMOXICILLIN + CLAVULANIC ACID	250 MG + 125 MG	REMEDICA LIMITED AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	2.0X10.0 TABLET BLISTER	01/07/2006
1837	NDA/MAL/HDP/2 314	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	RABEMAC-20	RABEPRAZOLE SODIUM	20MG	MACLEODS PHARMACEUTICALS LTD PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2005

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1838	NDA/MAL/HDP/2 315	MICRO LABS LTD	LABOREX UGANDA LIMITED	GRAMOCEF-O-50	CEFIXIME	50MG/5ML	MICRO LABS LIMITED, BOMMASANDRA PLOT NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X30.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2006
1839	NDA/MAL/HDP/2 318	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DIAPRIDE-4	GLIMEPIRIDE	4MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2006



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1840	NDA/MAL/HDP/2 319	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSMOL	PARACETAMOL	120MG/5ML	COSMOS LIMITEDRANGWE ROAD, OFF LUNGA ROAD - INDUSTRIAL AREA NAROBI	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1998
1841	NDA/MAL/HDP/2 320	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	ERO-125 DRY SYRUP	ERYTHROMYCIN ESTOLATE	125MG/5ML	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2006

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1842	NDA/MAL/HDP/2 322	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TREFLUCAN	FLUCONAZOLE	150MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X1.0 CAPSULE STRIP	01/07/2007
1843	NDA/MAL/HDP/2 324	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	SWISSCLOXA	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X7.5 ML VIAL	01/07/2011

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1844	NDA/MAL/HDP/2 330	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	COARTEM	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	NOVARTIS PHARMA AG- SCHAFFHAUSERSTRA SSE 4332 STEIN SWITZERLAND NORVATIS SAGLIK GIDA VE TARIM URENLERI SAN, VE TIC-AC-YENISEHIR MAHALLESİ IHLA VADISI SOKAK, NO.2, 34912 KURTKOY, INSTANBUL - TURKEY	SWITZERLAND TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X24.0 TABLET BLISTER,1.0X30.0X2 4.0 TABLET BLISTER,1.0X30.0X6 .0 TABLET BLISTER,1.0X36.0X6 .0 TABLET BLISTER,1.0X3.0X8. 0 TABLET BLISTER,1.0X30.0X1 2.0 TABLET BLISTER,1.0X30.0X1 8.0 TABLET BLISTER,1.0X4.0X6. 0 TABLET BLISTER	01/07/2005
1845	NDA/MAL/HDP/2 335	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOBEN TABLETS(THANE)	MEBENDAZOLE	100MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	10.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X10 0.0 TABLET CONTAINER,1.0X25 0.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	01/07/2001

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1846	NDA/MAL/HDP/2 338	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	CLAVULIN	AMOXICILLIN + CLAVULANIC ACID	200 MG + 28.5 MG	GLAXO WELLCOME PRODUCTIONZI DE LA PEYENNIERE, 53100, MAYENNE	FRANCE	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE,1.0X70.0 ML BOTTLE	01/07/2003
1847	NDA/MAL/HDP/2 350	ASTRA ZENECA AB	MACNAUGHTON LIMITED	PULMICORT TURBUHALER	BUDESONIDE	200MCG	ASTRAZENECA AB,GARTUNA & SNACKVIKEN STOCKHOLM	SWEDEN	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X100.0 DOSE CANNISTER	01/07/2001

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1848	NDA/MAL/HDP/2 352	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	COLD CAP DAY TIME	PARACETAMOL/P SEUDOEPHEDRIN E HCL/CAFFEINE	500MG+30MG+30 MG	REGAL PHARMACEUTICALS LIMITED PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X12.0 CAPSULE BLISTER	01/07/2007
1849	NDA/MAL/HDP/2 353	ASTRA ZENECA	MACNAUGHTON LIMITED	NEXIUM	ESOMEPRAZOLE (AS MAGNESIUM TRIHYDRATE)	10MG	ASTRA ZENECA ABSE- 151 85 SODERTALJE, SWEDEN (GARTUNAVAGEN & SNACKVIKEN)	SWEDEN	ORAL SOLID ORDINARY GRANULES	1.0X28.0 SACHET CARTON	01/07/2013

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1850	NDA/MAL/HDP/2 356	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	QUININE	QUININE DIHYDROCHLORID E	600MG/2ML	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119, N-113 MIDC TARAPUR BOISAR DIST. THANE 401506 MAHARASHTRA	CHINA INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2005
1851	NDA/MAL/HDP/2 357	ACINO PHARMA AG	LABOREX UGANDA LIMITED	TRABILIN- 50 CAPSULES	TRAMADOL	50MG	MERCKLE GMBH,LUDWIG MERCKLE STRASSE3 D-89143 BLAUBEUREN	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2003

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1852	NDA/MAL/HDP/2 359	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	ASPIREM 75	ASPIRIN	75MG	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X2.0X28.0 TABLET BLISTER	01/07/2007
1853	NDA/MAL/HDP/2 360	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	FUNGISTIN PESSARIES	NYSTATIN	100000 IU	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	VAGINAL TABLETS	1.0X14.0 PESSARY PACK,5.0X3.0 PESSARY STRIP,1.0X100.0 PESSARY CONTAINER	01/07/2002

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1854	NDA/MAL/HDP/2 361	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CLAREM 500	CLARITHROMYCIN	500MG	REMEDICA LTD HARNON STREET, LIMASSOL INDUSTRIAL ESTATE, 3056 LIMASSOL	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2007
1855	NDA/MAL/HDP/2 362	GALENTIC PHARMA LTD	VITACARE LIMITED	CANDISTATIN OINTMENT	NYSTATIN	100,000I.U	GALENTIC PHARMA PVT. LIMITED R-673, TTC MIDC, RUBALE, THANE BELAPUR NAVI MUMBAI 400 701 INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE	01/07/2009



## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1856	NDA/MAL/HDP/2 363	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	GENTAMICIN SULPHATE	GENTAMICIN SULPHATE	80MG/2ML	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE,1.0X10.0 X10.0X2.0 ML AMPOULE	01/07/2005
1857	NDA/MAL/HDP/2 364	AIVEEN (U) LIMITED	AIVEEN (U) LIMITED	VOXEL-500	LEVOFLOXACIN	500MG	MEDICO REMEDIES PVT LIMITED8 & 9 DEWAN & SONS, UDYOG NAGAR PALGAR, DISTRICT THANE MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2015

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1858	NDA/MAL/HDP/2 366	UNIQUE PHARMACEUTICAL S LTD	PLANET PHARMACEUTICAL S UGANDA LTD	IFICIPRO INJECTION	CIPROFLOXACIN	200MG/100ML	UNIQUE PHARMACEUTICALS LABS ( A DIV OF J.B CHEMICALS & PHARMACEUTICAL LTD)-304-308 ,GIDC , PANOLI 394116	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2005
1859	NDA/MAL/HDP/2 368	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	DERMIDEX CREAM	MICONAZOLE NITRATE	2%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2007

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1860	NDA/MAL/HDP/2 369	ARISTO PHARMACEUTICAL S	NORVIK ENTERPRISES LIMITED	TRANLOK 500MG INJECTION	TRANEXAMIC ACID	500MG/5ML	ARISTO PHARMACEUTICALS PVT. LIMITED PLOT NO. 208, NEW INDUSTRIAL AREA NO.II, MANDIDEEEP PRADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X5.0 ML AMPOULE	01/07/2010
1861	NDA/MAL/HDP/2 371	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	TOPIZONE CREAM	FUSIDIC ACID + BETAMETHASONE VALERATE	20MG/G+1MG/G	PHARMA INTERNATIONAL COMPANY MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2007

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1862	NDA/MAL/HDP/2 375	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	CLAVULIN 1G	AMOXICILLIN + CLAVULANIC ACID	875 MG + 125 MG	SMITHKLINE BEECHAM PHARMACEUTICALS, CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X1.0X7.0 TABLET BLISTER	01/07/2010
1863	NDA/MAL/HDP/2 379	PT SANBE FARMA	MEDVIN PHARMA LIMITED	PUMPITOR	OMEPRAZOLE	40MG	PT SANBE FARMA JI INDUSTRINO.8 KOMPLEKS INDUSTRI CIMAREME PADALARANG BANDUNG	INDONESIA	PARENTERAL ORDINARY VIALS	1.0X1.0 VIAL CARTON + 1 AMPOULE OF SOLVENT	01/07/2014

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1864	NDA/MAL/HDP/2 384	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CLARIX 500	CLARITHROMYCIN	500MG	PHARMA INTERNATIONAL COMPANY MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2007
1865	NDA/MAL/HDP/2 385	COSMOS LIMITED	ASTRA PHARMA (U) LIMITED	COZEPAM 5MG	DIAZEPAM	5MG	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2000

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1866	NDA/MAL/HDP/2 387	DAWA LIMITED	SUPER MEDIC LTD	VERMOUT	MEBENDAZOLE	100MG/5ML	DAWA LIMITED BABA DOGO RWARAKA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2010
1867	NDA/MAL/HDP/2 388	DAFRA PHARMA LTD	MULTIPHAR UGANDA LIMITED	DAFRACLAV	AMOXYCILLIN + POTASSIUM CLAVULANATE	400MG + 57MG	BILIM ILAC SAN. VE. TIC. A.S.CERKEZKOY ORGANIZE SANAYI BOLGESI, KARAAGAC, MH. 5. SK. NO. 6, KAPAKLI - TEKIRDAG 59510	TURKEY	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X70.0 ML BOTTLE	01/07/2011

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1868	NDA/MAL/HDP/2 389	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELOCIN	ERYTHROMYCIN	250MG	ELYS CHEMICAL INDUSTRIES LIMITED- ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2007
1869	NDA/MAL/HDP/2 390	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	P-ALAXIN	DIHYDROARTEMI SININ/ PIPERAQUINE PHOSPHATE	80MG /640MG	BLISS GVS PHARMA LTD PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA- INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X80.0 ML BOTTLE,1.0X120.0 ML BOTTLE	01/07/2008

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1870	NDA/MAL/HDP/2 391	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	HEADAID TABLETS	ASPIRIN + CAFFEINE + PARACETAMOL	300MG + 30MG + 250MG	MILAN LABORATORIES (INDIA ) PVT LTD PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X2.0 TABLET STRIP	01/07/1997
1871	NDA/MAL/HDP/2 394	MERCK SHARP & DOHME BV.	SURGIPHARM (U) LIMITED	STOCRIN	EFAVIRENZ	600MG	MERCK SHARP & DOHME B.V- WAARDENWEG 392031 BN, HAARLEM	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2004



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1872	NDA/MAL/HDP/2 395	A.MENARINI INDUSTRIE FARMACEUTICHE S.R.I	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	FASTUM GEL	KETOPROFEN	2.5%W/W	A. MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.LVIA SETTE SANTI 3, 50131 FIRENZE-ITALY	ITALY	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE,1.0X30.0 G TUBE,1.0X50.0 G TUBE,1.0X100.0 G TUBE	01/07/2005
1873	NDA/MAL/HDP/2 397	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	VITAMAKS	MULTI- INGREDIENT	MULTI- INGREDIENT	S KANT HEALTH CARE LTD PLOT 1802 - 1805	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2010

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1874	NDA/MAL/HDP/2 399	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	VOLINI	MULTI INGREDIENT	MULTI INGREDIENT	SUN PHARMACEUTICAL INDUSTRIES LIMITEDKH. NO. 1335-1340, NEAR EPIP-1, VILL - BHATOLI KALAN, BADDI, DISTT. SOLAN, HIMACHAL PRADESH - 173205, INDIA SUN PHARMACEUTICAL IND. LTD PLOT NO. B- 2, MADKAI INDUSTRIAL ESTATE, PONDA, GOA, INDIA.	INDIA	TOPICAL EXTERNAL OTHER GELS/SOLS	1.0X1.0X30.0 G TUBE	01/07/2005
1875	NDA/MAL/HDP/2 401	MEGA LIFSCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	ENAT	NATURAL VITAMIN E	400IU	MEGA LIFE SCIENCES PUBLIC COMPANY LIMITED384 SOIB PATTANA 3 RD BANGPOO INDUSTRIAL ESTATE SAMUTPRAKARN 10280	THAILAND	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2005

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1876	NDA/MAL/HDP/2 404	UNICHEM LABORATORIES LIMITEDV	EUROPA HEALTHCARE (U) LTD	LOSAR 50	LOSARTAN POTASSIUM	50MG	UNICHEM LABORATORIES LTD-- VILLAGE BHATAULI KALA, BADDI HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
1877	NDA/MAL/HDP/2 408	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	RENIRON TONIC	MULTI- INGREDIENT	MULTI- INGREDIENT	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2001

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1878	NDA/MAL/HDP/2 410	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	DOXYREN	DOXYCYCLINE	100MG	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2007
1879	NDA/MAL/HDP/2 411	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	DREZ	POVIDONE IODINE + METRONIDAZOLE	5%W/W + 1%W/W	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE,1.0X10.0 G TUBE,1.0X100.0 G TUBE,1.0X250.0 G TUBE	01/07/2010

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1880	NDA/MAL/HDP/2 414	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMCIL	AMPICILLIN	125MG/5ML	SPARSH BIO-TECH LTD PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1998
1881	NDA/MAL/HDP/2 415	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	SOLINA TABLETS	DIAZEPAM	5MG	CENTAUR PHARMACEUTICALS LTD PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER,1.0X100.0X 10.0 TABLET BLISTER	01/07/1997

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1882	NDA/MAL/HDP/2 426	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	PROBEX SYRUP	MULTI- INGREDIENT	MULTI- INGREDIENT	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X225.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2000
1883	NDA/MAL/HDP/2 427	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	CLONEM	CLOTRIMAZOLE	1%W/W	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/1997

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1884	NDA/MAL/HDP/2 428	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	CLOTRI-DENK 1% CREAM	CLOTRIMAZOLE	1%W/W	C.P.M. CONTRACTPHARMA GMBH & COMPANY KGFRUHLINGSTR. 7, 83620 FELDKIRCHEN- WESTERHAM	GERMANY	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/1998
1885	NDA/MAL/HDP/2 429	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	CLOTRI-DENK 100 VAGINAL	CLOTRIMAZOLE	100MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING ARTESAN PHARMA GMBH & CO. KG WENDLANDSTRABE 1,29439 LUCHOW,GERMANY	GERMANY	VAGINAL TABLETS	1.0X6.0 PESSARY CARTON	01/07/1998

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1886	NDA/MAL/HDP/2 434	STRIDES PHARMA SCIENCE LIMITED	DELMAW ENTERPRISES LIMITED	SOLCER	OMEPRAZOLE	40MG	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	01/07/2009
1887	NDA/MAL/HDP/2 438	INTAS, PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	HIFENAC	ACECLOFENAC	100MG	INTAS PHARMACEUTICALS LTDCAMP ROAD SELAQUI DEHRADUN	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2006



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1888	NDA/MAL/HDP/2 452	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	DELAISED CHEST COUGH SYRUP (NON DROWSY)	GUAIFENESIN + MENTHOL	100MG/5ML + 1.1MG/5ML	REGAL PHARMACEUTICALSP LOT 7879/18 BABA DOGO ROAD NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2007
1889	NDA/MAL/HDP/2 458	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	PRISTINEX 2% CREAM	KETOCONAZOLE	2%W/W	XEPA-SOUL PATTINSON (MALAYSIA) SDA BHD1-5, CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	2.0X15.0 G TUBE	01/07/2006

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1890	NDA/MAL/HDP/2459	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	P2	LEVONORGESTREL	0.75MG	MYLAN LABORATORIES LIMITED..PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, AHMEDABAD, GUJARAT, INDIA 382213 MYLAN LABORATORIES LIMITED.-PLOT NO. 1606-1609	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X2.0 TABLET BLISTER	01/07/2007
1891	NDA/MAL/HDP/2462	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	HISTALIN SYRUP	CHLORPHENIRAMINE MALEATE/PROMETHAZINE/DIPHENHYDRAMINE/EPHEDRINE/AMMONIUM CHLORIDE/SODIUM CITRATE	1.0MG+2.5MG+5.0MG+7.5MG+90.0MG+48.0MG/ 5ML.	REGAL PHARMACEUTICALS LTD..PLOT 7879/18 OFF BABA DOGO ROAD, RUARAKA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X5.0 L JERRYCAN	01/07/1997

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1892	NDA/MAL/HDP/2 471	GLAXOSMITHKLINE LIMITED-	UNITED HEALTHCARE DISTRIBUTORS LTD	OTRIVIN 0.1% NASAL DROPS	XYLOMETAZOLINE	0.1%W/V	GSK CONSUMER HEALTH SAGSK CONSUMER HEALTH SA, ROUTE DE L'ETRAZ, NYON, 1260, SWITZERLAND	SWITZERLAND	NASAL SYSTEMIC DROPS	1.0X10.0 ML BOTTLE	01/07/2003
1893	NDA/MAL/HDP/2 472	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	TRAN-GEL	DICLOFENAC DIETHYLAMMONI UM	1%W/W	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE, 1.0X20.0 G TUBE	01/07/2011

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1894	NDA/MAL/HDP/2 473	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NUGREL	CLOPIDOGREL	75MG	MICRO LABS LTD 92 SIPCOT 92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2010
1895	NDA/MAL/HDP/2 475	WIN-MEDICURE LTD	SURGIPHARM (U) LIMITED	URGENDOL INJECTION	TRAMADOL HYDROCHLORIDE	50MG/ML	WIN- MEDICARE LTDMODIPURAM - 250 110,UTTAR PRAADESH, INDIA.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE,1.0X2.0 ML AMPOULE	01/07/2001

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1896	NDA/MAL/HDP/2 476	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	DERIVA AQUEOUS GEL	ADAPALENE	0.1%W/W	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X15.0 G TUBE	01/07/2003
1897	NDA/MAL/HDP/2 478	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	DICLOMOL PLUS	PARACETAMOL+D ICLOFENAC	500MG+50MG	WIN MEDICARE PVT LIMITED MEERUT, MUZAFFARNAGER ROAD, MODIPURAM - 250110, UTTAR PRADESH -INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

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1898	NDA/MAL/HDP/2 479	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANCEPH-250 CAP	CEPHALEXIN	250MG	SANCE LABORATORIES PVT. LTD.VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT- 686573, KERALA, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2012
1899	NDA/MAL/HDP/2 481	GALENTIC PHARMA (PVT)LTD	VITACARE LIMITED	NETRACORT	HYDROCORTISON E	1%W/W	GALENTIC PHARMA PVT LIMITEDR- 673,MIDC TTC RABALE THANE- BELAPUR ROAD,NAVI MUMBAI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE,1.0X20.0 G TUBE	01/07/2005

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1900	NDA/MAL/HDP/2 492	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	PROFIL 25	PROMETHAZINE HYDROCHLORIDE	25MG	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED VANDALUR ROAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/1997
1901	NDA/MAL/HDP/2 502	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	PROBETA N EYE DROP	BETAMETHASONE + NEOMYCIN	0.1%W/V+0.5%W/ V	ATCO LABORATORIES PVT LTDB-18,S.I.T.E KARACHI 75700, PAKISTAN	PAKISTAN	OPHTHALMIC DROPS	1.0X7.5 ML VIAL	01/07/1997

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1902	NDA/MAL/HDP/2 504	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	RESTOCIN	PARACETAMOL + CHLORPHENIRAM INE MALEATE + CAFFEINE + PHENYLEPHRINE HCL	500MG+ 2MG+ 2MG + 30MG	LINCOLN PHARMACEUTICALS LIMITEDTRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X1.0X4.0 TABLET STRIP	01/07/2008
1903	NDA/MAL/HDP/2 507	CIPLA LTD	ABACUS PHARMA (AFRICA) LIMITED	EXERMET 1000	METFORMIN HCL	1000MG	CIPLA LTD ---D-7 MIDC INDUSTRIAL AREA, KURKUMBH, TAL	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2007



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1904	NDA/MAL/HDP/2 509	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	OPELE LOTION	BENZYL BENZOATE	25%W/V	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL LOTIONS	1.0X50.0 ML BOTTLE	01/07/1997
1905	NDA/MAL/HDP/2 510	PANACEA BIOTEC PHARMA LTD	VITACARE LIMITED	GIRO	ORDNIDAZOLE	500MG	PANACEA BIOTEC PHARMA LIMITEDMALPURI BADDI, DISTRICT SOLAN, HIMACHAL PRADESH-173205 - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0X2.0X10.0 TABLET BLISTER	01/07/2013

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1906	NDA/MAL/HDP/2 513	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	UNIPEN DRY SYRUP	PHENOXYMETHYL PENICILLIN	125MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997
1907	NDA/MAL/HDP/2 515	AFRICURE PHARMACEUTICAL S (INDIA) LTD	ROYAL PHARMA 2011 LIMITED	SIMFEN 200 TABLETS	IBUPROFEN	200MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITEDPLOT 9- 12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997

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1908	NDA/MAL/HDP/2 521	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	MOTINORM	DOMPERIDONE	10MG	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
1909	NDA/MAL/HDP/2 523	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	SULPHUR OINTMENT	SULPHUR	10%W/W	NEM LABORATORIES PVT LTD--133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X25.0 G TUBE	01/07/1997

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1910	NDA/MAL/HDP/2 525	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DICLO-DENK 100 RETARD	DICLOFENAC SODIUM	100MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID RETARD TABLETS	10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	01/07/1998
1911	NDA/MAL/HDP/2 526	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	UNISTEN COMBI PACK	CLOTRIMAZOLE	500MG & 1 %W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	VAGINAL COMBINATION PACK TABLETS	1.0X1.0 PESSARY BLISTER + 1*20G TUBE	01/07/2009

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1912	NDA/MAL/HDP/2 528	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LABESTEN	CLOTRIMAZOLE	1%W/W	LABORATORY & ALLIED LTD.--PLOT 209/10349 OFF MOMBASA RD NAIROBI	KENYA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE,1.0X1.0X20.0 G TUBE	01/07/1997
1913	NDA/MAL/HDP/2 529	B & O PHARM ZAC	TRIDEM PHARMA UGANDA LIMITED	G-CEFTRIA	CEFTRIAZONE	1G	CHINA NATIONAL MEDICINES, GUORUI PHARMACEUTICAL CO., LTD-CAOYANG EAST ROAD, HUAINAN ECONOMICAL AND TECHNOLOGICAL DEVELOPMENT ZONE, HUAINAN CITY ANHUI PROVINCE	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 10 ML AMPOULE WFI,1.0X1.0X50.0 G VIAL,1.0X1.0 VIAL CARTON	01/07/2012

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1914	NDA/MAL/HDP/2 545	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	TOBREX	TOBRAMYCIN	0.3%W/V	ALCON COUVREUR NVRIJKSWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/1997
1915	NDA/MAL/HDP/2 552	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	CAROFIT	VITAMIN C/ VITAMIN A/ ZINC SULPHATE	150MG/10MG/75 MG	AJANTA PHARMA LIMITEDB-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2005

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1916	NDA/MAL/HDP/2 553	GLENMARK PHARMACEUTICAL LTD.	STAR PHARMACEUTICAL S LTD	ESOZ-20	ESOMEPRAZOLE	20MG	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP,1.0X10.0 TABLET STRIP	01/07/2003
1917	NDA/MAL/HDP/2 554	GLENMARK PHARMACEUTICAL LTD.	STAR PHARMACEUTICAL S LTD	ESOZ	ESOMEPRAZOLE	40MG	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET STRIP,1.0X10.0X10. 0 TABLET STRIP	01/07/2005

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1918	NDA/MAL/HDP/2 555	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PHENOBARBITON E TABLETS BP 30MG	PHENOBARBITON E	30MG	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10 0.0 TABLET CONTAINER	01/07/1998
1919	NDA/MAL/HDP/2 556	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	TRUVADA	EMTRICITABINE/T ENOFOVIR	200MG/300MG	PATHEON INC- ADDRESS: 2100 SYNTEX COURT, MISSISSAUGA, ONTARIO L5N 7K9 COUNTRY: CANADA TAKEDA GMBH- 16515 ORANIENBURG GERMANY	CANADA GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2005



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1920	NDA/MAL/HDP/2 557	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	EPSITRON 25 TABLETS	CAPTOPRIL	25MG	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1999
1921	NDA/MAL/HDP/2 558	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	MYCOREN SUSPENSION	NYSTATIN	100000 I.U./ML	RENE INDUSTRIES LTD680,KAMULI,KIRE KA KAMPALA,UGANDA	UGANDA	ORAL TOPICAL SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2007

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1922	NDA/MAL/HDP/2 559	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	ERYTHROREN	ERYTHROMYCIN STEARATE	250MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2007
1923	NDA/MAL/HDP/2 561	PHARMATHEN LTD	GOODMAN INTERNATIONAL LTD	LANOMYCIN	AMIKACIN SULPHATE	500MG	PHARMATHEN S.A- 6,DERVENAKION STR,PALLINI,AHICA GREECE	GREECE	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE	35612

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1924	NDA/MAL/HDP/2 562	ACINO PHARMA AG	LABOREX UGANDA LIMITED	TRABILIN-100	TRAMADOL	100MG/2ML	MERCKLE GMBH,LUDWIG MERCKLE STRASSE3 D-89143 BLAUBEUREN	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X2.0 ML AMPOULE	01/07/2005
1925	NDA/MAL/HDP/2 565	ZYDUS LIFSCIENCES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TRAMAZAC INJECTION	TRAMADOL HYDROCHLORIDE	50MG/ML	FARBE FIRMAPLOT NO. 1508, GIDC ANKLESHWAR - 393002, GUJARAT INDIA GERMAN REMEDIES PHARMACEUTICALS PRIVATE LIMITED - PF 61 & 62, SANAND GIDC II INDUSTRIAL ESTATE, SANAND, AHMEDABAD – 382110, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	, 1X5X2 ML AMPOULE, 1X2 ML VIAL	07/01/2016

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1926	NDA/MAL/HDP/2 567	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CIPROBID-500	CIPROFLOXACIN	500MG	S.KANT HEALTHCARE LIMITED--PLOT NO. 1802-1805,GIDC PHASE II- 396195,DIST.VALSAD ,GUJARAT,INDIA PINNACLE LIFE SCIENCE PVT LTD- KHASRA NO. 1328 - 1330, VILLAGE MANPURA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH - 174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	10.0X10.0 TABLET BLISTER	01/07/1997
1927	NDA/MAL/HDP/2 568	GLAXO WELLCOME (KENYA) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZINNAT	CEFUROXIME AXETIL	500MG	GLAXOSMITHKLINE UK LTDHARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X50.0 TABLET CARTON	01/07/1997

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1928	NDA/MAL/HDP/2 571	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	CO-METHER	ARTEMETHER + LUMEFANTRINE	180 MG + 1080 MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE,1.0X30.0 ML BOTTLE	01/07/2010
1929	NDA/MAL/HDP/2 575	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	MYTEKA	MONTELUKAST SODIUM	10MG	HILTON PHARMA (PVT) LTD PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2005

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1930	NDA/MAL/HDP/2 576	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEQUINE TABLETS	CHLOROQUINE PHOSPHATE	250MG	RENE INDUSTRIES LTD680,KAMULI,KIRE KA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X250.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	01/07/2000
1931	NDA/MAL/HDP/2 578	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	MAGNOMINT TABLETS	ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE	125MG + 250MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X 10.0 TABLET BLISTER,1.0X50.0X2 .0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	01/07/1997

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1932	NDA/MAL/HDP/2 580	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	HEDON TABLETS	PARACETAMOL + ASPIRIN + CAFFEINE	250 MG+ 300 MG + 30 MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA MILAN LABORATORIES (INDIA) PVT LTD - 63,67,87,35,36, 64, 65 JAWAHAR CO-OP INDUSTRIAL ESTATE KAMOTHE, PANVEL NAVI MUMBAI LINCOLN PHARMACEUTICALS LTD,TRIMULI ESTATE	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X2.0 TABLET STRIP	01/07/1998
1933	NDA/MAL/HDP/2 591	HEALTHCARE LTD.	HEALTHCARE LTD.	VITAGLOBIN SYRUP	MULTI- INGREDIENT	MULTI- INGREDIENT	AL FAZAL PHARMA INDUSTRIES (PVT) LTD-PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X90.0 ML BOTTLE,1.0X250.0 ML BOTTLE	01/07/2001

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1934	NDA/MAL/HDP/2 593	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	ATENOLOL DENK 50	ATENOLOL	50MG	ARTESAN PHARMA GMBH & CO. KG WENDLANDSTRABE 1,29439 LUCHOW,GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
1935	NDA/MAL/HDP/2 594	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	FEF	FERROUS SULPHATE + FOLIC ACID	200MG + 0.4MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2009



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1936	NDA/MAL/HDP/2 595	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	ZEPILEN	CEFAZOLIN	1000MG	MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X1.0 G VIAL	01/07/2009
1937	NDA/MAL/HDP/2 597	E DENK OHG	BENLE CONSULT LIMITED	PARA DENK 250	PARACETAMOL	250MG	RUBIEPHARM ARZNEIMITTEL GMHH BRUDER- GRIMM-STRABE 62, 36396, STEINAU AN DER STRABE	GERMANY	RECTAL SYSTEMIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP,1.0X2.0X5.0 SUPPOSITORY STRIP	01/07/2005

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1938	NDA/MAL/HDP/2 597	E DENK OHG	BENLE CONSULT LIMITED	PARA DENK 250	PARACETAMOL	250MG	BENE-ARZNEIMITTEL GMBHHERTERICHST R. 1,81479 MUENCHEN, GERMANY	GERMANY	RECTAL SYSTEMIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP,1.0X2.0X5.0 SUPPOSITORY STRIP	01/07/2005
1939	NDA/MAL/HDP/2 600	IND SWIFT LTD	PLANET PHARMACEUTICAL S UGANDA LTD	CLARIE-OD	CLARITHROMYCIN (EXTENDED RELEASE)	500MG	IND-SWIFT- LTD,GLOBAL BUSINESS UNIT, JAWAHARPUR, OFF NH-21 DERABASSI	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X1.0X7.0 TABLET BLISTER	01/07/2008

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1940	NDA/MAL/HDP/2 601	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	AXETINE 750MG	CEFUROXIME	750MG	MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X750.0 MG VIAL	01/07/2009
1941	NDA/MAL/HDP/2 602	: ALKEM LABORATORIES LIMITEDV	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM BID	AMOXICILLIN + CLAVULANIC ACID	200 MG + 28.5 MG/ 5 ML	INDCHEMIE HEALTH SPECIALTIES PVT. LTD-(UNIT 3 BETA LACTAM BLOCK) VILLAGE: THANA, TEHSIL: BADDI, DISTRICT: SOLAN HIMACHAL PRADESH -173205 INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE,1.0X70.0 ML BOTTLE	01/07/2010

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1942	NDA/MAL/HDP/2 604	USV PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GROVIT SYRUP	MULTI- INGREDIENT	MULTI- INGREDIENT	SAKAR HEALTHCARE PVT LTDSAKAR HEALTHCARE PVT LTD, BLOCK NO 10- 13, M.N. DESA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2000
1943	NDA/MAL/HDP/2 612	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	RENIRON	MULTI- INGREDIENT	MULTI- INGREDIENT	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	3.0X10.0 CAPSULE BLISTER	01/07/2005

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1944	NDA/MAL/HDP/2 614	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	DIALIN	LOPERAMIDE HCL	2MG	REGAL PHARMACEUTICALS LIMITED PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/2007
1945	NDA/MAL/HDP/2 615	ASTRA ZENECA AB	MACNAUGHTON LIMITED	SYMBICORT TURBUHALER	BUDESONIDE+FO RMOTEROL	160MCG+4.5MCG/ DOSE	ASTRAZENECA AB,GARTUNA & SNACKVIKEN STOCKHOLM	SWEDEN	LUNG ADMINISTRATION METERED-DOSE POWDER INHALER	1.0X60.0 DOSE CANNISTER,1.0X12 0.0 DOSE CANNISTER	01/07/2001

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1946	NDA/MAL/HDP/2 628	MICRO LABS LTD 92 SIPCOT	LABOREX UGANDA LIMITED	AZILIDE-500	AZITHROMYCIN	500MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	01/07/2004
1947	NDA/MAL/HDP/2 641	MEDOCHÉMIE LTD	LABOREX UGANDA LIMITED	AXETINE 250MG	CEFUROXIME AXETIL	250MG	MEDOCHÉMIE LTD PHARMACEUTICAL INDUSTRY,FACTORY C-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIALAREA 4101 AGIOS ATHANASSIOS LIMASSOL CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET STRIP	01/07/2014

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1948	NDA/MAL/HDP/2 642	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MEDOXANUM	CEFTRIAZONE	1G	MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 10 ML AMPOULE WFI	01/07/2016
1949	NDA/MAL/HDP/2 645	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANZIDIME 1000	CEFTAZIDIME	1000MG	SANCE LABORATORIES PVT LTDVI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL	01/07/2010

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1950	NDA/MAL/HDP/2 647	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	IBUPROFEN DENK 400MG	IBUPROFEN	400MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X1.0X10 .0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2005
1951	NDA/MAL/HDP/2 648	E DENK OHG	BENLE CONSULT LIMITED	PARA DENK 125	PARACETAMOL	125MG	RUBIEPHARM ARZNEIMITTEL GMHH BRUDER- GRIMM-STRABE 62, 36396, STEINAU AN DER STRABE	GERMANY	RECTAL SYSTEMIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP,1.0X2.0X5.0 SUPPOSITORY STRIP	01/07/2005



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1952	NDA/MAL/HDP/2 648	E DENK OHG	BENLE CONSULT LIMITED	PARA DENK 125	PARACETAMOL	125MG	BENE-ARZNEIMITTEL GMBHHERTERICHST R. 1,81479 MUENCHEN, GERMANY	GERMANY	RECTAL SYSTEMIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP,1.0X2.0X5.0 SUPPOSITORY STRIP	01/07/2005
1953	NDA/MAL/HDP/2 649	MEDICAL UNION PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	ACICONE-S ORAL SUSPENSION	MAGALDRATE + SIMETHICONE	540MG/5ML + 40MG/5ML	MEDICAL UNION PHARMACEUTICALS (HEAD OFFICE 36 6TH DISTRICT NASR CITY CAIRO EGYPT PLANT ABUSULTAN ISMAILIA)	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS		01/07/2006

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1954	NDA/MAL/HDP/2 650	DENK PHARMA	BENLE CONSULT LIMITED	VIT-B-DENK	THIAMINE HCL + PYRIDOXINE HCL	100MG + 200MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET CARTON,1.0X10.0X 10.0 TABLET BLISTER	01/07/2005
1955	NDA/MAL/HDP/2 651	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	RINAVIT SYRUP	MULTIVITAMIN	MULTI- INGREDIENT	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/1997

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1956	NDA/MAL/HDP/2 653	BLUE CROSS LABORATORIES LTD	STAR PHARMACEUTICAL S LTD	SONADERM-GM	CLOBETASOL + MICONAZOLE + GENTAMICIN	0.05%W/W + 2% W/W+ 0.1%W/W	BLUE CROSS LABORATORIES LTDL- 17, VERNA INDUSTRIAL ESTATE,VERNA GOA- 403722	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE	01/07/2007
1957	NDA/MAL/HDP/2 654	MEDICAL UNION PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	BEBE VIT	VITAMIN A+ VITAMIN D3+VITAMIN E+ VITAMIN C +VITAMIN B1 + VITAMIN B2	1500IU+ 400IU+ 5MG+ 40MG+0.5MG+0.6 MG	MEDICAL UNION PHARMACEUTICAL CO.PLANT: ABU- SULTAN, ISMAILIA, EGYPT	EGYPT	ORAL LIQUID ORDINARY LIQUIDS	1.0X30.0 ML BOTTLE	01/07/2006

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1958	NDA/MAL/HDP/2 656	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AMINOPHYLLINE	AMINOPHYLLINE	100MG	SCOTT-EDIL PHARMACIA LTD (UNIT I)56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2008
1959	NDA/MAL/HDP/2 661	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	FUNGIFEN	CLOTRIMAZOLE	1%W/W	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED VANDALUR ROAD	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997

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1960	NDA/MAL/HDP/2 671	CIPLA LTD..	ABACUS PHARMA (AFRICA) LIMITED	DUOLIN RESPULES	IPRATROPIUM BROMIDE & SALBUTAMOL	500MG + 2.5 MG /2.5ML	CIPLA LTD.- PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	LUNG ADMINISTRATION LIQUID FOR INHALATION	4.0X5.0X2.5 ML VIAL	01/07/2005
1961	NDA/MAL/HDP/2 675	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	LIBITUS PLUS SYRUP	TERBUTALINE/ BROMHEXINE/ GUAIPHENESIN	1.25MG/ 4MG/ 50 MG	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2011

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1962	NDA/MAL/HDP/2 678	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	FORCAN-150	FLUCONAZOLE	150MG	CIPLA LTD PLOT NO. L-139, VERNA, GOA 403 722 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X5.0 CAPSULE BLISTER	01/07/2006
1963	NDA/MAL/HDP/2 680	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMPIREN CAPSULES	AMPICILLIN TRIHYDRATE	250MG	RENE INDUSTRIES LTD680,KAMULI,KIRE KA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER	01/07/2007

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1964	NDA/MAL/HDP/2 681	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMOXIREN	AMOXICILLIN TRIHYDRATE	250MG	RENE INDUSTRIES LTD680,KAMULI,KIRE KA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER	01/07/2007
1965	NDA/MAL/HDP/2 683	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	VITAMIN C	ASCORBIC ACID	100MG	RENE INDUSTRIES LTD680,KAMULI,KIRE KA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2005

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1966	NDA/MAL/HDP/2 685	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEDOL(SUSPEN SION)	PARACETAMOL	120MG/5ML	RENE INDUSTRIES LTD680,KAMULI,KIRE KA KAMPALA,UGANDA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60 .0 ML BOTTLE	01/07/2007
1967	NDA/MAL/HDP/2 690	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AMPIMAX-250	AMPICILLIN	250MG	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/2011



## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1968	NDA/MAL/HDP/2 691	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AMPIMAX-500	AMPICILLIN	500MG	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA INJECT CARE PARENTERALS PVT LTD PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195	CHINA INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X500.0 MG VIAL,1.0X100.0 VIAL CARTON	01/07/2011
1969	NDA/MAL/HDP/2 695	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	IDUMSTRA	PARACETAMOL + IBUPROFEN + CAFFEINE	325MG + 200MG + 40MG	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED VANDALUR ROAD	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X20.0X10.0 CAPSULE BLISTER	01/07/2009

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1970	NDA/MAL/HDP/2 696	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	AMPHOTRET	AMPHOTERICIN B	50MG	BHARAT SERUMS AND VACCINES LTD PLOT NO. K-27 ADDITIONAL MIDC AMBERNATH (E ) 412 501	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 VIAL CARTON	01/07/2012
1971	NDA/MAL/HDP/2 697	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	LUCIN OINTMENT	HYDROCORTISON E	1%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1972	NDA/MAL/HDP/2 698	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	AZICIN-500	AZITHROMYCIN	500MG	PINNACLE LIFE SCIENCE PVT LTD- KHASRA NO. 1328 - 1330, VILLAGE MANPURA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH - 174101 EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	01/07/2009
1973	NDA/MAL/HDP/2 703	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	KOACT 312.50	CO-AMOXICLAV (AMOXYCILLIN TRIHYDRATE+POT ASSIUM CLAVUNATE)	250+62.50MG/ 5ML	AUROBINDO PHARMA LTD, UNIT XII, SURVEY NO 314, BACHUPALLY VILLAGE, QUTHUBULLAPAR, R.R DISTRICT .A. PRADESH	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2007

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1974	NDA/MAL/HDP/2 705	ASTRAZENECA	MACNAUGHTON LIMITED	PULMICORT NEBULISER	BUDESONIDE	0.5MG/ML	ASTRA ZENECA SWEDEN OPERATIONS LIQUID PRODUCTION KVARNBERGAGATAN LZ SE-151- 85,SWEDEN	SWEDEN	LUNG ADMINISTRATION LIQUID FOR INHALATION	1.0X4.0X5.0X2.0 ML VIAL	01/07/2011
1975	NDA/MAL/HDP/2 707	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMCLOXA	CLOXACILLIN	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD PLOT M 444B STRETCHER ROAD NTINDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	100.0 CAPSULE CONTAINER,250.0 CAPSULE CONTAINER,500.0 CAPSULE CONTAINER,1000.0 CAPSULE CONTAINER,10.0 CAPSULE CONTAINER	01/07/1997

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1976	NDA/MAL/HDP/2 708	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	HYPER TABLETS	PROPRANOLOL HYDROCHLORIDE	40MG	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X2.0 X50.0 TABLET BLISTER	01/07/2000
1977	NDA/MAL/HDP/2 710	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	AUGMENTIN BD	AMOXICILLIN + CLAVULANIC ACID	500 MG + 125 MG	SMITHKLINE BEECHAM PHARMACEUTICALS, CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X14.0 TABLET BLISTER	01/07/1997

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1978	NDA/MAL/HDP/2 712	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	ANAWIN	BUPIVACAINE	0.025%W/V	NEON LABORATORIES LTD PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL	01/07/2014
1979	NDA/MAL/HDP/2 715	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LAMIVUDINE	LAMIVUDINE	150MG	MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X60.0 TABLET CONTAINER	01/07/2008

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1980	NDA/MAL/HDP/2 717	CENTAUR PHARMACEUTICAL S PRIVATE LIMITED	GITTOES PHARMACEUTICAL S LIMITED	OCUMYCIN EYE OINTMENT	CHLORAMPHENIC OL	1%W/W	CENTAUR PHARMA PVT. LTD PLOT 39-41, TIVIM INDUSTRIAL ESTATE, KARASWADA, MAPUSA GOA INDIA	INDIA	OPHTHALMIC OINTMENTS	1.0X3.5 G TUBE	01/07/2000
1981	NDA/MAL/HDP/2 719	SEDICO PHARMACEUTICAL CO.	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LORASED	LORATADINE	10MG	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET STRIP	01/07/2016

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1982	NDA/MAL/HDP/2 720	SEDICO PHARMACEUTICAL CO.	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FLUCAMOX 250MG POWDER FOR ORAL SUSPENSION	AMOXICILLIN +FLUCLOXACILLIN	125MG/5ML+125 MG/5ML	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X80.0 ML BOTTLE	01/07/2007
1983	NDA/MAL/HDP/2 721	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	PRIMAFEN TABLET	IBUPROFEN + PARACETAMOL	400MG + 325MG	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007



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1984	NDA/MAL/HDP/2 722	MACK BROWN PHARMACEUTICAL S PVT LIMITED	SHURIK LTD	NO SORES	CHOLINE SALICYLATE/LIDO CAINE	8.7%W/W+2%W/ W	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X10.0 G TUBE	01/07/2007
1985	NDA/MAL/HDP/2 723	TABROS PHARMA	HEALTHCARE LTD.	DURAGESIC TABLET	PARACETAMOL + ORPHENADRINE	450MG+35MG	TABROS PHARMAL- 20/B SECTOR 22 FB INDUSTRIAL AREA KARACHI PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997

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1986	NDA/MAL/HDP/2726	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	QUININE INJECTION	QUININE DIHYDROCHLORIDE	600MG/2ML	WUHAN FUXING BIOPHARMACEUTICAL CO., LTDNO.9, FUXING ROAD, HANCUAN ECONOMIC & DEVELOPMENT DISTRICT, HUBEI PROVINCE	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE,1.0X10.0X2.0 ML AMPOULE	01/07/2008
1987	NDA/MAL/HDP/2728	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	DEXAMETHASONE INJECTION	DEXAMETHASONE	4MG/ML	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	PARENTERAL ORDINARY I V AMPOULES	1.0X100.0X1.0 ML AMPOULE,1.0X100.0X1.0 ML AMPOULE (IN A 2ML AMPOULE)	01/07/2006

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1988	NDA/MAL/HDP/2 734	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	AMLODAR-10	AMLODIPINE BESILATE	10MG	DAR AL DAWANA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER	01/07/2009
1989	NDA/MAL/HDP/2 737	SHAIGAN PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	SENEX FORTE	SECNIDAZOLE	1G	SHAIGAN PHARMACEUTICALS (PVT) LTD14TH KM, ADYALA ROAD, RAWALPINDI- PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X2.0 TABLET BLISTER	07/01/2004

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1990	NDA/MAL/HDP/2 738	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	HEPA-MERZ INFUSION	L-ORNITHINE- L- ASPARTATE	5G/10ML	WIN-MEDICARE PRIVATE LIMITEDMEERUT- MUZAFFARNAGAR ROAD, MODIPURAM 250110 UTTAR PRADESH	INDIA	PARENTERAL ORDINARY I V VIALS	1.0X5.0X10.0 ML VIAL	01/07/2001
1991	NDA/MAL/HDP/2 739	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	BISPANOL TABLET	HYOSCINE BUTYLBROMIDE	10MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER,1.0X100.0X 10.0 TABLET BLISTER	01/07/2001

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1992	NDA/MAL/HDP/2 745	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENFORMIN	METFORMIN HYDROCHLORIDE	500MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2015
1993	NDA/MAL/HDP/2 746	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	ACYCLOVIR DENK 200	ACYCLOVIR	200MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X25.0 TABLET BLISTER	01/07/2000

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

1994	NDA/MAL/HDP/2 753	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	PRASIL	METOCLOPRAMI DE HYDROCHLORIDE	10MG	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
1995	NDA/MAL/HDP/2 754	FDC LTD	AIVEEN (U) LIMITED	ZATHRIN 500	AZITHROMYCIN DIHYDRATE	500MG	FDC LIMITED PLOT NO. L121 B PHASE 111A VERNA INDUSTRIAL ESTATE VERNA SALCETE GOA 403 722	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X1.0X3.0 TABLET BLISTER,1.0X50.0X1 .0X1.0X3.0 TABLET BLISTER	01/07/2016

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1996	NDA/MAL/HDP/2 756	PFIZER LABORATORIES LTD	LABOREX UGANDA LIMITED	CYTOTEC	MISOPROSTOL	200MCG	PIRAMAL HEALTHCARE LIMITEDWALTON ROAD MORPETH NORTHUMBERLAND NE 613YA	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2010
1997	NDA/MAL/HDP/2 760	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	DELAISED DRY COUGH SYRUP	DIPHENHYDRAMINE HYDROCHLORIDE +DEXTROMETHORPHAN+SODIUM CITRATE+MENTHOL	14MG+6.5MG+57 MG+2MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997

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1998	NDA/MAL/HDP/2 763	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	CANDISTAT	CLOTRIMAZOLE	100MG	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	VAGINAL SUPPOSITORIES	1.0X2.0X3.0 PESSARY STRIP	01/07/1997
1999	NDA/MAL/HDP/2 773	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	BISPANOL ELIXIR	HYOSCINE-N- BUTYLBROMIDE	5MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE, 1.0X1.0X10 0.0 ML BOTTLE	01/07/2004



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2000	NDA/MAL/HDP/2774	ACINO PHARMA AG -	LABOREX UGANDA LIMITED	BACTIFLOX NEO 500	CIPROFLOXACIN	500MG	ACINO PHARMA AG- BIRSWEG 2, 4253, LIESBERG - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2005
2001	NDA/MAL/HDP/2776	UNIQUE PHARMACEUTICAL S LABORATORIES	PLANET PHARMACEUTICAL S UGANDA LTD	TENSIMIN-100	ATENOLOL	100MG	UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)216-219 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,14.0X1 0.0 TABLET BLISTER	01/07/1997

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2002	NDA/MAL/HDP/2777	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	CO-DIOVAN 160/12.5MG TABLETS	VALSARTAN + HYDROCHLOROT HIAZIDE	160MG + 12.5MG	NOVARTIS PHARMA AGSCHAFFHAUSERSTRASSE 4332 STEIN SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER,1.0X2.0X14.0 TABLET BLISTER	01/07/2006
2003	NDA/MAL/HDP/2779	BROOKES PHARMACEUTICAL LABORATORIES L	HARLEYS UGANDA LIMITED	PYODINE SURGICAL SCRUB	POVIDONE IODINE	7.5%W/V	BROOKES PHARMACEUTICALS LABORATORIES (PAKISTAN) LTD PLOT 58 SECTOR 15 KORANGI INDUSTRIAL AREA, KARACHI-PAKISTAN	PAKISTAN	TOPICAL EXTERNAL LIQUIDS	1.0X60.0 ML BOTTLE,1.0X450.0 ML BOTTLE,1.0X500.0 ML BOTTLE	01/07/2016

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2004	NDA/MAL/HDP/2781	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	CARVETAS 6.25	CARVEDILOL	6.25MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
2005	NDA/MAL/HDP/2783	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN SUPPOSITORIES 25MG	DICLOFENAC SODIUM	25MG	DELPHARM HUNINGUE S.A.S-SITE INDUSTRIAL HUNINGUE26, RUE DE LA CHAPELLE, F-68330, HUNINGUE	FRANCE	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X10.0 SUPPOSITORY STRIP	01/07/2006

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2006	NDA/MAL/HDP/2787	MEDOPHARM PRIVATE LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	MEDOMOX 125 DT	AMOXICILLIN	125MG	MEDOPHARM PVT LTD.NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2013
2007	NDA/MAL/HDP/2788	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	MULTIREN	MULTIINGREDIENT	N/A	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER	01/07/2010

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2008	NDA/MAL/HDP/2 793	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	VIREAD	TENOFOVIR DISOPROXIL FUMARATE	300MG	TAKEDA GMBH,PLANT ORANIENBURG- LEHNITZSTRASSE 70- 98,16515,ORANIENB URG-GERMANY PATHEON YM INC. TORONTO- TORONTO, CANADA	GERMANY CANADA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X30.0 TABLET BOTTLE	01/07/2004
2009	NDA/MAL/HDP/2 796	ASTRA PHARMA (UK) LTD	ASTRA PHARMA (U) LIMITED	BENZYL PENICILLIN INJECTION	BENZYL PENICILLIN SODIUM	1,000,000I.U	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTDNO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSH OP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 VIAL CARTON,1.0X50.0 VIAL CARTON	01/07/2001

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2010	NDA/MAL/HDP/2797	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	LUMAREN	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X8.0 TABLET BLISTER	01/07/2010
2011	NDA/MAL/HDP/2800	NOVO NORDISK	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ACTRAPID FLEXPEN 100 I.U/ML	HUMAN INSULIN	100 I.U/ML	NOVO NORDISK PRODUCTION SAS45 AVENUE D'ORLEANS, 28000 CHARTRES, FRANCE NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDAAV. "C", 1413, DISTRITO INDUSTRIAL - 390404 004 MONTES CLAROS, MINAS GERAIS - BRAZIL NOVO NORDISK PHARMANOVO ALLE	DENMARK BRAZIL FRANCE	PARENTERAL ORDINARY PRE-FILLED PENS	1.0X5.0X3.0 ML PREFILLED PEN, 1.0X5.0X1.5 ML PREFILLED PEN	01/07/1997

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2012	NDA/MAL/HDP/2 802	CENTAUR PHARMACEUTICAL S PRIVATE LIMITED	GITTOES PHARMACEUTICAL S LIMITED	TASOL	CLOBETASOL	0.05%W/W	CENTAUR PHARMACEUTICALS PVT LTD -PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2005
2013	NDA/MAL/HDP/2 805	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	NIFELAT 20R TABLETS	NIFEDIPINE	20MG	REMEDICA LIMITED AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/1997

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2014	NDA/MAL/HDP/2 807	GUILIN PHARMACEUTICAL S CO.LTD	TRIDEM PHARMA UGANDA LIMITED	ASAQ GPSC	ARTESUNATE + AMODIAQUINE	100 MG + 270 MG	GUILIN PHARMACEUTICALS CO. LTDNO 43 QULIDIAN ROAD GUILIN GUANGXI CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X20.0X3.0 TABLET BLISTER,1.0X20.0X6 .0 TABLET BLISTER,1.0X25.0X3 .0 TABLET BLISTER,1.0X25.0X6 .0 TABLET BLISTER	01/07/2011
2015	NDA/MAL/HDP/2 811	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	SULPHUR OINTMENT	SULPHUR PRECIPITATED	10%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X25.0 G TUBE	01/07/2001



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2016	NDA/MAL/HDP/2 812	DAFRA PHARMA LTD	MULTIPHAR UGANDA LIMITED	CO-ARTESIANE	BETA ARTEMETHER + LUMEFANTRINE	180 MG/60ML + 1080 MG/60ML	S KANT HEALTHCARE LIMITED1802 – 1805, G.I.D.C., PHASE III, VAPI -396195 GUJARAT, INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE	01/07/2005
2017	NDA/MAL/HDP/2 813	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	INTACYCLINE SKIN OINTMENT	TETRACYCLINE HYDROCHLORIDE	3%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997

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2018	NDA/MAL/HDP/2 816	ZYDUS LIFESCIENCES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CATENOL-100 TABLETS	ATENOLOL	100MG	ZYDUS LIFESCIENCES LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER	01/07/1997
2019	NDA/MAL/HDP/2 821	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	DIOLIN-M	GLIBENCLAMIDE+ METFORMIN HYDROCHLORIDE TABLETS	5MG+500MG	LINCOLN PHARMACEUTICAL LIMITED..LINCOLN PHARMACEUTICALS LIMITED, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2011

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2020	NDA/MAL/HDP/2 826	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PIRITON SYRUP	CHLORPHENIRAM INE MALEATE	4MG/10ML	GLAXOSMITHKLINE LI KONI ROAD IND. AREA, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE, 1.0X2.0 L BOTTLE	01/07/1997
2021	NDA/MAL/HDP/2 835	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	SOLUDINE-M	POVIDONE IODINE / METRONIDAZOLE	5%W/W / 1%W/W	LINCOLN PHARMACEUTICALS LIMITED TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT - INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE, 1.0X125.0 G TUBE	01/07/2011

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2022	NDA/MAL/HDP/2 837	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	GRAMOFIL TABLETS	NALIDIXIC ACID	500MG	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED VANDALUR ROAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1997
2023	NDA/MAL/HDP/2 838	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	DILCONTIN XL 120	CONTROLLED RELEASE TABLETS OF DILTIAZEM HYDROCHLORIDE	120MG	MODI MUNDIPHARMA (PVT) LTDMEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP, 1.0X3.0X10.0 TABLET STRIP	01/07/2010

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2024	NDA/MAL/HDP/2 848	ORGANON SOUTH AFRICA (PTY) LTD	SURGIPHARM (U) LIMITED	DIPROGENTA OINTMENT	BETAMETHASONE /GENTAMICIN SULPHATE	0.5MG/G+1.0MG/ G	SCHERING-PLOUGH LABONV-INDUSTRIE PARK 30, B-220 HEIST-OP-DEN-BERG, BELGIUM	BELGIUM	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE,1.0X30.0 G TUBE	01/07/2001
2025	NDA/MAL/HDP/2 850	MEDICAL UNION PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	DISPERCAM	PIROXICAM	20MG	MEDICAL UNION PHARMACEUTICAL CO.PLANT: ABU- SULTAN, ISMAILIA, EGYPT	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X2.0X3.0X1.0 ML AMPOULE	01/07/2007

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2026	NDA/MAL/HDP/2 869	GLAXO SMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PRIORIX VACCINE	MEASLES + MUMPS + RUBELLA	103.0CCID50 + 103.7CCID50 + 103.0CCID50	GLAXO SMITHKLINE BIOLOGICALS S.ARUÉ DE L'INSTITUT, 89 B- 1330 RIXENSART	BELGIUM	PARENTERAL ORDINARY DRY VIALS	1.0X0.5 ML VIAL (1 DOSE)	01/07/2010
2027	NDA/MAL/HDP/2 873	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	HELIGO KIT	TINIDAZOLE/CLAR ITHROMYCIN/LAN SOPRAZOLE	500MG+ 250MG+30MG	INTAS PHARMACEUTICALS LTD .PLOT NOS. 457, 458 & 191/218P SARKHEJ-BAVLA HIGHWAY MATODA SANAND AHMEDABAD GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X7.0X6.0 TABLET BLISTER	01/07/2001

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2028	NDA/MAL/HDP/2 875	GLAXOSMITHKLINE LIMITED-	UNITED HEALTHCARE DISTRIBUTORS LTD	OTRIVIN 0.05% NASAL DROPS	XYLOMETAZOLINE	0.05%W/V	GSK CONSUMER HEALTH SAGSK CONSUMER HEALTH SA, ROUTE DE L'ETRAZ, NYON, 1260, SWITZERLAND	SWITZERLAND	NASAL TOPICAL DROPS	1.0X10.0 ML BOTTLE	01/07/2003
2029	NDA/MAL/HDP/2 880	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CARBIMAZOLE 5	CARBIMAZOLE	5MG	REMEDICA LIMITED,LIMASSOL INDUSTRIAL ESTATE, AHARNON ST, P.O. BOX 51706,3508 LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010

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2030	NDA/MAL/HDP/2 885	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	FORECOX-TRAC	RIFAMPICIN + ISONIAZID + PYRAZINAMIDE + ETHAMBUTOL	150MG + 75MG+ 400MG + 275MG	OXALIS LABS LIMITEDVILLAGE THEDA, P.O LODHIMAJRA, TEHSIL,BADDI, DIST.SOLAN, INDIA MACLEODS PHARMACEUTICALS LTD .PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X6.0 TABLET BLISTER,1.0X24.0X2 8.0 TABLET BLISTER	01/07/2005
2031	NDA/MAL/HDP/2 888	VHB MEDI SCIENCES LTD	NORVIK ENTERPRISES LIMITED	SUCCICORT	HYDROCORTISON E SODIUM SUCCINATE	100MG/VIAL	VHB MEDI SCIENCES LTD PLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	, 1X100 MG VIAL	07/01/2013



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2032	NDA/MAL/HDP/2891	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	TORVAST 20	ATORVASTATIN	20MG	MACLEODS PHARMACEUTICALS LTD .PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2006
2033	NDA/MAL/HDP/2892	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	NICARDIA-20 TABLETS	NIFEDIPINE	20MG	UNIQUE PHARMACEUTICAL LABORATORIES PLOT NO. 215-219, G.I.D.C. INDUSTRIAL AREA, PANOLI — 394 116, GUJARAT, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER, 1.0X10.0X10.0 TABLET BLISTER	01/07/1997

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2034	NDA/MAL/HDP/2 893	DAWA LIMITED	SUPER MEDIC LTD	STOPACID SUSPENSION	MAGNESIUM TRISILICATE + ALUMINIUM HYDROXIDE	250MG/5ML + 120MG/5ML	DAWAPLOT 7879, BABA DOGO ROAD RUARAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2009
2035	NDA/MAL/HDP/2 894	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MUCOGEL SUSPENSION	DRIED ALUMINIUM HYDROXIDE + MAGNESSIUM HYDROXIDE + OXETHAZAINE	8G/100ML + 2G/100ML + 0.2 G/100ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO EIPICO10TH OF RAMADAN CITY- FIRST INDUSTRIAL AREA -EGYPT	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X125.0 ML BOTTLE	01/07/2005

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2036	NDA/MAL/HDP/2 896	KPI INDUSTRIES(1996) LTED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	MCG CREAM	MICONAZOLE NITRATE BP + CLOBETASOL PROPIONATE BP + GENTAMYCIN SULPHATE	2.0%W/W + 0.05%W/W + 0.1 %W/W	KPI INDUSTRIES (1996) LTD PLOT NO.M444B STRETCHER RD, NTINDA, KAMPALA	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE,1.0X15.0 G TUBE,1.0X25.0 G TUBE	01/07/2005
2037	NDA/MAL/HDP/2 898	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	TORVAST 10	ATORVASTATIN	10MG	MACLEODS PHARMACEUTICALS LTD .PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2006

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2038	NDA/MAL/HDP/2 900	MICRO LABS LTD	LABOREX UGANDA LIMITED	GRAMOCEF-O- 200	CEFIXIME	200MG	MICRO LABS LIMITED, BOMMASANDRA PLOT NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/2005
2039	NDA/MAL/HDP/2 902	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	MEGALIS-20	TADALAFIL	20MG	MACLEODS PHARMACEUTICALS LIMITED (BLOCK -N1)VILLAGE THEDA, P.O. LODHI MAJRA,TEHSIL BADDI, HIMACHAL PRADESH - 174101,INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X15.0X1.0X4.0 TABLET STRIP	01/07/2005

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2040	NDA/MAL/HDP/2 905	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BRONCHOPHANE SYRUP	GUAIPHENESIN+ PHEDRINE HYDROCHLORIDE +DIPHENHYDRAM INE HYDROCHLORIDE +DEXTROMETHO RPHAN	50MG+7.5MG+5M G+4.58MG	ORCHIDIA10TH STREET RAMADAN CITY, FIST INDUSTRIES ARE	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X125.0 ML BOTTLE	01/07/2007
2041	NDA/MAL/HDP/2 906	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	RIFAMPICIN/ISON IAZID/ETHAMBUT OL	RIFAMPICIN+ISON IAZID+ETHAMBUT OL	150MG+75MG+27 5MG	MACLEODS PHARMACEUTICALS LTD .PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X24.0X28.0 TABLET BLISTER	01/07/2012

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2042	NDA/MAL/HDP/2 907	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	LONART DS	ARTEMETHER + LUMEFANTRINE	80 MG + 480 MG	BLISS GVS PHARMA LIMITEDNO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER	01/07/2008
2043	NDA/MAL/HDP/2 908	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	PAINGO MEDICATED CREAM	METHYLSALICYLA TE+CAPSICUM OLEORESIN+TURP ENTINE OIL	15%W/W + 1%W/W + 1.47%W/W	NEM LABORATORIES PVT LTDPLOT NO. 133 KRISHNA IND. ESTATE, VASAI E,DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL CREAMS	1.0X2.0X15.0 G TUBE	01/07/2010

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2044	NDA/MAL/HDP/2 910	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	TENVIR EM	TENOFOVIR DISOPROXIL FUMARATE + EMTRICITABINE	300MG+200MG	CIPLA LTD.- PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2009
2045	NDA/MAL/HDP/2 911	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL LORATADINE	LORATADINE	10MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010

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2046	NDA/MAL/HDP/2914	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	CHLOROCIDE SUSPENSION	CHLORAMPHENIC OL PALMITATE	125MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/1997
2047	NDA/MAL/HDP/2917	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	CETAMOL TABLETS	PARACETAMOL	500MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X2.0 TABLET STRIP,1.0X500.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET STRIP,1.0X100.0X10.0 TABLET BLISTER	01/07/1997



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2048	NDA/MAL/HDP/2 920	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	TRANSLIPO -C CREAM	CLOTRIMAZOLE	1%W/W	CENTAUR PHARMACEUTICALS PVT LTD -PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X20.0 G TUBE,1.0X10.0 G TUBE	01/07/2001
2049	NDA/MAL/HDP/2 940	CENTAUR PHARMACEUTICAL S PVT. LTD	GITTOES PHARMACEUTICAL S LIMITED	BENZOX 5 GEL	BENZOYL PEROXIDE	5%W/W	CENTAUR PHARMACEUTICALS LTD PLOT NO. 39 TIVIN IN	INDIA	TOPICAL EXTERNAL OTHER GELS/SOLS	1.0X20.0 G TUBE	01/07/2005

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2050	NDA/MAL/HDP/2 942	CENTAUR PHARMACEUTICAL S PRIVATE LIMITED	GITTOES PHARMACEUTICAL S LIMITED	ARGISSEPT CREAM	CHOLRHEXIDINE GLUCONATE/SILV ER SULPHADIAZINE	0.2%W/W / 1%W/W	CENTAUR PHARMACEUTICALS PVT LTD -PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE,1.0X10.0 G TUBE	01/07/2005
2051	NDA/MAL/HDP/2 946	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	TRIMAGO ORAL SUSPENSION	CO-TRIMOXAZOLE	240MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1998

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2052	NDA/MAL/HDP/2 947	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	TRIMAGO TABLETS	CO-TRIMOXAZOLE	480MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X25 0.0 BLISTER CARTON	01/07/1998
2053	NDA/MAL/HDP/2 948	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	METFORMIN DENK 850	METFORMIN HYDROCHLORIDE	850MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X15.0 TABLET BLISTER,1.0X8.0X15 .0 TABLET BLISTER	01/07/2007

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2054	NDA/MAL/HDP/2 951	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	LONART FORTE TABLETS	ARTEMETHER + LUMEFANTRINE	40 MG + 240 MG	BLISS GVS PHARMA LIMITEDNO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X2.0X6.0 TABLET BLISTER	01/07/2007
2055	NDA/MAL/HDP/2 956	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	TRANLOK 500MG TABLETS	TRANEXAMIC ACID	500MG	ARISTO PHARMACEUTICALS PVT LIMITEDPLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP- 462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2010

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2056	NDA/MAL/HDP/2 957	MEDIPHARM SALES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MEDITROL	CALCITRIOL	0.25MCG	MEGA LIFE SCIENCES LIMITED: PLANT 1 : 384 SOI 6, PATTANA 3 ROAD, BANGPOO INDUSTRIAL ESTATE, SAMUTPRAKAN 10280, THAILAND	THAILAND	ORAL SOLID ORDINARY CAPSULES	1.0X6.0X5.0 CAPSULE BLISTER,1.0X3.0X10 .0 CAPSULE BLISTER	01/07/2009
2057	NDA/MAL/HDP/2 959	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	CETAMOL SYRUP	PARACETAMOL	120MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/1997

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2058	NDA/MAL/HDP/2 960	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	CLAVODAR	AMOXICILLIN/CLA VULANIC ACID	400MG/57MG	DAR AL DAWANA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY GRANULES	1.0X70.0 ML BOTTLE	01/07/2010
2059	NDA/MAL/HDP/2 969	UNIQUE PHARMACEUTICAL S LTD	PLANET PHARMACEUTICAL S UGANDA LTD	TENSIMIN-50	ATENOLOL	50MG	UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)216-219 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,14.0X10.0 TABLET BLISTER	01/07/1997

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2060	NDA/MAL/HDP/2 970	USV PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GLYCOMET 500	METFORMIN	500MG	FREDUN PHARMACEUTICALS LIMITED--14,15,16 ZORABIAN INDUSTRIAL COMPLEX PALAGHAR (EAST), DIST THANE 401 404 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2000
2061	NDA/MAL/HDP/2 971	TORRENT PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S LTD.	LEFRA-20 TABLETS	LEFLUNOMIDE	20MG	TORRENT PHARMACEUTICALS LTDINDRAD-382 721, DIST.MEHSANA,INDI A.AT:VILL.MANAKPU R,TEH.NALAGARH,DI ST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2004

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2062	NDA/MAL/HDP/2 974	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	TRAVATAN	TRAVOPROST	4µG/ML	ALCON COUVREUR NVRIJKSWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X2.5 ML VIAL	01/07/2009
2063	NDA/MAL/HDP/2 979	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	BETADERM N CREAM	BETAMETHASONE VALERATE + NEOMYCIN	0.1%W/W + 0.5%W/W	ATCO LABORATORIES PVT LTDB-18,S.I.T.E KARACHI 75700, PAKISTAN	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE,1.0X15.0 G TUBE	01/07/1997



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2064	NDA/MAL/HDP/2 980	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	LONART TABLETS	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	BLISS GVS PHARMA LIMITEDNO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X3.0X8.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X2.0X6. 0 TABLET BLISTER,1.0X3.0X6. 0 TABLET BLISTER,1.0X24.0 TABLET BLISTER,1.0X12.0 TABLET BLISTER,1.0X18.0 TABLET BLISTER,1.0X24.0 TABLET BLISTER	01/07/2007
2065	NDA/MAL/HDP/2 982	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	NEURO-FORTE TABLETS	VITAMIN B1 + VITAMIN B6 + VITAMIN B12	200MG + 50MG + 1MG	CENTAUR PHARMACEUTICALS LTD PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2004

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2066	NDA/MAL/HDP/2 983	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	FUCOL 200	FLUCONAZOLE	200MG	CIPLA LTD PLOT NO. L-139, VERNA, GOA 403 722 INDIA CIPLA LTD KURKUMBHD-7 MIDC INDUSTRIAL AREA, KURKUMBH, TALUKA-DAUND, PUNE, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X1.0X4.0 CAPSULE BLISTER	01/07/2004
2067	NDA/MAL/HDP/2 985	SANOFI 410 THALES	LABOREX UGANDA LIMITED	EPILIM CHRONO	SODIUM VALPROATE PH. EUR	500MG	SANOFI WINTHROP INDUSTRIE1,RUE DE LA VIERGE ,AMBARES ET LAGRAVE 33565,CARBON BLANC CEDEX FRANCE	FRANCE	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2004

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2068	NDA/MAL/HDP/2990	MICRO LABS LTD	LABOREX UGANDA LIMITED	PULMOCEF-500	CEFUROXIME AXETIL USP	500MG	MICRO LABS LTD- NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X3.0X4.0 TABLET BLISTER	01/07/2004
2069	NDA/MAL/HDP/2995	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	GALLOP	LOPERAMIDE HYDROCHLORIDE USP	2MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0 CAPSULE CONTAINER	01/07/2007

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2070	NDA/MAL/HDP/2 997	MEDLEY PHARMACEUTICAL S	EUROPA HEALTHCARE (U) LTD	ACENAC TABLETS	ACECLOFENAC	100 MG	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007
2071	NDA/MAL/HDP/2 998	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	FITIN-5	LEVOCETIRIZINE DIHYDROCHLORID E	5MG	MEDLEY PHARMACEUTICALS LTD PLOT NO 18 & 19, SURVEY NO. 378/7& 8,379/2&3 ZARI AUSEWAY ROAD,, KACHIGAM, DAMAN-396 210	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009

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2072	NDA/MAL/HDP/3003	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOVIR	ACICLOVIR	200MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10.0 TABLET BLISTER	01/07/2007
2073	NDA/MAL/HDP/3005	ACINO PHARMA AG -	LABOREX UGANDA LIMITED	OLFEN-100 SR PROLONGED-RELEASE CAPSULES	DICLOFENAC SODIUM	100MG	ACINO PHARMA AGBIRSWEG 2, 4253, LIESBERG - SWITZERLAND	SWITZERLAND	ORAL SOLID RETARD CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/1997

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2074	NDA/MAL/HDP/3007	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	TORTAS 5	TORSEMIDE	5MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
2075	NDA/MAL/HDP/3009	VENUS REMEDIES LIMITED	HARLEYS UGANDA LIMITED	SULBACTOMAX 1.5G	CEFTRIAXONE+SULBACTAM	1000MG+500MG	VENUS REMEDIES LTD, UNIT II,HILL TOP INDUSTRIAL ESTATE, JHARMAJTI, EPIP, PHASE-1 (EXTENSION), BHATOLI KALAN, BADDI -HP	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL	01/07/2009

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2076	NDA/MAL/HDP/3 012	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	DICLOMOL TABLETS	DICLOFENAC SODIUM	50MG	WIN MEDICARE PVT LIMITEDMEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1998
2077	NDA/MAL/HDP/3 013	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOZOLE	ALBENDAZOLE	400MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X1.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER,1.0X50.0X1 .0 TABLET BLISTER	01/07/2007

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2078	NDA/MAL/HDP/3 017	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	LIDOCAINE INJECTION	LIDOCAINE HYDROCHLORIDE	20MG/ML	SANJAR PHARMA LLP HIMATNAGAR- VIJOPUR HIGHWAY, DEDHROTA HIMATNAGAR 383 220, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X25.0X20.0 ML VIAL,1.0X30.0 ML VIAL	01/07/2008
2079	NDA/MAL/HDP/3 019	MJ BIOPHARM PVT LTD	VITACARE LIMITED	BIOSULIN 30/70	INSULIN SOLUBLE + INSULIN ISOPHANE	30 I.U + 70 I.U	MJ BIOPHARM PRT LTDL-7 MIDC INDUSTRIAL AREA, TALOJA, NARI MUMBAI MAHARASHTRA	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	01/07/2008



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2080	NDA/MAL/HDP/3 020	M.J BIOPHARM PVT LTD	VITACARE LIMITED	BIOSULIN N	INSULIN ISOPHANE	100 I.U./ML	M.J .BIOPHARML7, M.I.D.C INDUSTRIAL AREA TALOJA, NAVI MUMBAI MAHARAHTRA	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL	01/07/2008
2081	NDA/MAL/HDP/3 021	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	GLIBENCLAMIDE TABLETS	GLIBENCLAMIDE	5MG	AGOG PHARMA LIMITEDPLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2007

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2082	NDA/MAL/HDP/3 023	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOTRAX	LEVAMISOLE HYDROCHLORIDE	40MG	AGOG PHARMA LTD.PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET STRIP,1.0X10.0X1.0 X3.0 TABLET STRIP,1.0X500.0 TABLET CONTAINER	01/07/2007
2083	NDA/MAL/HDP/3 024	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE	LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE	150MG + 200MG + 300MG	QUESTA CARE LIMITEDPLOT NO 209/7184 HOMABAY RD TERMINUS GATE NO-19, INDUSTRIAL AREA NAIROBI, KENYA. MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD - H-12 & H-13 MIDC	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2008

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2084	NDA/MAL/HDP/3 029	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOZOLE SUSPENSION	ALBENDAZOLE USP	200 MG/ 5 ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	01/07/2007
2085	NDA/MAL/HDP/3 030	MJ BIOPHARM PVT LTD	VITACARE LIMITED	BIOSULIN R	INSULIN SOLUBLE	100 IU/ML	M.J BIOPHARM PVT LTD -L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL	01/07/2008

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2086	NDA/MAL/HDP/3 031	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOMETHASONE	DEXAMETHASON E	0.5MG	AGOG PHARMA LTD.NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2007
2087	NDA/MAL/HDP/3 032	ACINO PHARMA AG -	LABOREX UGANDA LIMITED	XYLO-ACINO 0.05%	XYLOMETAZOLINE	0.05%W/V	MERCKLE GMBH,LUDWIG MERCKLE STRASSE3 D-89143 BLAUBEUREN	GERMANY	NASAL TOPICAL SPRAYS WITHOUT GAS	1.0X10.0 ML BOTTLE	01/07/2007

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2088	NDA/MAL/HDP/3 035	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOFORTE TONIC	FERRIC AMMONIUM CITRATE + FOLIC ACID + PYRIDOXINE HCL + THIAMINE HCL + NICOTINAMIDE + VITAMIN B12	50MG + 0.55MG + 2.4MG + 1.2MG + 11MG + 2.5MG	AGOG PHARMA LIMITEDPLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE,1.0X60.0 ML BOTTLE,1.0X1.0X10 0.0 ML BOTTLE	01/07/2007
2089	NDA/MAL/HDP/3 037	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOVIT SYRUP	VITAMIN A + VITAMIN D3 + VITAMIN B1 + VITAMIN B2 + NIACINAMIDE + VITAMIN B12 + VITAMIN C	1000I.U + 200I.U + 1.5MG + 1.5MG+ 10MG + 2.5MCG + 40MG	AGOG PHARMA LIMITEDPLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE,1.0X1.0X10 0.0 ML BOTTLE	01/07/2007

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2090	NDA/MAL/HDP/3040	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGODOX	DOXYCYCLINE	100MG	AGOG PHARMA LIMITED PLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER,1.0X100.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER	01/07/2007
2091	NDA/MAL/HDP/3044	ZYDUS LIFESCIENCES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PIRICAM-20 CAPSULES	PIROXICAM	20MG	ZYDUS LIFESCIENCES LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER,2.0X10.0 CAPSULE BLISTER	01/07/1997

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2092	NDA/MAL/HDP/3 046	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	CLAVULIN	AMOXICILLIN + CLAVULANIC ACID	400 MG + 57 MG	GLAXO WELLCOME PRODUCTIONZI DE LA PEYENNIERE, 53100, MAYENNE	FRANCE	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X70.0 ML BOTTLE	01/07/2009
2093	NDA/MAL/HDP/3 048	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	TRIMAGO-DS TABLETS	SULFAMETHOXAZ OLE/TRIMETHOPR IM	800MG/160MG	AGOG PHARMA LIMITEDPLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0X10.0 TABLET BLISTER,1.0X2.0X14 .0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET CONTAINER,1.0X3.0 X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2007

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2094	NDA/MAL/HDP/3051	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	BETROZOLE	DILOXANIDE FUROATE+METRONIDAZOLE BENZOATE+SIMETHICONE	125MG+160MG+25MG	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2005
2095	NDA/MAL/HDP/3057	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	COLD-A-GO CAPSULES	PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + DIPHENHYDRAMINE + CAFFEINE	400MG + 5MG + 12.5MG + 30MG	AGOG PHARMA LIMITED PLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER,1.0X10.0X10.0 CAPSULE BLISTER	01/07/2007



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2096	NDA/MAL/HDP/3 063	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGODIC-50	DICLOFENAC SODIUM	50MG	AGOG PHARMA LTD.NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10 0.0 TABLET CONTAINER,1.0X10 0.0X10.0 TABLET BLISTER	01/07/2007
2097	NDA/MAL/HDP/3 064	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	TIN-TIN TABLETS	TINIDAZOLE	500MG	AGOG PHARMA LTD.PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0 TABLET BLISTER,1.0X24.0X4 .0 TABLET BLISTER,25.0X4.0 TABLET BLISTER	01/07/2007

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2098	NDA/MAL/HDP/3 067	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	PROMAGO SYRUP	PROMETHAZINE	5MG/5ML	AGOG PHARMA LIMITEDPLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60 .0 ML BOTTLE	01/07/2007
2099	NDA/MAL/HDP/3 068	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	OPTACHLOR EYE DROPS	CHLORAMPHENIC OL	0.5%W/V	REMINGTON PHARMACEUTICAL INDUS. PVT LTD, 117 ALLAM	PAKISTAN	OPHTHALMIC DROPS	1.0X10.0 ML VIAL	01/07/1999

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2100	NDA/MAL/HDP/3 069	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOMOVE CAPSULES	PIROXICAM	20MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0 CAPSULE CONTAINER	01/07/2007
2101	NDA/MAL/HDP/3 072	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOMOL TABLETS(THANE)	PARACETAMOL	500 MG	AGOG PHARMA LIMITED PLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER,1.0X10 0.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/1998

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2102	NDA/MAL/HDP/3 076	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO TELVAS 40	TELMISARTAN	40MG	ARISTO PHAMACUTLAB PVT LTD PLOT NO.208 NEW INDUSTRIAL AREA NO.2 MANIDIDEEP 462.046	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP,3.0X10.0 TABLET BLISTER	01/07/2007
2103	NDA/MAL/HDP/3 077	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	UNISTEN HC CREAM	CLOTRIMAZOLE + HYDROCORTISON E	1%W/W + 1%W/W	REGAL PHERMACUTICALS PLOT 7879/18 OFF BABA RWARAKA NAIROBI KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2008

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2104	NDA/MAL/HDP/3078	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SINUTAB ALLERGY CONGESTION	PARACETAMOL + CHLORPHENIRAMINE MALEATE + PSEUDOEPHEDRINE HYDROCHLORIDE	500MG + 2MG + 30MG	JOHNSON&JOHNSON PTY LTD.EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2010
2105	NDA/MAL/HDP/3083	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO TELVAS 80	TELMISARTAN	80MG	ARISTO PHARMACEUTICALS PVT. LIMITEDPLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP,3.0X10.0 TABLET STRIP	01/07/2007

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

2106	NDA/MAL/HDP/3085	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCOLD TABLETS	PARACETAMOL+PHENYLEPHRINE HCL+CAFFEINE+CHLORPHENIRAMINE HYDROCHLORIDE	500.MG+5.0MG+30.0MG+2.0MG	AGOG PHARMA LIMITED PLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X25.0X4.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER,1.0X4.0 TABLET BLISTER,1.0X50.0X4.0 TABLET BLISTER	01/07/2007
2107	NDA/MAL/HDP/3090	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFODOX	CEFPODOXIME PROXETIL	100MG/5ML	PHARMA INTERNATIONAL CO.AMMAN JORDAN PLANT AL-QARTAL MARKETING DEPARTMENT ALBUJAH COMPLEX, ALJUBAIHA	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X50.0 ML BOTTLE	01/07/2004

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2108	NDA/MAL/HDP/3 091	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	ONDI	ONDANSETRON	2MG/ML	SAKAR HEALTH CARE PVT, LTDBLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ- BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X2.0 ML AMPOULE	01/07/2013
2109	NDA/MAL/HDP/3 092	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	EXFORGE HCT 10MG/160MG/12 .5MG	AMLODIPINE + VALSARTAN + HYDROCHLOROT HIAZIDE	10MG + 160MG +12.5MG	NOVARTIS PHARMA STEIN AGSCHAFFHARVSERT RASSE CH-4332 STEIN SWITZERLAND.	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER	01/07/2015

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2110	NDA/MAL/HDP/3 095	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	AMPHEN SUSPENSION	CHLORAMPHENIC OL PALMITATE	125MG/5ML	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2007
2111	NDA/MAL/HDP/3 098	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MOSEDIN	LORATADINE	5MG/5ML	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2004



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2112	NDA/MAL/HDP/3 099	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	ZONA 0.1% CREAM	HYDROCORTISON E 17-BUTYRATE	0.1%W/W	PHARMA INTERNATIONAL CO.,AL-QASTAL AREA, AIRPORT ROAD, 11941, AMMAN	JORDAN	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	01/07/2007
2113	NDA/MAL/HDP/3 101	DAWA LIMITED	SUPER MEDIC LTD	DACOLD SYRUP	PARACETAMOL + PSEUDOEPHEDRI NE HCL + CHLORPHENIRAM INE MALEATE	120MG/5ML+10M G/5ML+2MG/5ML	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2010

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2114	NDA/MAL/HDP/3 104	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	NYSTALEB ORAL SUSPENSION	NYSTATIN	100000IU/ML	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2007
2115	NDA/MAL/HDP/3 108	IPCA LABORATOIES LTD	MEDVIN PHARMA LIMITED	ZERODOL	ACECLOFENAC	100MG	IPCA LABORATORIES LTD,PLOT NO. T-139 SEJAVTA, RATLAM- 457 002 (M.P.) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2005

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2116	NDA/MAL/HDP/3 111	GLAXOSMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CALPOL	PARACETAMOL	120MG/5ML	GLAXOSMITHKLINE LIMITED - 78392- 00507, VIWANDANI LIKONI ROAD NAIROBI KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1997
2117	NDA/MAL/HDP/3 116	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	KLOXY	CLOXACILLIN	125MG/5ML	LABORATORY & ALLIED LTD.--PLOT 209/10349 OFF MOMBASA RD NAIROBI	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X100.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/1997

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2118	NDA/MAL/HDP/3117	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD	TATA UGANDA LIMITED	HYDROCORTISONE SODIUM SUCCINATE	HYDROCORTISONE SODIUM SUCCINATE	100MG	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD #14, II PHASE PIA, BANGALORE 560058	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X100.0 MG VIAL,1.0X50.0X100.0 MG VIAL	01/07/2010
2119	NDA/MAL/HDP/3118	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LUMARTEM	ARTEMETHER /LUMEFANTRINE	20MG /120MG	QUALITY CHEMICAL INDUSTRIES LIMITED. PLOT NO. 1-7 LUZIRA INDUSTRIAL PARK, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X24.0 TABLET BLISTER,1.0X30.0X18.0 TABLET BLISTER,1.0X30.0X24.0 TABLET BLISTER,1.0X30.0X12.0 TABLET BLISTER,1.0X30.0X6.0 TABLET BLISTER,1.0X1.0X18.0 TABLET BLISTER,1.0X1.0X12.0 TABLET BLISTER,1.0X1.0X6.0 TABLET	01/07/2011

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2120	NDA/MAL/HDP/3 122	USV PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GROVIT CHEWABLE TABLETS	MULTI- INGREDIENT	MULTI- INGREDIENT	REMIDEX PHARMA PVT LTD B-249+ 250 II STAGE PEENYA INDUSTRIAL ESTATE BANGLORE 560058.	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2002
2121	NDA/MAL/HDP/3 123	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	RECTOL 250 SUPPOSITORY	PARACETAMOL BP	250 MG	BLISS GVS PHARMA LIMITED PLOT NO. 10/11 SURVEY NO.39/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	RECTAL SYSTEMIC PAEDIATRIC SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY BLISTER	01/07/2007

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2122	NDA/MAL/HDP/3 125	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	AMLODAR 5	AMLODIPINE BESILATE	5MG	DAR AL DAWANA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER	01/07/2009
2123	NDA/MAL/HDP/3 134	PANACEA BIOTEC PHARMA LTD	VITACARE LIMITED	TOFF PLUS	PARACETAMOL+C HLORPHENIRAMI NE MALEATE+ DEXTROMETHOR PHAN + PHENYLEPHRINE	500 MG + 2 MG + 15 MG + 10 MG	PANACEA BIOTEC PHARMA LIMITEDMALPURI BADDI, DISTRICT SOLAN, HIMACHAL PRADESH-173205 - INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2004

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2124	NDA/MAL/HDP/3 136	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	TENOFOVIR DISOPROXIL FUMARATE	TENOFOVIR DISOPROXIL FUMARATE	300MG	MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2007
2125	NDA/MAL/HDP/3 139	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	OMEDAR	OMEPRAZOLE	20MG	DAR AI DAWANA UR PLANT,AMMAN,JOR DAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER,1.0X2.0X14 .0 TABLET BLISTER	01/07/2009

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2126	NDA/MAL/HDP/3 141	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	AMLOPRESS-5	AMLODIPINE BESYLATE	5MG	CIPLA LTDCIPLA LTD PLOT NO L- 139,VERNA IND ESTATE, VERNA GOA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER	01/07/2007
2127	NDA/MAL/HDP/3 144	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	ULSEC	OMEPRAZOLE	20MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE STRIP	01/07/2007



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2128	NDA/MAL/HDP/3 145	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AMOXICAP	AMOXYCILLIN	500MG	HOVID BHD 121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2010
2129	NDA/MAL/HDP/3 146	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	ZOKAST	MONTELUKAST SODIUM	10MG	UNICHEM LABORATORIES LTDUNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205 UNICHEM LABORATORIES LTD ,,,PLOT 17 & 18, PILERNE IND. ESTATE, PILERNE, BARDEZ GOA- 403511	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2016

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2130	NDA/MAL/HDP/3 147	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO TELVAS-H 40/12.5	TELMISARTAN/HY DROCHLOROTHIA ZIDE	40MG/12.5MG	ARISTO PHARMACEUTICALS PVT LIMITED PLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP- 462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP,3.0X10.0 TABLET BLISTER	01/07/2009
2131	NDA/MAL/HDP/3 156	PFIZER LABORATORIES (PTY)	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	BENYLIN DAYTIME FLU	PSEUDOEPHEDRI NE HCL + IBUPROFEN	30MG + 200MG	JOHNSON&JOHNSO N PTY LTD.EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET STRIP	01/07/2008

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2132	NDA/MAL/HDP/3 158	MJ BIOPHARM PVT LTD	VITACARE LIMITED	GLIBEX-5	GLIBENCLAMIDE	5MG	M.J BIOPHARM PVT LTD -L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2012
2133	NDA/MAL/HDP/3 159	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	LARTEM FORTE	ARTEMETHER + LUMEFANTRINE	80MG + 480MG	SKANT HEALTH CARE LTD 1802-1805 GIDC PHASE III VAPI GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER	01/07/2015

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2134	NDA/MAL/HDP/3 163	NORVATIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN SUPPOSITORIES 50MG	DICLOFENAC SODIUM	50MG	DELPHARM HUNINGUE S.A.S- SITE INDUSTRIAL HUNINGUE26, RUE DE LA CHAPELLE, F- 68330, HUNINGUE	FRANCE	RECTAL SYSTEMIC ADULT SUPPOSITORIES	1.0X1.0X10.0 SUPPOSITORY STRIP	01/07/2006
2135	NDA/MAL/HDP/3 167	MJ BIOPHARM PVT LTD	KIMSY MEDS LTD	MONAN-0.5G	MEROPENEM	0.5G	M.J BIOPHARM PVT LTD -L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X0.5 G VIAL	01/07/2010

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2136	NDA/MAL/HDP/3 169	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	RANOPHAGE OD	METFORMIN HCL	1000MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED INDUSTRIAL AREA 3, A.B. ROAD, DEWAS 455001, MADHYA PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008
2137	NDA/MAL/HDP/3 175	M.J.BIOPHARM PVT LTD	VITACARE LIMITED	SPACOVIN	DROTAVERINE	40MG	M.J. BIOPHARM PVT. LTDL-7, M.I.D.C. , TALOJA, DISTRICT RAIGAD - 410 208 NAVI MUMBAI, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2012

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2138	NDA/MAL/HDP/3 176	AFRICURE PHARMACEUTICAL S (INDIA) PRIVATE LIMITED	AFRICURE PHARMACEUTICAL S U LIMITED	DOXYRONE-100	DOXYCYCLINE HYDROCHLORIDE	100	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9- 12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CONTAINER,1.0X10. 0X10.0 CAPSULE BLISTER	01/07/2005
2139	NDA/MAL/HDP/3 177	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	BETADERM CREAM	BETAMETHASONE VALERATE	0.1%W/W	ATCO LABORATORIES PVT LTDB-18,S.I.T.E KARACHI 75700, PAKISTAN	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X5.0 G TUBE	01/07/1997

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2140	NDA/MAL/HDP/3 178	COSMOS LTD	ASTRA PHARMA (U) LIMITED	BENDURIC TABLETS	BENDROFLUMET HIAZIDE	5MG	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2005
2141	NDA/MAL/HDP/3 179	GOOD DAY PHARMACY LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	SULFUR OINTMENT	SULPHUR	10%W/W	KREMOINT PHARMA PVT LTD--B-8 ADDITIONAL AMBERNATH MIDC OPP. ANAND NAGAR POLICE CHECK POST AMBERNATH (E) DIST THANE 421 506	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X25.0 G TUBE	01/07/2013

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2142	NDA/MAL/HDP/3 181	THEMIS MEDICARE LTD	STAR PHARMACEUTICAL S LTD	EMAL	ALPHA & BETA ARTEETHER	150MG/2ML	THEMIS MEDICARE LIMITEDSECTOR 6A, PLOT NO. 16 TO18, IIE, BHEL HARIDWA, UTTARAKHAND	INDIA	PARENTERAL ORDINARY AMPOULES	3.0X2.0 ML VIAL	01/07/2009
2143	NDA/MAL/HDP/3 184	M.J BOPHARM PUT LTD	KIMSY MEDS LTD	MONAN	MEROPENEM	1G	M.J BIOPHARM PUT LTD L-7 MIDC INDUSTRIOL DIST GAIDED TOLOJA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2008



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2144	NDA/MAL/HDP/3 191	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	ERECTO -100	SILDENAFIL CITRATE	100 MG	CIPLA LIMITED PUNEMIDC, KURKUMBH DISTRICT PUNE 413802	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0 TABLET BLISTER	01/07/2007
2145	NDA/MAL/HDP/3 192	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ANZAVIR-R	ATAZANAVIR + RITONAVIR	300 MG + 100 MG	MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2013

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2146	NDA/MAL/HDP/3 193	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	ERECTO- 50	SILDENAFIL CITRATE	50MG	CIPLA LIMITED PUNEMIDC, KURKUMBH DISTRICT PUNE 413802	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0 TABLET BLISTER	01/07/2005
2147	NDA/MAL/HDP/3 196	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	MOTINORM	DOMPERIDONE	10MG	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X30.0 ML BOTTLE	01/07/2000

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2148	NDA/MAL/HDP/3 197	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	TRIAM-DENK 40 INJECTION	TRIAMCINOLON E ACETONIDE	40 MG/ML	FISIOPHARMA S.R.L.- NUCLEOO INDUSTRIALE, 84020, PALOMONTE (SA) - ITALY	ITALY	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2004
2149	NDA/MAL/HDP/3 200	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LETRAX	LEVAMISOLE HYDROCHLORIDE	40MG	LABORATORY & ALLIED LTD-PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X20 0.0 TABLET CONTAINER,1.0X25. 0X3.0 TABLET BLISTER,1.0X3.0 TABLET BLISTER	01/07/1997

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2150	NDA/MAL/HDP/3 202	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	PRESARTAN-50	LOSARTAN	50MG	IPCA LABORATORIES LTD PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2008
2151	NDA/MAL/HDP/3 204	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	RELCEER GEL	ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE + LIQUORICE	365MG/5ML + 80MG/5ML + 100MG/5ML + 400MG/5ML	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X180.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2000

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2152	NDA/MAL/HDP/3 206	HEALTHCARE LTD.	HEALTHCARE LTD.	POSTINOR 2	LEVONORGESTRE L	0.75MG	GEDEON RICHTER PLC1103 BUDAPEST GYOMROI UT 19-21	HUNGARY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X2.0 TABLET BLISTER	01/07/2010
2153	NDA/MAL/HDP/3 207	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	DILCONTIN XL 90	CONTROLLED RELEASE TABLETS OF DILTIAZEM HYDROCHLORIDE	90MG	MODI MUNDIPHARMA (PVT) LTD MEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2010

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2154	NDA/MAL/HDP/3 212	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	CLOPRESS 75MG	CLOPIDOGREL BISULPHATE	75MG	CIPLA LTD-PLOT NO L 139,VERNA IND ESTATE, VERNA GOA- 403 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2005
2155	NDA/MAL/HDP/3 214	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	INDICONTIN	INDAPAMIDE	1.5MG	MODI MUNDIPHARMA PVT. LTDMEERUT- MUZAFFARNAGAR ROAD, MODIPURAM – 250110 UTTAR PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010

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2156	NDA/MAL/HDP/3 215	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	SEROCORT 125	SALMETEROL XINAFOATE + FLUTICASONE PROPIONATE	25MCG + 125MCG	CIPLA LTDCIPLA LTD PLOT NO L- 139,VERNA IND ESTATE, VERNA GOA INDIA	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER	01/07/2009
2157	NDA/MAL/HDP/3 219	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOPHENOL ORAL SUSPENSION	CHLORAMPHENIC OL	125MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/1998

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2158	NDA/MAL/HDP/3 220	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	PYLO KIT	LANSOPRAZOLE+T INIDAZOLE+CLARI THROMYCIN	30MG+500MG+25 0 MG	CIPLA LIMITED PUNEMIDC, KURKUMBH DISTRICT PUNE 413802	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X7.0X1.0X6.0 TABLET BLISTER (BLISTER CONTAINS 2 CAPSULES AND 4 TABLETS)	01/07/2005
2159	NDA/MAL/HDP/3 221	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	OPTADEX-N EYE DROPS	DEXAMETHASON E/NEOMYCIN	1MG/3MG	REMINGTON PHARMACEUTICAL INDUS. PVT LTD, 117 ALLAM	PAKISTAN	OPHTHALMIC DROPS	1.0X5.0 ML VIAL	01/07/1999



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2160	NDA/MAL/HDP/3 224	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM FLUFED ELIXIR	MULTI- INGREDIENT	MULTI- INGREDIENT	TIL HEALTHCARE PVT LIMITED PLOT 100, WEST R-5, SOUTH, SRICITY SEZ, CHERIVE9 (VI), DISTRICT: CHITTOOR 517588 ANDHRA PRADESH-	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X60.0 ML BOTTLE	01/07/1997
2161	NDA/MAL/HDP/3 225	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	DIFLAME	DICLOFENAC DIETHYLAMINE + LINSEED OIL + METHYL SALICYLATE MENTHOL	N/A	LINCOLN PHARMACEUTICAL LIMITED TRIMAL ESTATE KHATRAJ KOLOL, GUJARAT INDIA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X15.0 G TUBE, 1.0X30.0 G TUBE	01/07/2010

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2162	NDA/MAL/HDP/3 226	SEARLE PAKISTAN LIMITED	SURGIPHARM (U) LIMITED	PEDITRAL	ORAL REHYDRATION SALT	N/A	SEARLE PAKISTAN LTD..F-319, S.I.T.E., OPP. KESC POWER STATION, KARACHI	PAKISTAN	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X29.5 G SACHET	01/07/1997
2163	NDA/MAL/HDP/3 231	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	FLUCOMOL	PARACETAMOL/P HENYLEPHRINE HCL/DEXTROMET HORPHAN HBR/CHLORPHENI RAMINE MALEATE	500MG/10MG/15 MG/2MG	LINCOLN PHARMACEUTICAL LIMITEDTRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER,1.0X10.0X1 .0X10.0 CAPSULE BLISTER	01/07/2008

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2164	NDA/MAL/HDP/3 236	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM COTRI	CO-TRIMOXAZOLE	480MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER,1.0X25 0.0 TABLET CONTAINER,1.0X50 0.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER,1.0X10 0.0X10.0 TABLET BLISTER	01/07/1997
2165	NDA/MAL/HDP/3 237	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	KONAZOL CREAM	KETOCONAZOLE	2% W/W	LINCOLN PHARMACEUTICAL LIMITEDTRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2008

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2166	NDA/MAL/HDP/3 241	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	CLOTRILIN	CLOTRIMAZOLE	1%W/W	LINCOLN PHARMACEUTICALS LTD-TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE,1.0X15.0 G TUBE	01/07/2008
2167	NDA/MAL/HDP/3 243	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	RAPITUS	LEVODROPROPIZI NE	30MG/5ML	MACLEODS PHARMACEUTICALS LTD BLOCK N2, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2016

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2168	NDA/MAL/HDP/3 244	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	UMICILLIN	AMPICILLIN	250MG	UNI MEDICOLABS. 21 22 PHARMACY SELAQUI DEHRADUN 248197	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2015
2169	NDA/MAL/HDP/3 245	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NYSTATIN ORAL DROPS	NYSTATIN	100,000 I.U./ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL TOPICAL DROPS	1.0X30.0 ML BOTTLE	01/07/2013

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2170	NDA/MAL/HDP/3 246	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	COMPOUND MAGNESIUM TRISILICATE	MAGNESIUM TRISILICATE	370MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2000
2171	NDA/MAL/HDP/3 252	GALENTIC PHARMA LTD	VITACARE LIMITED	PYLOOCAIN	BETAMETHASONE + PHENYLEPHRINE + LIDOCAINE	0.5 MG/G + 1 MG/G + 25 MG/G	GALENTIC PHARMA( INDIA ) PVT LTDR- 673,MIDC TTC RABALE THANE- BELAPUR ROAD,NAVI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X30.0 G TUBE	01/07/2005

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2172	NDA/MAL/HDP/3 255	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	SATISFIL-50	SILDENAFIL CITRATE	50MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2011
2173	NDA/MAL/HDP/3 259	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	TIGBODERM	BETAMETHASONE + CHLOROCRESOL + GENTAMICIN + CLIOQUINOL + TOLNAFTATE	0.05% W/W + 0.1% W/W + 0.1% W/W + 1% W/W + 1% W/W	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997

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2174	NDA/MAL/HDP/3 261	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	TENOFOVIR DF + EMTRICITABINE + EFAVIRENZ	TENOFOVIR DF + EMTRICITABINE + EFAVIRENZ	300MG+200MG+6 00MG	MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD - PLOT NO. H-12 & H- 13 MIDCWALUJ INDUSTRIAL AREA AURANGABAD 431136 MAHARASTRA MYLAN	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2008
2175	NDA/MAL/HDP/3 262	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEGEL	MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE	250MG + 250MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007



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2176	NDA/MAL/HDP/3 263	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	TRIMEX MUCOLYTIC SYRUP	SALBUTAMOL SULPHATE + BROMHEXINE HYDROCHLORIDE + GUAIFENESIN	2MG/5ML + 4MG/5ML + 100MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2009
2177	NDA/MAL/HDP/3 265	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AMOXICILLIN	AMOXICILLIN TRIHYDRATE	250MG	CSPC ZHONGNUO PHARMACEUTICALS (SHIJIAZHUANG) CO. LTD-SHIJIAZHUANG CITY	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,10.0X1 0.0 CAPSULE BLISTER	01/07/2010

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2178	NDA/MAL/HDP/3 266	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	SALIMIA LINIMENT	METHYL SALICYLATE+TURP ENTINE OIL	5ML+25ML	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL LIQUIDS	1.0X60.0 ML BOTTLE,1.0X50.0 ML BOTTLE	01/07/1997
2179	NDA/MAL/HDP/3 270	ASTRA PHARMA (UK) LTD	ASTRA PHARMA (U) LIMITED	FORTIFIED PROCAINE PENICILLIN	FORTIFIED PROCAINE PENICILLIN	4000000 IU	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTDNO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSH OP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 VIAL CARTON,1.0X50.0 VIAL CARTON	01/07/2001

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2180	NDA/MAL/HDP/3 273	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	BETASOL CREAM	BETAMETHASONE VALERATE	0.1%W/W	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X30.0 G TUBE	01/07/1997
2181	NDA/MAL/HDP/3 275	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	MEFLIN-500	MEFENAMIC ACID	500MG	LINCOLN PHARMACEUTICALS LIMITED 10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010

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2182	NDA/MAL/HDP/3 276	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICAL S LTD	ROSUVAS 10	ROSUVASTATIN	10MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER	01/07/2014
2183	NDA/MAL/HDP/3 277	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	TRANSAMIN CAPSULES 500MG	TRANEXAMIC ACID	500MG	HILTON PHARMA (PVT) LTD PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2001

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2184	NDA/MAL/HDP/3 279	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	HAEMOFORTE SYRUP	MULTI- INGREDIENT	MULTI- INGREDIENT	MILAN LABORATORIES (INDIA ) PVT LTD PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA BAROQUE PHARMACEUTICALS PVT LTD -S.NO.192/2 & S.NO.192/2 &3 SOKHADA-388 620 KHAMBHAT. DIST. ANAND GUJARAT INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X90.0 ML BOTTLE,1.0X250.0 ML BOTTLE,1.0X200.0 ML BOTTLE	01/07/1997
2185	NDA/MAL/HDP/3 282	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	KOFF-GO	PHENYLEPHRINE HCL + CHLORPHENIRAM INE MALEATE + DEXTROMETHOR PHAN	5MG/5ML + 2MG/5ML + 10MG/5ML	TORQUE PHARMACEUTICALS (P) LTDP.O.DAPPAR VILLISS	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	01/07/2009

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2186	NDA/MAL/HDP/3 284	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	CHALEATE	CHLORPHENIRAMINE MALEATE	4MG	LABORATORY & ALLIED LTD-PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997
2187	NDA/MAL/HDP/3 285	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	AMOXIL FORTE 250MG/5ML	AMOXYCILLIN	250MG/5ML	GLAXO WELLCOME PRODUCTION.ZONE INDUSTRIELLE DE LA PEYENNIERE 53100 MAYENNE, FRANCE	FRANCE	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

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2188	NDA/MAL/HDP/3 288	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	DELAISED CHESTY COUGHS SYRUP	DIPHENHYDRAMINE HCL BP+AMMONIUM CHLORIDE BP+SODIUM CITRATE BP+MENTHOL BP	14MG+135MG+57 MG+1.1MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1997
2189	NDA/MAL/HDP/3 289	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	CANDID DUSTING POWDER	CLOTRIMAZOLE	1%W/W	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL DUSTING POWDERS	1.0X30.0 G BOTTLE,1.0X100.0 G BOTTLE	01/07/1999

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2190	NDA/MAL/HDP/3 291	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICAL S LTD	FINTOP	BUTENAFINE HCL	1%W/W	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2003
2191	NDA/MAL/HDP/3 292	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	DELATED PAEDIATRIC SYRUP	DIPHENHYDRAMINE HYDROCHLORIDE +SODIUM CITRATE+MENTHOL	7MG+28.5MG+0.5 5MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1997



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2192	NDA/MAL/HDP/3 294	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	URGENDOL CAPSULES	TRAMADOL HYDROCHLORIDE	50 MG	WIN- MEDICARE LTDMODIPURAM - 250 110,UTTAR PRAADESH, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2004
2193	NDA/MAL/HDP/3 295	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICAL S LTD	GLEVATE	CLOBETASOL	0.05%W/W	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2008

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2194	NDA/MAL/HDP/3 297	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	NEPIN-SR-20	NIFEDIPINE	20MG	LINCOLN PHARMACEUTICALS LIMITED TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT - INDIA	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER, 1.0X10.0X1 0.0 TABLET BLISTER	01/07/2011
2195	NDA/MAL/HDP/3 300	MEDICAL UNION PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	MUCOSOL PEDIATRIC SYRUP	CARBOCISTEINE	125 MG/5 ML	MEDICAL UNION PHARMA .COABU- SULTAN ISMAILIA EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2003



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2198	NDA/MAL/HDP/3 314	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	SILVEREX	SILVER SULFADIAZINE + CHLORHEXIDINE GLUCONATE	10MG/G+10MG/G	SUN PHARMACEUTICALS IND. LTDB- 2,MADAKAI INDUSTRIAL ESTATE, PONDA,GOA- 403404, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X250.0 G TUBE,1.0X25.0 G TUBE,1.0X10.0 G TUBE	01/07/2004
2199	NDA/MAL/HDP/3 315	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	ERO-250 TABLETS	ERYTHROMYCIN STEARATE	250MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2003

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2200	NDA/MAL/HDP/3 316	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMOX	AMOXYCILLIN TRIHYDRATE	125MG/5ML	SPARSH BIO-TECH LTD PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1998
2201	NDA/MAL/HDP/3 318	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENETRIM TABLETS	CO-TRIMOXAZOLE	480MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2000

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2202	NDA/MAL/HDP/3 319	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	FERROTONE CAPSULES	FERROUS FUMERATE+FOLIC ACID+VITAMIN B12	162MG +0.75MG +7.5MCG	MEGA LIFESCIENCES LTD.384 PATTANA 3 ROAD BANGPOO INDUSTRIAL ESTATE SUMUTPRAKAN	THAILAND	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X10.0 CAPSULE BLISTER	01/07/2005
2203	NDA/MAL/HDP/3 321	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	DERMOLIN-GM	CLOBETASOL+GE NTAMICIN+MICO NAZOLE	0.05%W/W+0.1% W/W+2%W/W	LINCOLN PHARMACEUTICALS LIMITEDTRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT - INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2008

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2204	NDA/MAL/HDP/3 328	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	BENZYL PENICILLIN INJECTION	BENZYL PENICILLIN	1 MU	CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHANG) CO. LTD WORKSHOP NO. 88 YANGZI ROAD, SHIJIAZHANG CITY, HEBEI PROVINCE, CHINA WORKSHOP 406 AND 407	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X1.0 MU VIAL,1.0X10.0X1.0 MU VIAL	01/07/2001
2205	NDA/MAL/HDP/3 333	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	NOVA CLAV-625	AMOXICILLIN + CLAVULANATE POTASSIUM	500 MG + 125 MG	MEDISPRAY LABORATORIES PVT LTD, UNIT II368-348 KUNDAIM INDUSTRIAL ESTATE, KUNDAIM GOA - 403115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X5.0 TABLET BLISTER	01/07/2009

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2206	NDA/MAL/HDP/334	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MYCLAV 375	AMOXICILLIN + CLAVULANIC ACID	250 MG + 125 MG	UNICHEM LABORATORIES LIMITED UNIT IIVILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET STRIP,1.0X10.0X6.0 TABLET STRIP	01/07/2005
2207	NDA/MAL/HDP/341	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	AZILIN-250	AZITHROMYCIN	250MG	LINCOLN PHARMACEUTICALS LIMITEDTRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT - INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X6.0 TABLET BLISTER	01/07/2008



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2208	NDA/MAL/HDP/3 342	SEARLE PAKISTAN LTD	HEALTHCARE LTD.	METODINE DF TABLETS	METRONIDAZOLE +DILOXANIDE	400MG+500MG	SEARLE PAKISTAN LTD..F-319, S.I.T.E., OPP. KESC POWER STATION, KARACHI	PAKISTAN	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X3.0X5.0 TABLET BLISTER	01/07/2004
2209	NDA/MAL/HDP/3 343	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	MEDIVEN-CREAM	BETAMETHASONE VALERATE	0.1%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997

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2210	NDA/MAL/HDP/3 346	WOCKHARDT LTD	STAR PHARMACEUTICAL S LTD	ZEDEX	BROMHEXINE +AMMONIUM CHLORIDE+ MENTHOL + DEXTROMETHOR PHAN	8MG+100MG+5MG +10MG	NAXPAR PHARMA PRIVATE LIMITED182, VILLAGE GURUMAJRA, TEHSIL NALAGARH, BADDI, DIST. SOLAN (H.P), 174101 INDIA.	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997
2211	NDA/MAL/HDP/3 347	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	UNIPEN TABLETS	PHENOXYMETHYL PENICILLIN	250MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1997

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2212	NDA/MAL/HDP/3 348	VENUS REMEDIES LTD	HARLEYS UGANDA LIMITED	PIMCEF	CEFEPIME USP	1G	VENUS REMEDIES LTD.UNIT 11 HOLL TOP INDUSTRIAL ESTATE JHARMAJRI	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL	01/07/2007
2213	NDA/MAL/HDP/3 354	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	MEDIVEN OINTMENT	BETAMETHASONE VALERATE	0.1%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997

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2214	NDA/MAL/HDP/3 357	CENTAUR PHAMACUITICALS	GITTOES PHARMACEUTICAL S LIMITED	ESOREST 20	ESOMEPRAZOLE	20MG	CENTAUR PHARMACEUTICALS PVT L.T.D.CENTAUR HOUSE NEAR	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008
2215	NDA/MAL/HDP/3 359	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	ARTI	ARTEMETHER	80MG/ML	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE	01/07/2011

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2216	NDA/MAL/HDP/3 364	CENTAUR PHAMACUITICALS	GITTOES PHARMACEUTICAL S LIMITED	ESOREST 40	ESOMEPRAZOLE	40MG	CENTAUR PHARMACEUTICALS PVT L.T.D.CENTAUR HOUSE NEAR	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008
2217	NDA/MAL/HDP/3 367	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOMOL SUSPENSION	PARACETAMOL	125 MG/5ML	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE, 1.0X100.0 ML BOTTLE	01/07/2000

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2218	NDA/MAL/HDP/3 369	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	AZILIN-500	AZITHROMYCIN	500MG	LINCOLN PHARMACEUTICALS LIMITED TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X3.0 TABLET BLISTER	01/07/2008
2219	NDA/MAL/HDP/3 370	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	DERMOREN 500	GRISEOFULVIN	500MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009

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2220	NDA/MAL/HDP/3 372	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	MUCOLEX	AMBROXOL HYDROCHLORIDE + SALBUTAMOL SULPHATE + GUAIFENESIN + MENTHOL	30 MG/5ML + 1 MG/5ML + 50 MG/5ML + 0.5 MG/5ML	S KANT HEALTHCARE LTD1802-1805 GIDC PHASE III VAPI 396 195	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2014
2221	NDA/MAL/HDP/3 373	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	MYCLAV 625	AMOXILLICIN/CLA VULANATE	500MG/125MG	UNICHEM LABORATORIES LIMITED UNIT IIVILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET STRIP,1.0X10.0X6.0 TABLET STRIP	01/07/2005

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2222	NDA/MAL/HDP/3 374	COSMOS LIMITED	ASTRA PHARMA (U) LIMITED	ZITHROX 250MG	AZITHROMYCIN	250MG	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	01/07/2008
2223	NDA/MAL/HDP/3 377	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AMILINE	AMITRIPTYLINE	25 MG	AGOG PHARMA LTD.PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER,1.0X100.0X 10.0 TABLET BLISTER	01/07/2011



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2224	NDA/MAL/HDP/3 378	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	CHLOZINE TABLETS	CHLORPROMAZIN E	100MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2011
2225	NDA/MAL/HDP/3 379	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIFASI	HUMAN CHORIONIC GONADOTROPIN	5000I.U	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X2.0 AMPOULE CARTON	01/07/2011

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2226	NDA/MAL/HDP/3 382	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOFEN SUSPENSION	IBUPROFEN	100MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X60.0 ML BOTTLE,1.0X1.0X10 0.0 ML BOTTLE	01/07/2010
2227	NDA/MAL/HDP/3 383	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	ZEPIN-200	CARBAMAZEPINE	200 MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2010

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2228	NDA/MAL/HDP/3 384	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PROXIMEXA 250MG	CEFUROXIME AXETIL	250MG	GLAXOSMITHKLINE UK LTD HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2007
2229	NDA/MAL/HDP/3 385	BLUE CROSS LABORATORIES LTD	STAR PHARMACEUTICAL S LTD	MEFTAL-P- SUSPENSION	MEFENAMIC ACID	100MG/5ML	BLUE CROSS LABORATORIES LTD- 17, VERNA INDUSTRIAL ESTATE, VERNA GOA- 403722	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE	01/07/2007

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2230	NDA/MAL/HDP/3 387	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PROXIMEXA 500MG	CEFUROXIME AXETIL	500MG	GLAXOSMITHKLINE UK LTD HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2007
2231	NDA/MAL/HDP/3 390	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ALUGEL	ALUMINIUM HYDROXIDEL / MAGNESIUM TRISILICATE	120MG/250MG	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE, 1.0X5.0 ML JERRYCAN	01/07/1997

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2232	NDA/MAL/HDP/3 391	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	CEZIN TABLET	CETIRIZINE	10MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X5.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER,100.0X10.0 TABLET BLISTER	01/07/2012
2233	NDA/MAL/HDP/3 393	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	AUGMENTIN 375MG	AMOXICILLIN + CLAVULANIC ACID	250 MG + 125 MG	SMITHKLINE BEECHAM PHARMACEUTICALS, CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	2.0X10.0 TABLET BLISTER	01/07/1997

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2234	NDA/MAL/HDP/3 399	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LDNIL 10	ROSUVASTATIN	10MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
2235	NDA/MAL/HDP/3 400	ACINO PHARMA AG	LABOREX UGANDA LIMITED	OLFEN GEL	DICLOFENAC SODIUM	1%W/W	SOFARIMEX INDUSTRIA QUIMIRA E FARMACEUTICA SAAV. DAS INDUSTRIAS - ALTO DO COLARIDE, 2735- 213 AGUALVA CACEM	PORTUGAL	TOPICAL EXTERNAL GELS AND SOLS	1.0X50.0 G TUBE, 1.0X20.0 G TUBE	01/07/1997

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2236	NDA/MAL/HDP/3 405	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PANADOL BABY AND INFANT 120MG/5ML	PARACETAMOL	120MG/5ML	GLAXOSMITHKLINE LIMITEDLIKONI ROAD, INDUSTRIAL AREA, P.O. BOX 78392-00507, VIWANDANI, NAIROBI	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2008
2237	NDA/MAL/HDP/3 406	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	MICRONEMA	SODIUM CITRATE + SODIUM LAURYL SULPHATE + GLYCERIN	450MG/10ML+75 MG/10ML+ 90%V/V	ATCO LABORATORIES PVT LTDB-18,S.I.T.E KARACHI, PAKISTAN	PAKISTAN	RECTAL SYSTEMIC ENEMA LIQUIDS	1.0X10.0 ML BOTTLE,1.0X20.0 ML BOTTLE	01/07/2005

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2238	NDA/MAL/HDP/3 409	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	CLARITYNE	LORATADINE	10MG	BAYER BITTERFELD GMBHORTSTEIL GREPPIN SALEGASTER CHAUSSEE 1, 06803 BITTERFELD, WOLFEN - GERMANY	NULL	ORAL SOLID ORDINARY TABLETS	3.0X10.0 TABLET BLISTER,1.0X1.0X10 .0 TABLET BLISTER	01/07/2000
2239	NDA/MAL/HDP/3 411	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABNAL NASAL DROPS	SODIUM CHLORIDE	0.9%W/V	ABACUS PARENTERAL DRUGS LTD.PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	NASAL SYSTEMIC DROPS	1.0X10.0 ML VIAL	01/07/2011



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2240	NDA/MAL/HDP/3 414	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	EXFORGE 10MG/160MG	AMLODIPINE + VALSARTAN	10 MG + 160 MG	NOVARTIS PHARMA STEIN AGH-4332 STEIN SCHAFFHAUSERTRASS E	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2007
2241	NDA/MAL/HDP/3 415	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	CANDID V-1	CLOTRIMAZOLE	500MG	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	VAGINAL TABLETS	1.0X1.0 PESSARY STRIP	01/07/2004

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2242	NDA/MAL/HDP/3 423	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	AMOXICLAV- DENK 1000/125	AMOXICILLIN TRIHYDTATE + POTASSIUM CLAVULANATE	1000 MG + 125 MG	PENCEF PHARMA GMBHBRTENBACHS TR ASSE 13 D-13509 BERLIN	GERMANY	ORAL LIQUID ORDINARY UNIT DOSE POWDERS	1.0X12.0X3.0 G SACHET,1.0X8.0X3. 0 G SACHET	01/07/2011
2243	NDA/MAL/HDP/3 426	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	RUBEM CREAM	METHYL NICOTINATE + CAPSICUM OLEORESIN+ METHYLSALICYLA TE	1%W/W+0.1%W/ W+5%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE	01/07/1997

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2244	NDA/MAL/HDP/3 429	XEPA-SOUL PATTINSON	DELMAW ENTERPRISES LIMITED	EZEDE	LORATADINE	10MG	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2006
2245	NDA/MAL/HDP/3 433	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	CO-DIOVAN 80/12.5	VALSARTAN + HYDROCHLOROT HIAZIDE	80 MG +12.5 MG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND NOVARTIS PHARMA SPA,-TORRE ANNUNZIATA ITALY	ITALY SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2006

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2246	NDA/MAL/HDP/3 434	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	SEPTRIN	CO-TRIMOXAZOLE	480MG	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO. LR 209/6554, MOGADISHU ROAD INDUSTRIAL AREA, NAIROBI KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0 TABLET CARTON,1.0X50.0 TABLET CARTON,1.0X10.0X 10.0 TABLET BLISTER,1.0X2.0X10 .0 TABLET BLISTER	01/07/1997
2247	NDA/MAL/HDP/3 437	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	REMYCIN 100 CAPSULES	DOXYCYCLINE HYDROCHLORIDE	100MG	REMEDICA LIMITED AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1997

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2248	NDA/MAL/HDP/3 439	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENECHLOR CAPSULE	CHLORAMPHENIC OL	250MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,10.0X1 0.0 CAPSULE BLISTER	01/07/2000
2249	NDA/MAL/HDP/3 440	ELI-LILLY EXPORT SA	LABOREX UGANDA LIMITED	HUMALOG	INSULIN LISPRO	100IU	LILLY FRANCE SAFRANCE	FRANCE	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL	01/07/2000

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2250	NDA/MAL/HDP/3 444	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	CORVADIL 10	AMLODIPINE BESILATE	10MG	UNICHEM LABORATORIES LIMITEDUNICHEM LABORATORIES LIMITED. UNIT II, VILLAGE BHATAULI KALAN, BADDI, DIST. SOLAN PIN CODE 173 205, HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2010
2251	NDA/MAL/HDP/3 449	VENUS REMEDIES LTD	HARLEYS UGANDA LIMITED	IMMUNOX	CEFTRIAXONE SODIUM	1000MG	VENUS REMEDIES LIMITED ,HILL TOP,INDUSTRIAL ESTATE,JHARMAJRI, EPIP,PHASE 1,(EXTN.) ,BHATOLI KALAN,BADDI - H.P.INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL,1.0X10.0X1.0X 10.0 ML VIAL	01/07/2008

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2252	NDA/MAL/HDP/3 451	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOPHENOL CAPSULES (THANEO)	CHLORAMPHENIC OL	250MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER,1.0X100.0 CAPSULE CONTAINER,1.0X10 00.0 CAPSULE CONTAINER,1.0X50 0.0 CAPSULE CONTAINER	01/07/1998
2253	NDA/MAL/HDP/3 458	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	UNIXIL 250MG	AMOXYCILLIN TRIHYDRATE	250MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/1997

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2254	NDA/MAL/HDP/3 459	AMOUN PHARMACEUTICAL S COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ENEMAX	HYPERTONIC SOLUTION OF SODIUM PHOSPHATES	6GM AND 16GM/100ML	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY CAIRO EGYPT	EGYPT	RECTAL SYSTEMIC ENEMA LIQUIDS	1.0X120.0 ML BOTTLE	01/07/1997
2255	NDA/MAL/HDP/3 460	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	MALANIL ADULT TABLETS	ATOVAQUONE + PROGUANIL HCL	250MG + 100MG	GLAXO WELLCOME S.A ARANDAARANDA AVDA EXTREMADURA 3, 09400 ARANDA DE DUERO BURGOS	SPAIN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X12.0 TABLET BLISTER	01/07/2007



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2256	NDA/MAL/HDP/3 464	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TARTAR CONTROL LISTERINE ANTISEPTIC	ZINC CHLORIDE + DENATURED ALCOHOL MENTHOL 95% + THYMOL	18MG/ 20ML + 0.9ML/20ML + 12.7MG/20ML	JOHNSON&JOHNSO N PTY LTD..241 MAIN ROAD RETREAT 794	SOUTH AFRICA	ORAL LIQUID ORDINARY OTHER LIQUIDS	1.0X500.0 ML BOTTLE,1.0X250.0 ML BOTTLE	01/07/2007
2257	NDA/MAL/HDP/3 465	MONDI-MUNDI PHARMA PVT LIMITED	SURGIPHARM (U) LIMITED	FECONTIN-Z	FERROUS GLYCINE SULPHATE+ZINC SULPHATE+FOLIC ACID	100MG+61.8MG+0 .5MG	MODI MUNDIPHARMA (PVT) LTDMEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008

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2258	NDA/MAL/HDP/3 466	DAWA LIMITED	SUPER MEDIC LTD	DAWASEC	SECNIDAZOLE	1G	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	01/07/2015
2259	NDA/MAL/HDP/3 467	VENUS REMEDIES LTD	HARLEYS UGANDA LIMITED	RONEM	MEROPENEM TRIHYDRATE	1000MG	VENUS REMEDIES LTD -UNIT II HILL TOP INDUSTRIAL ESTATE JHARMAJRI EPIP PHASE I BHATOLI KALAN BADDI (H.P)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL	01/07/2008

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2260	NDA/MAL/HDP/3 473	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TRIXONE	CEFTRIAZONE	1G	P.R & INJECT CARE PARENTERALS PVT LTD-PLOT 130, SILVASSA ROAD,G.I.D.C,VAPI- 396195,GUJARAT,IN DIA ZEISS PHARMA LIMITED-IGC,SIDCO, PHASE II, SAMBA, JAMMU - 184121,(J&K)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL,1.0X10.0X1.0 G VIAL	01/07/2016
2261	NDA/MAL/HDP/3 474	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMCLOREN DRY SYRUP	AMPICILLIN + CLOXACILLIN	125MG+125MG/5 ML	RENE INDUSTRIES LTD680,KAMULI,KIRE KA KAMPALA,UGANDA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2008

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2262	NDA/MAL/HDP/3 475	VENUS REMIDIES LTD	HARLEYS UGANDA LIMITED	RONEM	MEROPENEM	500MG	VENUS REMEDIES LTD, UNIT II,HILL TOP INDUSTRIAL ESTATE, JHARMAJTI, EPIP, PHASE-1 (EXTENSION), BHATOLI KALAN, BADDI -HP	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL	01/07/2010
2263	NDA/MAL/HDP/3 476	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	PARAFIL	PARACETAMOL	500MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDAL UR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1997

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2264	NDA/MAL/HDP/3 478	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	DICLOREN	DICLOFENAC SODIUM BP	50MG	RENE INDUSTRIES LTD680,KAMULI,KIRE KA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
2265	NDA/MAL/HDP/3 483	JOHNSON&JOHNS ON PTY LTD. 241	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	SINUTAB 3-WAY	IBUPROFEN + PSEUDOEPHEDRI NE HCL	200MG + 30MG	JOHNSON&JOHNSO N PTY LTD.EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2007

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2266	NDA/MAL/HDP/3 485	CIRON DRUGS & PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	ERGOMETRINE	ERGOMETRINE MALEATE	0.5MG/ML	CIRON DRUGS AND PHARMACEUTICALS PRIVATE LTDN-118 MIDC TARAPUM BOISAR DIST THANE 401506 MAHARASHTRA, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X1.0 ML AMPOULE	01/07/2007
2267	NDA/MAL/HDP/3 490	MEDICAL UNION PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	LAXOLAC SYRUP	LACTULOSE	67G/100ML	MEDICAL UNION PHARMACEUTICALS LTDABU SULTAN, ISMAILIA, EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2003

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2268	NDA/MAL/HDP/3 492	ACINO PHARMA AG -	LABOREX UGANDA LIMITED	OLFEN-50 GASTRO- RESISTANT TABLETS	DICLOFENAC SODIUM	50MG	ACINO PHARMA AGBIRSWEG 2, 4253, LIESBERG - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/1997
2269	NDA/MAL/HDP/3 494	FERRER INTERNATIONAL, S.A.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	GAMALATE B6 SOLUTION	MAGNESIUM GLUTAMATE HYDROBROMIDE + AMINOBUTYRIC ACID + AMINO HYDROXYBUTYRIC ACID + VITAMIN B6	2G + 2G + 1G +1G	FERRER INTERNATIONAL, S.A.C/JOAN BUSCALLA, 1- 9.08173 SANT CUGAT DEL VALLES, BARCELONA	SPAIN	ORAL LIQUID ORDINARY LIQUIDS	1.0X80.0 ML BOTTLE	01/07/2015

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2270	NDA/MAL/HDP/3 497	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	LIVOLIN FORTE	MULTI- INGREDIENT	MULTI- INGREDIENT	MEGA LIFE SCIENCES LIMITED: PLANT 1 : 384 SOI 6, PATTANA 3 ROAD, BANGPOO INDUSTRIAL ESTATE, SAMUTPRAKAN 10280, THAILAND	THAILAND	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2009
2271	NDA/MAL/HDP/3 500	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	GIZLAN 300	IRBESARTAN	300MG	DAR AI DAWANA UR PLANT,AMMAN,JOR DAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014



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2272	NDA/MAL/HDP/3 502	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HYDROCORTISON E SODIUM SUCCINATE	HYDROCORTISON E SODIUM SUCCINATE	100MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X100.0 MG VIAL + 1*2ML AMPOULE OF WFI	01/07/2010
2273	NDA/MAL/HDP/3 504	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	BIFRIL	ZOFENOPRIL	30MG	A.MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.IVIA CAMPO DI PILE 67100 L'AQUILA	ITALY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER,1.0X1.0X7. 0 TABLET BLISTER	01/07/2015

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2274	NDA/MAL/HDP/3 506	ABBVIE (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ULTANE	SEVOFLURANE	100%W/W	AESICA QUEENSBOROUGH LTD NORTH RD. QUEENSBOROUGH KENT ABBVIE SRLS.R. 148 PONTINA KM 52 - 04011 CAMPOVERDE DI APRILIA (LT) - ITALY	ITALY UNITED KINGDOM	NASAL SYSTEMIC UNIT DOSE LIQUIDS	1.0X250.0 ML BOTTLE	01/07/2011
2275	NDA/MAL/HDP/3 507	MEDOPHARM PRIVATE LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	MEDOMOX 250	AMOXICILLIN	250MG	MEDOPHARM PVT LTD.NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/2011

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2276	NDA/MAL/HDP/3 512	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	LAMISIL 250MG	TERBINAFINE	250MG	NORVATIS PHARMA PRODUKTIONS GMBH 79644 WEHR/BADEN- GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X14.0 TABLET CARTON	01/07/1997
2277	NDA/MAL/HDP/3 515	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN 40/240	ARTEMETHER + LUMEFANTRINE	40 MG + 40 MG	AJANTA PHARMA LTD .B-4//5/6, MIDC INDUSTRIALAREA, PAITHAN-431 128, AURANGBAD AJANTA PHARMA LIMITEDPLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT- 392130	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X6.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER (WITH AMFM LOGO),1.0X30.0X1. 0X6.0 TABLET BLISTER (WITH AMFM LOGO),1.0X30.0X1. 0X6.0 TABLET BLISTER (WITHOUT AMFM LOGO)	01/07/2007

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2278	NDA/MAL/HDP/3 516	COSMOS LTD	ASTRA PHARMA (U) LIMITED	BENZHEXOL TABLETS BP 5MG	TRIHENYPHENIDY L HYDROCHLORIDE	5MG	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10 0.0 TABLET BLISTER	01/07/1998
2279	NDA/MAL/HDP/3 517	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TOTO ZINC	ZINC SULPHATE	20MG	MEDICAMEN BIOTECH LTDSP- 1192, A & B, PHASE A€"IV, INDUSTRIAL AREA BHIWADI -301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013

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2280	NDA/MAL/HDP/3 520	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	DREZ POWDER	POVIDONE IODINE + METRONIDAZOLE	1%W/W + 5%W/W	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	TOPICAL EXTERNAL POWDERS	1.0X100.0 G BOTTLE,1.0X10.0 G BOTTLE,1.0X40.0 G CONTAINER	01/07/2010
2281	NDA/MAL/HDP/3 522	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	CLOXACILLIN SODIUM FOR INJECTION	CLOXACILLIN SODIUM	500MG	CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHUANG) CO. LTD WORKSHOP NO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA WORKSHOP 406 AND 407	CHINA	PARENTERAL ORDINARY VIALS	1.0X10.0X500.0 MG VIAL	01/07/2011

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2282	NDA/MAL/HDP/3 525	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOCLLIN	AMPICILLIN TRIHYDRATE	250MG	MILAN LABORATORIES (INDIA ) PVT LTD PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTRA-410209,INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER,1.0X10 0.0X10.0 CAPSULE BLISTER	01/07/1998
2283	NDA/MAL/HDP/3 526	CYANO PHARMA(P)	RENE PHARMACY LTD	PROMETHAZINE TABLETS	PROMETHAZINE HYDROCHLORIDE	25MG	CYANO PHARMA(P)115-C IND ESTATE POLO GROUND INDORE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2001

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2284	NDA/MAL/HDP/3 527	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	LEVOTOP-500	LEVOFLOXACIN	500MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2009
2285	NDA/MAL/HDP/3 533	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	LEVOZIN	LEVOCETIRIZINE	5MG	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008

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2286	NDA/MAL/HDP/3 535	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	ADIFLAM-50	DICLOFENAC SODIUM GASTRO- RESISTANT TABLETS BP	50MG	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007
2287	NDA/MAL/HDP/3 540	EAGLEVET UGANDA LIMITED	MEDVIN PHARMA LIMITED	CLOPACT-75	CLOPIDOGREL	75 MG	IPCA LABORATORIESLIMIT ED-IPCA LABORATORIES LTD P.O SEJANTA DISTRICT RATLAM 457002 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008



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2288	NDA/MAL/HDP/3 542	BETA HEALTH CARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	MARA MOJA	ASPIRIN + PARACETAMOL + CAFFEINE	400MG + 200MG + 50MG	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X2.0 TABLET STRIP,1.0X110.0X2. 0 TABLET STRIP	01/07/2005
2289	NDA/MAL/HDP/3 545	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	CANDID MOUTH PAINT	CLOTRIMAZOLE	1%W/W	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	ORAL TOPICAL LIQUIDS	1.0X15.0 ML BOTTLE	01/07/2000

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2290	NDA/MAL/HDP/3 546	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENETRIM D.S	SULPHAMETHOX AZOLE + TRIMETHOPRIM	800MG + 160MG	RENE INDUSTRIES LIMITEDPLOT 680 KAMULI KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	01/07/2013
2291	NDA/MAL/HDP/3 547	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	CORBIS-10	BISOPROLOL	10 MG	UNICHEM LABORATORIES LIMITED UNIT IIVILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2008

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2292	NDA/MAL/HDP/3 548	CIPLA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BECORT 200	BECLOMETASONE	200MCG/DOSE	CIPLA LTD.- PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER	01/07/2009
2293	NDA/MAL/HDP/3 549	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	TRIMEX PAEDIATRIC COUGH EXPECTORANT	CHLORPHENIRAM INE MALEATE+PSEUD O EPHEDRINE HCL+GUAIPHENISI N+MENTHOL	1.0MG+15.0MG+5 0.0MG+0.5MG / 5ML	REGAL PHARMACEUTICALS LIMITED PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2007

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2294	NDA/MAL/HDP/3 551	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ZAHA-500MG	AZITHROMYCIN	500MG	AJANTA PHARMA LIMITEDPLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT- 392130 AJANTA PHARMA LIMITED PAITHANMANUFACT URING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER,1.0X10.0X1 .0X3.0 TABLET BLISTER	01/07/2009
2295	NDA/MAL/HDP/3 553	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	FALCIMON 25/67.5 B/L	ARTESUNATE+AM ODIAQUINE	25MG+67.5MG	CIPLA LTD UNIT IIA- 42 MIDC PATALGANGA DISTRICT RAIGAD MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0 TABLET BLISTER,1.0X25.0X3 .0 TABLET BLISTER,1.0X25.0X6 .0 TABLET BLISTER	01/07/2014

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2296	NDA/MAL/HDP/3 556	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	GRISACTIN-500 TABLETS	GRISEOFULVIN TABLETS	500MG	REGAL PHARMACEUTICALS LIMITED PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007
2297	NDA/MAL/HDP/3 558	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	SEROCORT 250	SALMETEROL+ FLUTICASONE PROPIONATE	25MCG + 250MCG	CIPLA LTD.- PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER	01/07/2009

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2298	NDA/MAL/HDP/3 561	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOCILLIN ORAL SUSPENSION	AMPICILLIN TRIHYDRATE	125MG/5ML	MILAN LABORATORIES (INDIA ) PVT LTD PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1998
2299	NDA/MAL/HDP/3 566	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	ARTESUN	ARTESUNATE	60 MG	GUILIN PHARMACEUTICAL CO LTD-NO. 43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 1*5% NAHCO3 + 5 ML NAACL INJECTION	01/07/2008

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2300	NDA/MAL/HDP/3 571	CADILA PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	CADIPHEN EXPECTORANT	CHLORPHENIRAM INE/GUAIFENESIN /AMMONIUM CHLORIDE	2MG//80MG/100 MG	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/1997
2301	NDA/MAL/HDP/3 573	VENUS REMEDIES LTD	REDDYS PHARMA LIMITED	PARIN-E	ENOXAPARIN SODIUM	40MG/0.4ML	VENUS REMEDIES LTD -UNIT II HILL TOP INDUSTRIAL ESTATE JHARMAJRI EPIP PHASE I BHATOLI KALAN BADDI (H.P)	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X2.0X0.4 ML PRE FILLED SYRINGE	01/07/2008

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2302	NDA/MAL/HDP/3 574	CENTAUR PHARMACEUTICAL S PRIVATE LIMITED	GITTOES PHARMACEUTICAL S LIMITED	METOZ 2.5 TABLET	METOLAZONE TABLETS USP	2.5MG	CENTAUR PHARMA PVT.LIMITED-PLANT IPLOT3,TIVIM INDUSTRIAL ESTATE,KARASWADA ,MAPUSA GOA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2007
2303	NDA/MAL/HDP/3 575	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFIX 400 CAPSULES	CEFIXIME	400MG	PHARMA INTERNATIONAL CO.,AL-QASTAL AREA, AIRPORT ROAD, 11941, AMMAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X5.0 CAPSULE BLISTER	01/07/2007



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2304	NDA/MAL/HDP/3 577	ASTRA PHARMA (U) LTD	ASTRA PHARMA (U) LIMITED	METOCLOPRAMID E	METOCLOPRAMI DE	5MG/ML	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE,1.0X10.0 X10.0X2.0 ML AMPOULE	01/07/2009
2305	NDA/MAL/HDP/3 578	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CINNARON 25	CINNARIZINE	25MG	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2005

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2306	NDA/MAL/HDP/3 580	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	FEXOFEN-120	FEXOFENADINE HYDROCHLORIDE	120MG	ARISTO PHARMACEUTICALS PVT LTD PLOT NO 208 NEW INDUSTRIAL AREA NO 11 MANDIDEEP	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X6.0 TABLET BLISTER	01/07/2008
2307	NDA/MAL/HDP/3 581	CENTAUR PHARMACEUTICAL S PRIVATE LIMITED	GITTOES PHARMACEUTICAL S LIMITED	METZOZ 5	METOLAZONE	5MG	CENTAUR PHARMA PVT.LTD-PLANT I PLOT 3,TIVIM INDUSTRIAL ESTATE,KARASWADA ,MAPUSA GOA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2007

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2308	NDA/MAL/HDP/3 588	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	FEXOFEN-180	FEXOFENADINE	180MG	ARISTO PHARMACEUTICALS PVT LTD PLOT NO 208 NEW INDUSTRIAL AREA NO 11 MANDIDEEP	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X6.0 TABLET BLISTER	01/07/2008
2309	NDA/MAL/HDP/3 590	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	ALFOXAN 500 FC TABLETS	MEFENAMIC ACID	500MG	REMEDICA LIMITED LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2004

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2310	NDA/MAL/HDP/3 591	DAFRA PHARMA LTD	MULTIPHAR UGANDA LIMITED	ARTESIANE 80MG/ML	ARTEMETHER	80MG/ML	ANFARM HELLAS S.A.61ST KM. NATIONAL ROAD, ATHENS-LAMIA, 320 09 SCHIMATARI VIOTIAS - GREECE	GREECE	PARENTERAL ORDINARY I M AMPOULES	1.0X5.0X1.0 ML AMPOULE	01/07/1998
2311	NDA/MAL/HDP/3 592	FOURRTS (INDIA) LABORATORIES PUT LTD	DELMAW ENTERPRISES LIMITED	MEGATRIM DS	CO-TRIMOXAZOLE BP	960 MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDAL UR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2008

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2312	NDA/MAL/HDP/3 593	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DROX 500	CEFADROXIL	500MG	AUROBINDO PHARMA LIMITED, FORMULATIONS UNIT-VI- R7AUROBINDO PHARMA LIMITED, FORMULATIONS UNIT-VI SY.NO.329/39 & 329/47 CHITKUL(V) PATANCHERU MANDAL, SANGA REDDY DISTTELANGANA502 307	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER,1.0X10.0X1 0.0 CAPSULE BLISTER	01/07/2007
2313	NDA/MAL/HDP/3 594	CIRON DRUGS & PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	STERILE QUININE DIHYDROCHLORID E	QUININE DIHYDROCHLORID E	300MG/ML	CIRON DRUGS AND PHARMACEUTICALS PVT LIMITEDN-118, N119, N113, MIDC TARAPUR BOISAR DIST THANE 401506, INIDA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X2.0 ML AMPOULE	01/07/2007

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2314	NDA/MAL/HDP/3 598	WIN-MEDICURE LTD	SURGIPHARM (U) LIMITED	MYOSPAZ	PARACETAMOL + CHLORZOXAZONE	500MG + 250MG	WIN- MEDICARE LTD MODIPURAM - 250 110,UTTAR PRAADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
2315	NDA/MAL/HDP/3 600	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	P-ALAXIN TABLETS	DIHYDROARTEMI SININ + PIPERAQUINE PHOSPHATE	40MG + 320MG	BLISS GVS PHARMA LTD PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA- INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X9.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X12.0 TABLET BLISTER,1.0X15.0 TABLET BLISTER	01/07/2008

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2316	NDA/MAL/HDP/3 601	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	HYDROKANT	HYDROCORTISON E ACETATE	1%W/W	SKANT HEALTH CARE LTD 1802-1805 GIDC PHASE III VAPI GUJARAT	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2009
2317	NDA/MAL/HDP/3 603	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	VUMTREX SYRUP	LEVAMISOLE	40MG/5ML	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X30.0 ML BOTTLE	01/07/2003

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2318	NDA/MAL/HDP/3 604	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	AC-FENAC	ACECLOFENAC	100MG	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008
2319	NDA/MAL/HDP/3 607	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	LINOPRIL	LISINOPRIL DIHYDRATE	20MG	PHARMA INTERNATIONAL COMPANYMAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X14.0X2.0 TABLET BLISTER	01/07/2004



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2320	NDA/MAL/HDP/3 609	AMOUN PHARMACEUTICAL S COMPANY	BOOTS PHARMACEUTICAL S LIMITED	ANTINAL	NIFUROXAZIDE	200MG	AMOUN PHARMACEUTICALS COMPANY1ST INDUSTRIAL ZONE EL OBOUR CITY CAIRO EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X12.0 CAPSULE BLISTER,1.0X12.0 CAPSULE BLISTER	01/07/1997
2321	NDA/MAL/HDP/3 610	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PROMETHAZINE TABLETS BP 25MG	PROMETHAZINE HYDROCHLORIDE	25MG	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10 0.0 TABLET CONTAINER	01/07/1998

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2322	NDA/MAL/HDP/3 611	SHELYS PHARMACEUTICAL S LTD	BETA HEALTHCARE UGANDA LIMITED	COLDRIIL SYRUP	PARACETAMOL + CHLORPHENIRAM INE + PSEUDOEPHEDRI NE	120MG+1MG+10M G	BETA HEALTHCARE INTERNATIONAL LIMITED-PLOT NUMBER LR 209/6554,MOGADIS HU ROAD,OFF LUNGA LUNGA ROAD INDUSTRIAL AREA, P.O.BOX 42569- 00100 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2000
2323	NDA/MAL/HDP/3 612	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	LOSARTAS-H 12.5	LOSARTAN POTASSIUM + HYDROCHLOROT HIAZIDE	50MG + 12.5MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011

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2324	NDA/MAL/HDP/3 613	HETERO LABS LTD	AIVEEN (U) LIMITED	ZIDOVUDINE ORAL SOLUTION	ZIDOVUDINE	50MG/5ML	HETERO LABS LTD UNIT III22-110 IDA JEEEDIMETIA HYDERABAD ANDHRA PRADESH ,	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X240.0 ML BOTTLE	01/07/2013
2325	NDA/MAL/HDP/3 614	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	ERYTHROREN SUSPENSION	ERYTHROMYCIN STEARATE	125MG/5ML	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2008

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2326	NDA/MAL/HDP/3 618	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	CLOXACILLIN SODIUM	CLOXACILLIN SODIUM	500MG	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTDNO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSH OP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0 VIAL CARTON, 1.0X10.0 VIAL CARTON	01/07/2011
2327	NDA/MAL/HDP/3 619	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	CAPTOPRIL DENK - 25	CAPTOPRIL	25MG	DENK PHARMA, GOLLSTR.,1-D-845 529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,2.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	01/07/2000

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2328	NDA/MAL/HDP/3 620	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	HALOXEN 10 TABLETS	HALOPERIDOL BP	10MG	REMEDICA LIMITED LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER	01/07/2004
2329	NDA/MAL/HDP/3 622	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PROXIMEXA	CEFUROXIME AXETIL	125MG/5ML	GLAXOSMITHKLINE UK LTD HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X50.0 ML BOTTLE	01/07/2008

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2330	NDA/MAL/HDP/3 626	ZYDUS LIFESCIENCES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ORIPHEX CAPSULES	CEPHALEXIN	250MG	SPARSH BIO-TECH LTD PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006 SAKAR HEALTHCARE LIMITED BLOCK NO. 10-13, SARKHEJ- BAVLA HIGHWAY, VILL: CHANGODAR, DIST: AHMEDABAD- 382213, GUJARAT – INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1997
2331	NDA/MAL/HDP/3 628	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	CELEMIN 5S	AMINO ACIDS/SORBITOL	5%W/V+5%W/V	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X500.0 ML BOTTLE	01/07/2001

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2332	NDA/MAL/HDP/3 630	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	UNICONTIN 600	THEOPHYLLINE	600MG	MODI MUNDIPHARMA (PVT) LTDMEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
2333	NDA/MAL/HDP/3 631	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	ENA-DENK 10	ENALAPRIL MALEATE	10MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008

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2334	NDA/MAL/HDP/3 634	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOPLUS	PARACETAMOL+D EXTROMETHORP HAN HCL+ CHLORPHENIRAM INE+PHENYLEPHR INE HCL	500MG+15MG+2M G+10MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2008
2335	NDA/MAL/HDP/3 635	CIRON DRUGS & PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	CIROGAN	PROMETHAZINE HYDROCHLORIDE	25MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE	01/07/2011



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2336	NDA/MAL/HDP/3 637	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	TINODERM	MULTI- INGREDIENT	MULTI- INGREDIENT	NEM LABORATORIES PVT LTD133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X18.0 G TUBE	01/07/1997
2337	NDA/MAL/HDP/3 639	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PANADOL ADVANCE	PARACETAMOL	500MG	GLAXOSMITHKLINE DUNGARAVAN LTDKNOCKBRACK DUNGARVAN CO. WATERFORD	IRELAND	ORAL SOLID ORDINARY TABLETS	1.0X11.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER,1.0X2.0X10 .0 TABLET BLISTER	01/07/2010

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2338	NDA/MAL/HDP/3 641	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	TRD-CONTIN 100	TRAMADOL HYDROCHLORIDE	100MG	MODI MUNDIPHARMA (PVT) LTDMEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2009
2339	NDA/MAL/HDP/3 642	IND-SWIFT	PLANET PHARMACEUTICAL S UGANDA LTD	CLARIE 250	CLARITHROMYCIN	250MG	IND-SWIFT- LTD,GLOBAL BUSINESS UNIT, JAWAHARPUR, OFF NH-21 DERABASSI	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X2.0X7.0 TABLET BLISTER	01/07/2007

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2340	NDA/MAL/HDP/3 647	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	NYSTAGO ORAL SUSPENSION	NYSTATIN	100000 IU	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL TOPICAL SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2008
2341	NDA/MAL/HDP/3 648	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	UNICONTIN 400	THEOPHYLLINE	400MG	MODI MUNDIPHARMA (PVT) LTD MEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009

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2342	NDA/MAL/HDP/3 649	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	LAMISIL	TERBINAFINE	125MG	NOVARTIS BARBERA SPAIN	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/1997
2343	NDA/MAL/HDP/3 650	AMOUN PHARMACEUTICAL S COMPANY	BOOTS PHARMACEUTICAL S LIMITED	ANTINAL	NIFUROXAZIDE	220MG/5ML	AMOUN PHARMACEUTICALS COMPANY1ST INDUSTRIAL ZONE EL OBOUR CITY, CAIRO EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2011

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2344	NDA/MAL/HDP/3 651	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ORIPHEX SYRUP	CEPHALEXIN	125MG/5ML	SPARSH BIO-TECH LTD PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006 SAKAR HEALTHCARE LIMITED BLOCK NO. 10-13, SARKHEJ- BAVLA HIGHWAY, VILL: CHANGODAR, DIST: AHMEDABAD- 382213, GUJARAT – INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997
2345	NDA/MAL/HDP/3 653	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN	ARTEMETHER + LUMEFANTRINE	80 MG + 480 MG	AJANTA PHARMA LIMITED PLOT NO.Z/103/A, DAHEJ SEZ PART 11, DISTRICT: BHARUCH, GUJARAT- 392130 AJANTA PHARMA LIMITED PAITHAN MANUFACT URING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER (WITH AMFM LOGO), 1.0X6.0 TABLET BLISTER (WITHOUT AMFM LOGO), 30.0X1.0X6. 0 TABLET BLISTER (WITH AMFM LOGO), 30.0X1.0X6. 0 TABLET BLISTER (WITHOUT AMFM LOGO)	01/07/2008

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2346	NDA/MAL/HDP/3 655	FOURRTS (INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	QUADRAJEL GEL	CHLORHEXIDINE+ METRONIDAZOLE +LIDOCAINE	5%W/W+1.61%W/ W+2.13%W/W	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDAL UR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X15.0 G TUBE	01/07/2008
2347	NDA/MAL/HDP/3 656	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	LUMERAX	ARTEMETHER / LUMEFANTRINE	80MG/480MG	IPCA LABORATORIES LTD,- SEJAVTA,RATLAM 457-002 REG.OFF.48 KANDIVLI IND.ESTATE MUMBAI 400067	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X6.0 TABLET BLISTER	01/07/2011

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

2348	NDA/MAL/HDP/3 657	DAWA LIMITED	SUPER MEDIC LTD	DAWASTIN	NYSTATIN	100000IU/ML	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2009
2349	NDA/MAL/HDP/3 664	MACK BROWN PHARMACEUTICAL S PVT LIMITED	SHURIK LTD	AZZY	AZITHROMYCIN	500MG	TORQUE PHARMACEUTICALS PVT LTDISAAPUR P.O DAPPAR 140056 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER	01/07/2011

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

2350	NDA/MAL/HDP/3 666	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICAL S LIMITED	STROM 50	TRAMADOL HYDROCHLORIDE	50MG	LINCOLN PHARMACEUTICAL LIMITEDTRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2008
2351	NDA/MAL/HDP/3 668	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	AUGMENTIN BD	AMOXICILLIN + CLAVULANIC ACID	200 MG/ 5 ML + 28.5 MG/ 5 ML	GLAXO WELLCOME PRODUCTIONZI DE LA PEYENNIERE, 53100, MAYENNE	FRANCE	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X70.0 ML BOTTLE,1.0X140.0 ML BOTTLE	01/07/1998



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2352	NDA/MAL/HDP/3 669	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	CO-TRIMOXAZOLE	SULFAMETHOXAZ OLE/TRIMETHOPR IM	200MG/40MG	MEDICAMEN BIOTECH LTD - SP- 1192 A&B PHASE IV INDUSTRIAL AREA BHIWADI 301019 DIST. ALWAR (RAJASTHAN) - INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2014
2353	NDA/MAL/HDP/3 670	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	TETRAREN CAPSULES	TETRACYCLINE HYDROCHLORIDE	250MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X10. 0X10.0 CAPSULE BLISTER	01/07/2000

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2354	NDA/MAL/HDP/3 671	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	CLAVULIN TABLETS	AMOXICILLIN + CLAVULANIC ACID	500 MG + 125 MG	SMITHKLINE BEECHAM PHARMACEUTICALS, CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X14.0 TABLET STRIP,10.0X10.0 TABLET STRIP,1.0X20.0 TABLET STRIP	01/07/2003
2355	NDA/MAL/HDP/3 672	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	NITROCONTIN 6.4	NITROGLYCERIN	6.4MG	MODI MUNDIPHARMA (PVT) LTDMEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID ORDINARY SUBLINGUAL TABLETS	1.0X25.0 TABLET CONTAINER	01/07/2008

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2356	NDA/MAL/HDP/3 674	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	INTAMINE SYRUP	PROMETHAZINE HYDROCHLORIDE	5MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X5.0 L JERRYCAN	01/07/1997
2357	NDA/MAL/HDP/3 677	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	IBUREN	IBUPROFEN	200MG	RENE INDUSTRIES LTD680,KAMULI,KIRE KA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008

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2358	NDA/MAL/HDP/3 678	FOURRTS LABORATORIES LTD	DELMAW ENTERPRISES LIMITED	REDINPLUS	IRON PENTACARBONYL + ZINC SULPHATE MONOHYDRATE + FOLIC ACID + SODIUM SELENITE + LYSINE HYDROCHLORIDE + HISTIDINE HYDROCHLORIDE + CHOLINE BITARTRATE	100MG + 30MG + 7.5MG + 0.11MG + 26MG + 4.4MG + 52MG	FOURRTS (INDIA) LABS PVT LTD .VANDALUR ROAD. KELAMBAKK AM- 603103 TAMIL, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X30.0 CAPSULE BLISTER	01/07/2008
2359	NDA/MAL/HDP/3 681	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEDOL	PARACETAMOL	500MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER, 1.0X1000.0 TABLET CONTAINER	01/07/2000

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2360	NDA/MAL/HDP/3 683	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	COLD TABS FORTINSA	PARACETAMOL + PHENYLEPHRINE +CHLORPHENIRA MINE + CAFFEINE	500MG + 5MG + 2MG + 30MG	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED VANDALUR ROAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X25.0 TABLET BLISTER,1.0X50.0X4 .0 TABLET STRIP	01/07/2013
2361	NDA/MAL/HDP/3 685	GALPHAR LABORATORIES LTD	DAWASANA PHARMACEUTICAL S LTD	ODICEF	CEFTRIAZONE	1G	INJECT CARE PARENTERALS PVT LTD PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2013

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2362	NDA/MAL/HDP/3 686	ACINO PHARMA AG -	LABOREX UGANDA LIMITED	NEURORUBINE™- FORTE 20 FILM- COATED TABLETS	MULTIVITAMIN	MULTINGREDIENT	ACINO PHARMA AGBIRSWEG 2, 4253, LIESBERG - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X100.0X 10.0 TABLET BLISTER	01/07/1997
2363	NDA/MAL/HDP/3 687	DAWA LIMITED	SUPER MEDIC LTD	DAWA-PROM	PROMETHAZINE HCL	5MG/5ML	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE	01/07/2010

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2364	NDA/MAL/HDP/3 688	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	NEUTRAFLUX MINT FLAVOUR	ALGNIC ACID + MAGNESIUM HYDROXIDE +ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE + SIMETHICONE	200MG +250MG + 250MG + 250MG + 125MG	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE,1.0X30.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2013
2365	NDA/MAL/HDP/3 698	CADILA HEALTHCARE PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	HIPEN SYRUP	AMOXICILLIN	125MG/5ML	SPARSH BIO-TECH LTD PLOT NO. 1, SURVEY NO. 42/243/244, VILLAGE LAKHABAVAD POST KHODIYAR COLONY DISTRICT, JAMNAGAR – 361006 GUJARAT INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

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2366	NDA/MAL/HDP/3 699	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SINOPRIL 5MG TABLETS	LISINOPRIL	5MG	GLOBAL NAPI PHARMACEUTICALS - 2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2005
2367	NDA/MAL/HDP/3 702	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORFIT-20	ATORVASTATIN	20MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2005



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2368	NDA/MAL/HDP/3 703	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	SONATEC	CETYLPYRIDINIU M CHLORIDE	0.05%W/V	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL TOPICAL LIQUIDS	1.0X250.0 ML BOTTLE	01/07/2014
2369	NDA/MAL/HDP/3 705	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SORAL 20MG CAPSULES	TENOXICAM	20MG	GLOBAL NAPI PHARMACEUTICALS - 2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER,1.0X2.0X10 .0 CAPSULE BLISTER	01/07/2005

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2370	NDA/MAL/HDP/3 707	INTAS PHARMACEUTICAL S LIMITED	NORVIK ENTERPRISES LIMITED	OBETAS-120	ORLISTAT	120MG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI- 248197,DEHRADUN UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2010
2371	NDA/MAL/HDP/3 709	MEDICAL UNION PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	NIGHT & DAY -N	PARACETAMOL/ DIPHENHYDRAMINE CHLORIDE + PARACETAMOL/ PSEUDOEPHEDRI NE	500MG/ 25MG +600MG/ 90MG	MEDICAL UNION PHARMA .COABU- SULTAN ISMAILIA EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2010

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2372	NDA/MAL/HDP/3 710	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LACILLIN	AMPICILLIN	250MG	LABORATORY & ALLIED LTD-PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/1997
2373	NDA/MAL/HDP/3 711	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	POLY-MXB	POLYMYXIN B	500,000 UNITS	BHARAT SERUMS AND VACCINES LIMITED,PLOT NO. K- 27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X5.0 ML VIAL	01/07/2013

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2374	NDA/MAL/HDP/3 712	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	AMLOZAAR	LOSARTAN POTASSIUM / AMLODIPINE	50MG + 5MG	MICRO LABS LTD92,SIPCOT INDUSTRIAL COMPLEX,HOSUR- 635-126(T.N)INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2010
2375	NDA/MAL/HDP/3 714	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	ADALAT LA	NIFEDIPINE	30MG	BAYER PHARMA AGD 51368 LEVERKUSEN, GERMANY	GERMANY	ORAL SOLID RETARD FILM- COATED TABLETS	2.0X14.0 TABLET BLISTER,3.0X10.0 TABLET BLISTER	01/07/2001

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2376	NDA/MAL/HDP/3 717	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	CEFTRIAZONE SODIUM	CEFTRIAZONE SODIUM	1G	CSPC ZHONGNUO PHARMACEUTICALS LTDNO. 88, YANGZI ROAD, SHIJIAZHANG CITY CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL,1.0X10.0X1.0 G VIAL	01/07/2011
2377	NDA/MAL/HDP/3 723	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	LACILLIN	AMPICILLIN	125MG/5ML	LABORATORY & ALLIED LTD-PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X100.0 ML BOTTLE	07/07/1997

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2378	NDA/MAL/HDP/3 724	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	EPIGAB	PREGABALIN	150MG	DAR AL DAWANA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X14.0 CAPSULE BLISTER	01/07/2015
2379	NDA/MAL/HDP/3 725	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	NEW TUXIRIL	DEXTROMETHOR PHAN HBR + PHENYLEPHRINE HCL + MENTHOL	10MG/ML + 5MG/10ML + 5MG/10ML	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2007

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2380	NDA/MAL/HDP/3 728	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DICLO-DENK 50	DICLOFENAC SODIUM	50MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	10.0X10.0 TABLET BLISTER + 1 * 10 SAMPLE	01/07/1998
2381	NDA/MAL/HDP/3 729	MEDLEY PHARMACEUTICAL S	EUROPA HEALTHCARE (U) LTD	DECIFEN-SR	DICLOFENAC SODIUM	100MG	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID RETARD ENTERIC- COATED TABLETS	1.0X10.0X20.0 TABLET STRIP, 1.0X3.0X10.0 TABLET STRIP	01/07/2008

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2382	NDA/MAL/HDP/3 730	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	AVELOX	MOXIFLOXACIN HYDROCHLORIDE	400MG	BAYER PHARMA AG 51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	2.0X5.0 TABLET BLISTER,1.0X5.0 TABLET BLISTER	01/07/2001
2383	NDA/MAL/HDP/3 732	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	ALBASOL TABLETS 200MG	ALBENDAZOLE	200MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET STRIP	01/07/2003



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2384	NDA/MAL/HDP/3 734	XEPA-SOUL PATTINSON	DELMAW ENTERPRISES LIMITED	ZARICORT CREAM	MICONAZOLE + HYDROCORTISON E	2%W/W + 1%W/W	XEPA SAUL PATTINSON MALAYSIA1-5 INDUSTRIAL ESTATE 75250 MELAKA MALYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1998
2385	NDA/MAL/HDP/3 736	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	RECTOL 125 SUPPOSITORY	PARACETAMOL	125MG	BLISS GVS PHARMA LIMITEDPLOT NO. 10/11, SURVEY NO. 38/1, DEWAN UDYOG NAGAR, ALIYALI VILLAGE	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY BLISTER	01/07/2007

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2386	NDA/MAL/HDP/3737	MEDLEY PHARMACEUTICALS LTD	EUROPA HEALTHCARE (U) LTD	ECOFLOX 500 TABLETS	CIPROFLOXACIN HYDROCHLORIDE	500MG	MEDLEY PHARMACEUTICALS LTD LANE 03, PHASE 1, SIDCO INDUSTRIAL COMPLEX, BARI BRAHMANA JAMMU 181133 MEDLEY PHARMACEUTICALS LTD..PLOT NO. 18 & 19, SURVEY NO.378/7&8, 379/2&3,ZARI CAUSEWAY ROAD, KACHIGAM,DAMAN (U.T) 396210-INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
2387	NDA/MAL/HDP/3738	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD	TATA UGANDA LIMITED	AMPICILLIN SODIUM	AMPICILLIN SODIUM	500MG	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD #14, II PHASE PIA, BANGALORE 560058	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X500.0 MG VIAL,1.0X50.0X500.0 MG VIAL	01/07/2010

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2388	NDA/MAL/HDP/3 741	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	ACTIZINE	CETIRIZINE HYDROCHLORIDE	10MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD PLOT M 444B STRETCHER ROAD NTINDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X15.0X10.0 TABLET BLISTER	01/07/2006
2389	NDA/MAL/HDP/3 744	ABBOTT HEALTHCARE PRODUCTS B.V.	HARLEYS UGANDA LIMITED	DUPHALAC SOLUTION	LACTULOSE	67G/100ML	ABBOTT BIOLOGICALS B.V ABBOTT BIOLOGICALS B.V VEERWEG 12 8121 AA OLST	NETHERLANDS	ORAL LIQUID ORDINARY LIQUIDS	1.0X200.0 ML BOTTLE, 1.0X10.0X1 5.0 ML BOTTLE	01/07/2001

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2390	NDA/MAL/HDP/3 745	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	WINDERM CREAM	BECLOMETHASON E+MICONAZOLE+ NEOMYCIN	0.025%W/W + 2%W/W + 0.5%W/W	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	01/07/2008
2391	NDA/MAL/HDP/3 746	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	BENDRO	BENDROFLUMET HIAZIDE	5MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2011

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2392	NDA/MAL/HDP/3 747	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	ALZOL TABLETS	ALBENDAZOLE	200MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	30.0X2.0 TABLET BLISTER	01/07/2002
2393	NDA/MAL/HDP/3 753	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	MYFORTIC 180	MYCOPHENOLAT E SODIUM	180MG	NORVATIS PHARMA STEIN AGSCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND NORVATIS PHARMA PRODUCTIONS GMBH, WEHROEFLINGER STR. 4479664 WEHR GERMANY	SWITZERLAND GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X12.0X10.0 TABLET BLISTER	01/07/2006

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2394	NDA/MAL/HDP/3 754	CENTAUR PHARMACEUTICAL S PRIVATE LIMITED	GITTOES PHARMACEUTICAL S LIMITED	SINAREST PD NASAL DROPS	OXYMETAZOLINE HYDROCHLORIDE	0.025%W/V	CENTAUR PHARMACEUTICALS LTD PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	NASAL TOPICAL DROPS	1.0X10.0 ML BOTTLE	01/07/2006
2395	NDA/MAL/HDP/3 757	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNITRIM SUSPENSION	CO-TRIMOXAZOLE	240MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA, NAIROBI, K ENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE, 1.0X60.0 ML BOTTLE	01/07/1997

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2396	NDA/MAL/HDP/3 760	AFRICURE PHARMACEUTICAL S (INDIA) PRIVATE LIMITED	AFRICURE PHARMACEUTICAL S U LIMITED	COMPOUND MAGNESIUM TRISILICATE	MAGNESIUM TRISILICATE	370MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED PLOT 9- 12, DEWAN & SONS INDL. AREA, VEOOR, PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X1000.0 TABLET CONTAINER	01/07/1997
2397	NDA/MAL/HDP/3 761	COSMOS LTD	ASTRA PHARMA (U) LIMITED	RIFACOS-300	RIFAMPICIN	300 MG	COSMOS LIMITED DRANGWE ROAD, OFF LUNGA ROAD - INDUSTRIAL AREA NAROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER, 1.0X1000.0 CAPSULE CONTAINER	01/07/1997

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2398	NDA/MAL/HDP/3 765	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ALPRIM	CO-TRIMOXAZOLE	480MG	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1997
2399	NDA/MAL/HDP/3 766	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	BUKOL TABLETS	HYOSCINE N- BUTYLBROMIDE	10MG	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997



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2400	NDA/MAL/HDP/3 767	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	AMPOXIN 500	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	UNICHEM LABORATORIES LIMITED UNIT IIVILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER	01/07/1999
2401	NDA/MAL/HDP/3 768	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	NIMOTOP 30MG	NIMODIPINE	30MG	BAYER PHARMA AG 51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009

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2402	NDA/MAL/HDP/3 770	AMOUN PHARMACEUTICAL S COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	XITHRONE	AZITHROMYCIN	500 MG	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY, CAIRO EGYPT	EGYPT	ORAL SOLID ORDINARY COATED TABLETS	1.0X1.0X5.0 TABLET BLISTER	01/07/2005
2403	NDA/MAL/HDP/3 771	FAES FARMA S.A	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	BRONQUIDIAZINA C.R	TRIMETHOPRIM/S ULFAMETHOXAZO LE/BROMHEXINE/ SODIUM BENZOATE/TOLU BALSAM	80MG/400MG/4M G/250MG/325MG	FAES FARMA, S.A MAXIMO AGUIRRE, 14, LEJONA 48940 VIZCAYA	SPAIN	ORAL LIQUID ORDINARY LIQUIDS	1.0X150.0 ML BOTTLE	01/07/2014

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2404	NDA/MAL/HDP/3 772	ELI-LILLY (SUISSE) SA	LABOREX UGANDA LIMITED	HUMULIN N NPH	HUMAN INSULIN ISOPHANE	100IU	LILLY EGYPT S.A.E. & ELI LILLY AND COMPANY LILLY TECHNOLOGY CENTRE INDIANAPOLIS,INDIA NA 46285 USA	UNITED STATES	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE	01/07/2005
2405	NDA/MAL/HDP/3 773	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOBUTOL-4	SALBUTAMOL SULPHATE	4 MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10 0.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2005

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2406	NDA/MAL/HDP/3 778	AMOUN PHARMACEUTICAL S COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	XITHRONE	AZITHROMYCIN	200MG/5ML	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY, CAIRO EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X15.0 ML BOTTLE	01/07/2004
2407	NDA/MAL/HDP/3 781	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ALZENTAL	ALBENDAZOLE	20MG/ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X20.0 ML BOTTLE	01/07/2014

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2408	NDA/MAL/HDP/3 782	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LAE-PEN V	PHENOXYMETHYL PENICILLIN	250MG	LABORATORY & ALLIED LTD-PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1997
2409	NDA/MAL/HDP/3 784	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	CIPIUM	CHLORPHENIRAM INE	2MG/5ML	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2011

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2410	NDA/MAL/HDP/3 787	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPENIV	PHENOXYMETHYL PENICILLIN	125MG/5ML	SPARSH BIO-TECH PVT. LTD .PLOT NO. 1, SURVEY NO. 42/243/244, VILLAGE LAKHABAVAD POST KHODIYAR COLONY DISTRICT, JAMNAGAR – 361006 GUJARAT INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2004
2411	NDA/MAL/HDP/3 789	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	LEVITRA	VARDENAFIL HCL	5MG	BAYER PHARMA AG 51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2005

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2412	NDA/MAL/HDP/3 790	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOFLOX-P	PEFLOXACIN	400MG	AGOG PHARMAPLOT 33 SECTOR THE VASAI-TULUKA CO- OP ESTATE LTD INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,10.0X1.0X1 0.0 TABLET BLISTER	01/07/2005
2413	NDA/MAL/HDP/3 793	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AMPICILLIN	AMPICILLIN TRIHYDRATE	250MG	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTDNO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSH OP 406 AND 407)	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CONTAINER	01/07/2010

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2414	NDA/MAL/HDP/3 794	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOMET-200	METRONIDAZOLE	200MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2005
2415	NDA/MAL/HDP/3 798	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEUROTON TABLET	MULTI- INGREDIENT	N/A	AMOUN PHARMACETICAL COMPANY-1ST INDUSTRIAL ZONE, EL OBOUR CITY, CAIRO, EGYPT	EGYPT	ORAL SOLID ORDINARY COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2004



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2416	NDA/MAL/HDP/3 801	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	FUNGISTIN ORAL SUSPENSION	NYSTATIN	100000 IU/ML	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2002
2417	NDA/MAL/HDP/3 802	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	LEVITRA 10MG	VARDENAFIL MONOHYDROCHL ORIDE TRIHYDRATE	10 MG	BAYER PHARMA AG 51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2005

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2418	NDA/MAL/HDP/3 803	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	DICLODYNE SUPPOSITORY	DICLOFENAC SODIUM	100MG	BLISS GVS PHARMA LTD PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA- INDIA	INDIA	RECTAL SYSTEMIC ADULT SUPPOSITORIES	1.0X5.0 SUPPOSITORY BLISTER	01/07/2007
2419	NDA/MAL/HDP/3 804	ACINO PHARMA AG	LABOREX UGANDA LIMITED	NEURORUBINE IM	VITAMIN B1+VITAMIN B6+VITAMIN B12	100MG+100MG+1 MG	MERCKLE GMBH (A MEMBER OF RATIOPHARM GROUP)LUDWIG MERCKLE STR. 3, 89143 BLAUBEUREN WEILER HAUPT PHARMA WULFING GMBH.BETHELNER LANDSTR. 18, 31028 GRONAU/LEINE	SWITZERLAND GERMANY	PARENTERAL ORDINARY I M AMPOULES	1.0X5.0X3.0 ML AMPOULE	01/07/1997

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2420	NDA/MAL/HDP/3 806	INDOCO REMEDIES LTD	STAR PHARMACEUTICAL S LTD	NOCID GEL	ALUMINIUM HYDROXIDE + SIMETHICONE + MAGNESIUM	400MG/5ML + 25MG/5ML + 100MG/5ML	INDOCO REMEDIES LTDB-20, MIDC, WALUJ, AURANGABAB 431136 INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X20 0.0 ML BOTTLE	01/07/2007
2421	NDA/MAL/HDP/3 807	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	ARTEMETHER INJECTION	ARTEMETHER	80MG/ML	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	CHINA INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE	01/07/2008

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2422	NDA/MAL/HDP/3 808	NORVATIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN SUPPOSITORIES 12.5MG	DICLOFENAC SODIUM	12.5MG	DELPHARM HUNINGUE S.A.S- SITE INDUSTRIAL HUNINGUE26, RUE DE LA CHAPELLE, F- 68330, HUNINGUE	FRANCE	RECTAL SYSTEMIC PAEDIATRIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY STRIP	01/07/2006
2423	NDA/MAL/HDP/3 809	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	COLDRID DAY & NIGHT	PARACETAMOL+C HLORPHENIRAMI NE MALEATE+PHENY LEPRINE HYDROCHLORIDE + CAFFEINE	500MG+2MG+5MG +15MG	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X9.0X10.0 TABLET STRIP	01/07/2006

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2424	NDA/MAL/HDP/3 812	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	B-TONE	PHENOBARBITON E	30MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0 TABLET BLISTER	01/07/1997
2425	NDA/MAL/HDP/3 813	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	ACTIPAR	PIPERAZINE CITRATE	500MG/5ML	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X30.0 ML BOTTLE	01/07/1997

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2426	NDA/MAL/HDP/3 814	MARTINDALE PHARMACEUTICAL S LTD	LABOREX UGANDA LIMITED	PETHIDINE INJECTION	PETHIDINE	50MG/1ML	MARTINDALE PHARMACEUTICAL LIMITED BAMP TON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/1997
2427	NDA/MAL/HDP/3 817	ROYAL PHARMA	ROYAL PHARMA 2011 LIMITED	BENZYL PENICILLIN INJECTION	BENZYL PENICILLIN SODIUM	1000000 I.U	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTD NO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSH OP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 MU VIAL	01/07/2002

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2428	NDA/MAL/HDP/3 823	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	D-WORM ORAL SUSPENSION	ALBENDAZOLE	200MG/5ML	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	01/07/2009
2429	NDA/MAL/HDP/3 825	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	UMOXIL 250	AMOXICILLIN	250MG	UNI MEDICOLABS. 21 22 PHARMACITY SELAQUI DEHRADUN 248197	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2015

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2430	NDA/MAL/HDP/3 827	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORFIT-10	ATORVASTATIN	10MG	AJANTA PHARMA LIMITED PAITHANMANUFACT URING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2005
2431	NDA/MAL/HDP/3 829	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	BETACOOOL	DRIED ALUMINUM HYDROXIDE/MAG NESIUM HYDROXIDE /MAGNESIUM ALUMINUM SILICATE/SIMETHI CANE	300MG / 25MG / 50MG / 25MG	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X50.0 TABLET STRIP	01/07/2006



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2432	NDA/MAL/HDP/3 831	ABBVIE (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	ALUVIA	LOPINAVIR+RITO NAVIR	200MG+50MG	ABBVIE DEUTSCHLAND GMBH & CO. KG.KNOLLSTASSE 50, D-67061, LUDWIGSHAFEN, GERMANY.	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X120.0 TABLET CONTAINER	01/07/2007
2433	NDA/MAL/HDP/3 833	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	LABSTATIN VAGINAL TABLETS	NYSTATIN	100.000 I.U	LABORATORY & ALLIED LTD.PLOT 209/10349 OFF MOMBASA RD NAIROBI	KENYA	VAGINAL TABLETS	1.0X3.0X5.0 PESSARY STRIP (WITH APPLICATOR)	01/07/2000

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2434	NDA/MAL/HDP/3 835	GLAXOSMITHKLINE LTD	BETA HEALTHCARE UGANDA LIMITED	HEDEX CAPLETS	PARACETAMOL+A SPIRIN+CAFFEINE ANHYDROUS	200MG+400MG+5 0MG	SMITHKLINE BEECHAM (NAIROBI)NAIROBI, KENYA DINLAS PHARMA EPZ LIMITEDPLOT NO. LR 7149/121, MOMBASA ROAD, SYOKIMAU BETA HEALTHCARE INTERNATIONAL LTD PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X20.0 TABLET PACK,1.0X110.0 TABLET PACK,1.0X100.0 TABLET PACK	01/07/1997
2435	NDA/MAL/HDP/3 837	COSMOS LTD	ASTRA PHARMA (U) LIMITED	NITROFURANTOIN	NITROFURANTOI N	100MG	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	01/07/1998

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2436	NDA/MAL/HDP/3 839	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLURID	ACETAMINOPHEN + PHENIRAMINE MALEATE	500 MG + 10.5 MG	KAMPALA PHARMACEUTICALS INDUSTRIES PLOT M 444B STRETCHER NTINDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X4.0 TABLET BLISTER	01/07/2006
2437	NDA/MAL/HDP/3 840	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	TORACTIN TABLETS	CYPROHEPTADIN E	4MG	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	2.0X50.0 TABLET BLISTER, 1.0X1000.0 TABLET CONTAINER	01/07/2000

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2438	NDA/MAL/HDP/3 841	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	MEGATRIM TABLETS	CO-TRIMOXAZOLE	480MG	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED VANDALUR ROAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997
2439	NDA/MAL/HDP/3 844	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN RETARD	DICLOFENAC SODIUM	100MG	NOVARTIS PHARMA STEIN AG- SCHAFFHARVSERTRA SSE CH-4332 STEIN SWITZERLAND. NORVATIS FARMA SPA--VIA PROVINCIALE SCHITO, 131 1- 80052, TORRE ANNUNCIATA (NA) ITALY	SWITZERLAND ITALY	ORAL SOLID RETARD TABLETS	1.0X30.0 TABLET CONTAINER	01/07/1997

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2440	NDA/MAL/HDP/3 845	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	CARDIPAC	AMLODIPINE	5MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2011
2441	NDA/MAL/HDP/3 846	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	LEVITRA	VARDENAFIL HCL	20 MG	BAYER PHARMA AG 51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2005

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2442	NDA/MAL/HDP/3 850	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ANGIZAAR-H	LOSARTAN POTASSIUM + HYDROCHLOROT HIAZIDE	50MG + 12.5MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2009
2443	NDA/MAL/HDP/3 854	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LOSARTAS 50 TABLETS	LOSARTAN POTASSIUM	50MG	INTAS PHARMACEUTICALS LTDCAMP ROAD SELAQUI DEHRADUN	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER	01/07/2003

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2444	NDA/MAL/HDP/3 859	UNIQUE PHARMACEUTICAL S LABORATORIES	PLANET PHARMACEUTICAL S UGANDA LTD	IFIMOL	PARACETAMOL	10MG/ML	UNIQUE PHARMACEUTICAL LABORATORIES-PLOT NO. 4 PASE IV, GIDC PANOLI -394 116 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2011
2445	NDA/MAL/HDP/3 860	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOLAC	LACTULOSE	3.35MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE,1.0X200.0 ML BOTTLE	01/07/2009

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2446	NDA/MAL/HDP/3 862	TORRENT PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S LTD.	LAMITOR 100	LAMOTRIGINE	100MG	TORRENT PHAMACEUTICALS LTD TORRENT PHAMACEUTICALS LTD INDRAD 382721 DIST MEHSANA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008
2447	NDA/MAL/HDP/3 866	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	RL	COMPOUND SODIUM LACTATE INFUSION BP	0.6/ 0.25 /0.04 / 0.027 % W/V	ABACUS PARENTERAL DRUGS LTD.PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X250.0 ML BOTTLE,1.0X500.0 ML BOTTLE	01/07/2010



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2448	NDA/MAL/HDP/3 867	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	BETADERM OINTMENT	BETAMETHASONE VALERATE	0.1%W/W	ATCO LABORATORIES PVT LTDB-18,S.I.T.E KARACHI 75700, PAKISTAN	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X5.0 G TUBE	01/07/1997
2449	NDA/MAL/HDP/3 871	INTAS PHARMACEUTICAL S LIMITED	NORVIK ENTERPRISES LIMITED	DOVERIN 40	DROTAVERINE HYDROCHLORIDE	40MG	INTAS PHARMACEUTICALS LIMITEDPLOT NO. 457 / 458 SARKHEJ-BAVLA HIGHWAY, MATODA 382 210, TALUKA - SANAND, DISTRICT - AHMEDABAD, STATE -	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008

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2450	NDA/MAL/HDP/3 872	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	ZYNCET SYRUP	CETIRIZINE HYDROCHLORIDE	5MG/5ML	THE MADRAS PHARMACEUTICALS- 137-B OLD MAHABALIPURAM ROAD KARAPAKKAM CHENNAI 600 096	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE	01/07/2006
2451	NDA/MAL/HDP/3 873	CIRON DRUGS & PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	CHLORPROMAZIN E INJECTION B.P	CHLORPROMAZIN E	25MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE	01/07/2011

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2452	NDA/MAL/HDP/3 874	AJANTA PHARMA LTD 31-0	ABACUS PHARMA (AFRICA) LIMITED	RIDMAL 40/320	DIHYDROARTEMI SININ + PIPERAQUINE	40MG + 320MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X12.0 TABLET BLISTER,1.0X1.0X3. 0 TABLET BLISTER,1.0X1.0X8. 0 TABLET BLISTER,1.0X1.0X9. 0 TABLET BLISTER,1.0X1.0X6. 0 TABLET BLISTER	01/07/2010
2453	NDA/MAL/HDP/3 875	PHAMA INTERNATIONAL CO	OMAB UGANDA LIMITED	OPTIMAL(0.05% GEL	TRETINOIN USP	0.25MG/1G	PHARMA INTERNATIONAL COMPANY .MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN	JORDAN	TOPICAL EXTERNAL GELS AND SOLS	1.0X1.0X30.0 G TUBE	01/07/2005

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2454	NDA/MAL/HDP/3 881	MEDICAL UNION PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	MOXACIL	AMOXYCILLIN TRIHYDRATE	125MG/5ML	MEDICAL UNION PHARMA .COABU- SULTAN ISMAILIA EGYPT	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2009
2455	NDA/MAL/HDP/3 883	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	MYFORTIC 360	MYCOPHENOLAT E SODIUM	360MG	NOVARTIS PHARMA STEIN AGSCHAFFHARVSERT RASSE CH-4332 STEIN SWITZERLAND.	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X12.0X10.0 TABLET BLISTER	01/07/2006

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2456	NDA/MAL/HDP/3 886	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	DELOR	CLOBETASOL PROPIONATE	0.5 MG/G	PHARMA INTERNATIONAL COMPANY MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE	01/07/2004
2457	NDA/MAL/HDP/3 888	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	PYRIREN	PYRIDOXINE HYDROCHLORIDE	25MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10. 0X10.0 TABLET BLISTER	01/07/2014

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2458	NDA/MAL/HDP/3 891	PHARMATHEN S.A	GOODMAN INTERNATIONAL LTD	LADININ	CIPROFLOXACIN	500MG	PHARMATHEN S.A- 6,DERVENAKION STR .153 51,PALLINI,AHICA GREECE	GREECE	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/1997
2459	NDA/MAL/HDP/3 892	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	TETRAX	LEVAMISOLE HYDROCHLORIDE	40MG/5ML	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X15.0 ML BOTTLE	01/07/1997

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2460	NDA/MAL/HDP/3 893	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	EPINEPHRINE INJECTION USP	EPINEPHRINE HCL	1MG/ML	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	CHINA INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2008
2461	NDA/MAL/HDP/3 896	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	VALCONTIN 500	SODIUM VALPROATE (CONTROLLED RELEASE)	500MG	MODI MUNDIPHARMA PVT. LTDMEERUT- MUZAFFARNAGAR ROAD, MODIPURAM – 250110 UTTAR PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	01/07/2010

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2462	NDA/MAL/HDP/3 897	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	CLAVODAR	AMOXICILLIN/CLA VULANIC ACID	875MG/125MG	DAR AL DAWANA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2010
2463	NDA/MAL/HDP/3 899	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	FEDATE SYRUP	SODIUM FEREDATE + PYRIDOXINE + CYANOCOBALAMI N + FOLIC ACID	216.87MG + 1.5MG + 7.5MCG + 1.5MG	AJANTA PHARMA LIMITED31-0 MIDC INDUSTRIAL AREA CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA STATE	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2013



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2464	NDA/MAL/HDP/3 906	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	LEROLE	PANTOPRAZOLE	40MG	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL 1*10ML 0.9%NACL AMPOULE	01/07/2011
2465	NDA/MAL/HDP/3 913	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	VALCONTIN	SODIUM VALPROATE	200 MG	MODI MUNDIPHARMA PVT. LTDMEERUT- MUZAFFARNAGAR ROAD, MODIPURAM – 250110 UTTAR PRADESH	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2012

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2466	NDA/MAL/HDP/3 914	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	AUGMENTIN	AMOXICILLIN + CLAVULANATE POTASSIUM	875 MG + 125 MG	SMITHKLINE BEECHAM PHARMACEUTICALS, CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X1.0X7.0 TABLET BLISTER	01/07/2010
2467	NDA/MAL/HDP/3 916	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	METOCLOPRAMI DE HYDROCHLORIDE INJECTION	METOCLOPRAMI DE HYDROCHLORIDE	5MG/ML	SCOTT-EDIL PHARMACIA LTD (UNIT I)-56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE,1.0X10.0 X10.0X2.0 ML AMPOULE	01/07/2016

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2468	NDA/MAL/HDP/3 922	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	DIAZI	DIAZEPAM	5MG/ML	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2011
2469	NDA/MAL/HDP/3 924	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLUFED	PARACETAMOL+P SEUDOEPHEDRIN E HYDROCHLORIDE +TRIPOLIDINE HYDROCHLORIDE	300MG+36MG+1.5 MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10 0.0 TABLET CONTAINER,1.0X25 0.0 TABLET CONTAINER,1.0X50 0.0 TABLET CONTAINER,1.0X10. 0 TABLET BLISTER	01/07/1997

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2470	NDA/MAL/HDP/3 927	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL CEPHALEXIN 125	CEPHALEXIN MONOHYDRATE	125MG/5ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2008
2471	NDA/MAL/HDP/3 928	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	MALAREN	SULPHADOXINE + PYRIMETHAMINE	500MG/25MG	RENE INDUSTRIES LTD .PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER,1.0X50.0X3 .0 TABLET BLISTER	01/07/2004

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2472	NDA/MAL/HDP/3 931	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	COARTEM 80/480	ARTEMETHER + LUMEFANTRINE	80MG +480MG	NORVATIS SAGLIK GIDA VE TARIM URENLERI SAN, VE TIC-AC-YENISEHIR MAHALLESİ İHLA VADISI SOKAK, NO.2, 34912 KURTKOY, INSTANBUL - TURKEY	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER	01/07/2014
2473	NDA/MAL/HDP/3 932	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIRAX TABLETS	CLIDINIUM BROMIDE + CHLORDIAZEPOXI DE	2.5MG + 5MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2008

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2474	NDA/MAL/HDP/3 933	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	TOZAAR-50	LOSARTAN POTASSIUM	50MG	TORRENT PHARMACEUTICAL LTD AHMEDABAD- MEHSANA HIGHWAY, TALUKA- KADI, DIST. MEHSANA , INDRAD-382721	INDIA	ORAL SOLID ORDINARY TABLETS	5.0X10.0 TABLET BLISTER	01/07/2001
2475	NDA/MAL/HDP/3 938	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	ADRENALINE INJECTION	ADRENALINE	1MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X1.0 ML AMPOULE	01/07/2013

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2476	NDA/MAL/HDP/3 945	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	CEFONE	CEFTRIAZONE	1G	SWISS PARENTERALS LTD, UNIT- IIPLOT NO. 402,412-414 KERALA INDUSTRIAL ESTATE, GIDC, NEAR BAVLA, DIST: AHMEDABAD	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL,1.0X10.0X1.0 G VIAL	01/07/2011
2477	NDA/MAL/HDP/3 947	INTAS PHARMACUITICALS LTD	NORVIK ENTERPRISES LIMITED	RABTAS-20	RABEPRAZOLE SODIUM	20 MG	INTAS PHARMACEUTICALS LTD .PLOT NOS. 457, 458 & 191/218P SARKHEJ-BAVLA HIGHWAY MATODA SANAND AHMEDABAD GUJARAT INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2008

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2478	NDA/MAL/HDP/3 949	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	MAGNOMINT SUSPENSION	COMPOUND MAGNESIUM TRISILICATE	N/A	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/1997
2479	NDA/MAL/HDP/3 951	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMCLOX	AMPICILLIN + CLOXACILLIN	125MG/5ML + 125MG/5ML	SPARSH BIO-TECH LTD PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2004



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2480	NDA/MAL/HDP/3 954	WOCKHARDT LTD	STAR PHARMACEUTICAL S LTD	POWERCEF 1GM INJECTION	CEFTRIAZONE SODIUM	1GM	ZEISS PHARMACEUTICALS PVT. LIMITEDPLOT NO. 72, EPIP I, JHARMAJIRI, BADDI (HP), INDIA WOCKHARDT LIMITEDB-15/2 MIDC, WALUJ, AURANGABAD 431136, MAHARASHTRA STATE, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 1*10ML AMPOULE OF WFI	01/07/2001
2481	NDA/MAL/HDP/3 960	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	IBUPAR	PARACETAMOL/IB UPROFEN	325/400MG	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER	01/07/2008

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2482	NDA/MAL/HDP/3 963	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	COARTEM DISPERSIBLE TABLETS	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	NOVARTIS URUNLERI TURKEYYENISEHIR MAHALLESİ, IHLARA VADISI SOKAK, NO. 2, TR 34912, PENDİK, İSTANBUL, TURKEY.	TURKEY	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X2.0X6.0 TABLET BLISTER,1.0X30.0X6 .0 TABLET BLISTER,1.0X1.0X6. 0 TABLET BLISTER	01/07/2009
2483	NDA/MAL/HDP/3 965	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	OROFER SYRUP	IRON(II) HYDROXIDE POLYMALTOSE COMPLEX	50MG/5ML	EMCURE PHARMACEUTICALS LTD LANE NO.3 PHASE II,SIDCO INDUSTRIAL COMPLEX,BARI- BRAHMANA JAMMU 181 133, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X150.0 ML BOTTLE	01/07/2004

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2484	NDA/MAL/HDP/3 966	DAWA LIMITED	SUPER MEDIC LTD	ASCORBIC ACID TABLETS	ASCORBIC ACID	100 MG	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER,10.0X1 0.0 TABLET BLISTER	01/07/2008
2485	NDA/MAL/HDP/3 967	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOCLOX-125	CLOXACILLIN	125MG/5ML	MILAN LABORATORIES (INDIA) PVT LTD PLOT NOS 63, 67 & 87, JAWAHAR CO-OP. INDUSTRIAL ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2011

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2486	NDA/MAL/HDP/3 969	PHARCO PHARMACEUTICAL S	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FAWAR FRUIT EFFERVESCENT GRANULES	SODIUM CARBONATE + TARTARIC ACID + CITRIC ACID	2.8G + 1.33G + 0.82G	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT, P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY EFFERVESCENT POWDERS/GRANU LES	1.0X6.5 G SACHET	01/07/2002
2487	NDA/MAL/HDP/3 970	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LECOTRIM	CO-TRIMOXAZOLE	480MG	LABORATORY & ALLIED LTD-PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1997

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2488	NDA/MAL/HDP/3 971	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	VIRIAXONE-SL	CEFTRIAZONE + SULBACTAM	1G+500MG	INJECT CARE PARENTERALS PVT LTD PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 10 ML AMPOULE WFI	01/07/2013
2489	NDA/MAL/HDP/3 983	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	EXTRADOL	PARACETAMOL/C AFFEINE TABLETS	500MG/65MG	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X50.0X2 .0 TABLET BLISTER	01/07/2008

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2490	NDA/MAL/HDP/3 985	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOMYCIN SUSPENSION	ERYTHROMYCIN ESTOLATE	125MG/5ML	AGOG PHARMAPLOT 33 SECTOR THE VASAI-TULUKA CO- OP ESTATE LTD INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	01/07/2008
2491	NDA/MAL/HDP/3 987	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	ROHISOL SYRUP	LEVAMISOLE HYDROCHLORIDE	40MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X500.0 ML BOTTLE,1.0X15.0 ML BOTTLE	01/07/1997

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2492	NDA/MAL/HDP/3 989	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	UNICELIB 200	CELECOXIB	200MG	UNICHEM LABORATORIES LTD- PLOT 17 & 18, PILERNE IND. ESTATE, PILERNE, BARDEZ GOA- 403511 UNICHEM LABORATORIES LTD UNIT II ,,VILLAGE, BHATAULI KALAN BADDI DIST. SOLAN (H.P) 173 205	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2003
2493	NDA/MAL/HDP/3 990	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	UNIXIL SYRUP	AMOXYCILLIN TRIHYDRATE	125MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X100.0 ML BOTTLE	01/07/1997

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2494	NDA/MAL/HDP/3 991	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOFULVIN	GRISEOFULVIN TABLETS	500MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008
2495	NDA/MAL/HDP/3 993	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	NEM SCAB	MULTI- INGREDIENT	MULTI- INGREDIENT	NEM LABORATORIES PVT LTD133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997



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2496	NDA/MAL/HDP/3 996	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOTOIN TABLETS	NITROFURANTOI N BP	100MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2007
2497	NDA/MAL/HDP/3 998	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOKOFF SYRUP	TERBUTALINE SULPHATE +GUAIFENESIN+B ROMHEXINE HYDROCHLORIDE +LEVOMENTHOL	1.25MG/5ML+50M G//5ML+4MG/5ML +2.5MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60 .0 ML BOTTLE	01/07/2008

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2498	NDA/MAL/HDP/4000	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APIDONE SYRUP	CHLORPHENARIM INE MALEATE/DEXAM ETHASONE	2MG/5ML + 0.5MG/5ML	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY, CAIRO EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X125.0 ML BOTTLE	01/07/2008
2499	NDA/MAL/HDP/4001	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOCOLD PLUS SYRUP	PARACETAMOL+P HENYLEPHRINE+C HLORPHENIRAMI NE+SODIUM CITRATE	125MG/5ML+2.5M G/5ML+1MG/5ML+ 60MG /5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60 .0 ML BOTTLE	01/07/2008

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2500	NDA/MAL/HDP/4002	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCID	ALUMINIUM HYDROXIDE+MAGNESIUM HYDROXIDE	250MG/5ML+250MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X170.0 ML BOTTLE	01/07/2007
2501	NDA/MAL/HDP/4004	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	ANTHEL	ALBENDAZOLE	400MG	LINCOLN PHARMACEUTICALS LTD-TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X1.0 TABLET BLISTER	01/07/2005

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2502	NDA/MAL/HDP/4 007	SANOFI PASTEUR.	LABOREX UGANDA LIMITED	SHANCHOL CHOLERA VACCINE	V.CHOLERA STRAINS- 01 INABA FORMALDEHYDE KILLED +01 OGAWA HEAT KILLED + 01 OGAWA FORMALDEHYDE KILLED + 01 INABA HEAT KILLED + 0139 FORMALDEHYDE KILLED	600 + 300 +300 +300 + 600 ELISA UNITS(EU) OF LIPOPOLYSACCHAR IDE (LPS)	SANOFI HEALTHCARE INDIA PRIVATE LIMITEDSURVEY NO. 247, ATHVELLI VILLAGE, MEDCHAL MANDAL - 501401, MEDCHAL - MALKAJGIRI DISTRICT, TELANGANA - INDIA	INDIA	PARENTERAL ORDINARY I M VIALS	1.0X10.0X1.5 ML VIAL (1 DOSE)	01/07/2016
2503	NDA/MAL/HDP/4 010	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	PYRI	PYRIDOXINE HYDROCHLORIDE	25MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER,1.0X50 0.0 TABLET CONTAINER,1.0X25 0.0 TABLET CONTAINER,1.0X10. 0 TABLET BLISTER	01/07/1997

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2504	NDA/MAL/HDP/4 012	ACINO PHARMA AG	LABOREX UGANDA LIMITED	MESPORIN 2000	CEFTRIAZONE	2000MG	LABESFAL LABORATORIOS ALMIRO, S.A ,ZONA INDUSTRIAL DO LABENGO, 3465-157 SANTIAGO DE BESTEIROS	PORTUGAL	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X50.0 ML VIAL	01/07/2004
2505	NDA/MAL/HDP/4 015	CADILA PHARMACEUTICAL S LIMITED	AAFIYA (A) LTD	TAMBAC 50	CEFPODOXIME PROXETIL	50MG/5ML	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE,1.0X1.0X10 0.0 ML BOTTLE	01/07/2005

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2506	NDA/MAL/HDP/4 016	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	COMPOUND SODIUM LACATE INTRAVENOUS INFUSION	MULTI- INGREDIENT	MULTI- INGREDIENT	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTDVILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2007
2507	NDA/MAL/HDP/4 019	SEDICO PHARMACEUTICAL CO.	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FLUCAMOX 1G	AMOXICILLIN + FLUCLOXACILLIN	500 MG + 500 MG	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT	EGYPT	PARENTERAL ORDINARY VIALS	1.0X1.0 G VIAL	01/07/2007

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2508	NDA/MAL/HDP/4 023	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	SINAREST LINCTUS	CHLORPHENAMIN E MALEATE+DEXTR OMETHORPHAN HYDROBROMIDE+ MENTHOL	(4MG +10MG +3MG)/10ML	CENTAUR PHARMACEUTICALS PVT LTD PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997
2509	NDA/MAL/HDP/4 024	SEDICO PHARMACEUTICAL CO.	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SEDALAC SYRUP	LACTULOSE	3.350G/5ML	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA, EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2007

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2510	NDA/MAL/HDP/4 030	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	XBETA- N	BETAMETHASONE + NEOMYCIN	0.1%W/V +0.5%W/V	ABACUS PARENTERAL DRUGS LTD PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE,  MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL,1.0X5.0 ML VIAL	01/07/2011
2511	NDA/MAL/HDP/4 033	JOHNSON&JOHNS ON PTY LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	BENYLIN PAEDIATRIC SYRUP	DIPHENHYDRAMINE HYDROCHLORIDE	7MG/5ML	JOHNSON&JOHNSON PTY LTD.EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	01/07/2007



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2512	NDA/MAL/HDP/4 035	BAYER SCHERING PHARMA	SURGIPHARM (U) LIMITED	YASMIN	DROSPIRENONE + ETHINYLESTRADI OL	3MG+0.3MG	BAYER PHARMA A.GMULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X21.0 TABLET BLISTER	01/07/2010
2513	NDA/MAL/HDP/4 038	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	PREDSONE-5	PREDNISOLONE	5MG	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2012

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2514	NDA/MAL/HDP/4 042	SWISS PARENTERALS PVT. LTD.	SHREEJI PHARMACEUTICAL S LIMITED	S-CHLOR	CHLORAMPHENIC OL	1G	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2011
2515	NDA/MAL/HDP/4 047	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	NEOGAB	GABAPENTIN	300MG	HILTON PHARMA (PVT) LTD PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/2007

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2516	NDA/MAL/HDP/4 055	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	BAYER ASPIRIN CARDIO	ACETYLSALICYLIC ACID	100MG	BAYER PHARMA AGD 51368 LEVERKUSEN, GERMANY	GERMANY	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2006
2517	NDA/MAL/HDP/4 060	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	TOBRADEX	TOBRAMYCIN/DE XAMETHASONE	0.3%W/V+ 0.1%W/V	ALCON COUVREUR NVRIJKSWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/1997

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2518	NDA/MAL/HDP/4 062	VIIV HEALTHCARE UK LTD-	UNITED HEALTHCARE DISTRIBUTORS LTD	KIVEXA	ABACAVIR SULFATE + LAMIVUDINE	600 MG + 300 MG	GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS)PRIORITY STREET, WARE, SG12 ODJ	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X1.0X30.0 TABLET CONTAINER,1.0X3.0 X10.0 TABLET BLISTER	01/07/2006
2519	NDA/MAL/HDP/4 063	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	AVOCOMB TABLET	LAMIVUDINE/ZID OVUDINE	150MG/300MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2003

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2520	NDA/MAL/HDP/4 064	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	TERAFINE	TERBINAFINE	250MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER	01/07/2010
2521	NDA/MAL/HDP/4 075	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICAL S LTD	CHERICOF COUGH FORMULAR	CHLORPHENIRAM INE/DEXTROMET HORPHAN HBR/PHENYLEPH RINE HCL	2MG/10MG/5MG	RANBAXY LABORATORIES LTD AT: THE MADRAS PHARMACEUTICALS1 37-B OLD MAHABALIPURAM ROAD KARAPAKKAM CHENNAI 600 096	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2015

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2522	NDA/MAL/HDP/4 078	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	EPIGAB	PREGABALIN	75MG	DAR AI DAWANA UR PLANT,AMMAN,JOR DAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X14.0 CAPSULE BLISTER	01/07/2013
2523	NDA/MAL/HDP/4 079	PHARMA INTL CO..	OMAB UGANDA LIMITED	NERVAMINE	MECOBALAMIN	500MCG	PHARMA INTERNATIONAL CO.AMMAN JORDAN PLANT AL-QARTAL MARKETING DEPARTMENT ALBUJAH COMPLEX, ALJUBAIHA	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2009

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2524	NDA/MAL/HDP/4 086	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	KELVIN SUSPENSION	PARACETAMOL	120MG/5ML	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE	01/07/2008
2525	NDA/MAL/HDP/4 091	HILTON PHARMA PVT LTD	HEALTHCARE LTD.	MYTEKA TABLETS	MONTELUKAST SODIUM	5MG	HILTON PHARMA PVT,LTD13 SECTOR 15,KORANG,IND.ARE A,8TH FLOOR PROGRESSIVE PLAZA,BEAMONT RD,KARACHI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2005

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2526	NDA/MAL/HDP/4 092	PRISMA PHARMACEUTICAL S LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	FLORANORM	SACCHAROMYCES BOULARDII	250MG	BHARAT BIOTECH INTERNATIONAL LTD- TURKPALLY SHAMEX 500 078 MYDERAHAD INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X2.0X250.0 MG SACHET,1.0X10.0X2 50.0 MG SACHET	01/07/2010
2527	NDA/MAL/HDP/4 093	LEBEN LABORATORIES LTD	MALIX PHARMA (U) LIMITED	BECLOMIN OINTMENT	BECLOMETHASON E+MICONAZOLE+ NEOMYCIN	0.025%W/W + 2%W/W + 0.5%W/W	LEBEN LAB PVT LTDL4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/2007



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2528	NDA/MAL/HDP/4 095	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	IBUT-200	IBUPROFEN	200MG	LEBEN LAB PVT LTD L4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER,1.0X100.0X 10.0 TABLET BLISTER	01/07/2007
2529	NDA/MAL/HDP/4 097	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	DERMOVATE	CLOBETASOL PROPIONATE	0.05%W/W	GLAXOSMITHKLINE HARMIRE GLAXOSMITHKLINE HARMIRE ROAD BARNARD CASTLE DURHAM	UNITED KINGDOM	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE,1.0X30.0 G TUBE	01/07/1997

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2530	NDA/MAL/HDP/4 099	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	GLEVO I.V	LEVOFLOXACIN	500MG/100ML	AMANTA HEALTHCARE LIMITED PLOT NO. 876 N.H. NO. 8 VILLAGE-HIRIYALA TALUKA, MATAR, DIST KHEDA-387 411, GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2007
2531	NDA/MAL/HDP/4 100	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	NORETHISTERONE	NORETHISTERON E	5MG	REMEDICA LIMITED AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2007

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2532	NDA/MAL/HDP/4 101	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	AMLOTRUST 5	AMLODIPINE	5MG	CENTAUR PHARMACEUTICALS PVT LTD PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2015
2533	NDA/MAL/HDP/4 103	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	POLIO SABIN - ONE AND THREE [ORAL]	LIVE ATTENUATED POLIOMYELITIS VIRUS VACCINE OF THE SABIN STRAINS TYPE 1 +TYPE 2	$10^6$ CCID <sub>50</sub> + $10^5$ . <sup>8</sup> CCI D <sub>50</sub>	GLAXO SMITHKLINE BIOLOGICALS S.ARUE DE L'INSTITUT, 89 B- 1330 RIXENSART	BELGIUM	ORAL LIQUID ORDINARY DROPS	1.0X100.0X2.0 ML VIAL (20 DOSES)	01/07/2016

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2534	NDA/MAL/HDP/4 104	DAWA LIMITED	SUPER MEDIC LTD	DAWA-PROM	PROMETHAZINE HCL	25MG	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2009
2535	NDA/MAL/HDP/4 113	MICRO LABS LTD	LABOREX UGANDA LIMITED	EROSTIN 10	EBASTINE	10 MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	01/07/2005

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2536	NDA/MAL/HDP/4 114	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	RINALIN SYRUP	CHLORPHENIRAM INE MALEATE	2MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/1997
2537	NDA/MAL/HDP/4 115	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	PREDILONE	PREDNISOLONE	5.0 MG	REGAL PHARMACEUICALS LTD PLOT NO 7879 OFF BABA DOGO ROAD KUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X 10.0 TABLET BLISTER	01/07/2007

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2538	NDA/MAL/HDP/4 118	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	OCUREST-AH	PHENYLEPHRINE HYDROCHLORIDE +NAPHAZOLINE HYDROCHLORIDE +CHLORPHRENIR AMINE MALEATE+MENT HOL+CAMPHOR	0.12%+0.05%+0.1% +0.005%+0.01%	CENTAUR PHARMACEUTICALS PRIVATE LIMITEDPLOT NO.3,TIVIM INDUSTRIAL ESTATE KARASWADA MUPUSA-GOA 403 526 INDIA	INDIA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL	01/07/2005
2539	NDA/MAL/HDP/4 126	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	UNICELIB 100	CELECOXIB	100MG	UNICHEM LABORATORIES LTDUNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2003

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2540	NDA/MAL/HDP/4 127	SANOFI 410 THALES	LABOREX UGANDA LIMITED	EPILIM	SODIUM VALPROATE	200MG/5ML	UNITHER LIQUID MANUFACTURING INDUSTRIE - COLOMIERS 1-3 ALLE DE LA NESTE L DEN SIGAL 31770	FRANCE	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE,1.0X300.0 ML BOTTLE	01/07/1998
2541	NDA/MAL/HDP/4 128	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	VITAREN SYRUP	VITAMIN A + VITAMIN B2 + VITAMIN B1 + VITAMIN B6 + VITAMIN C + VITAMIN E + VITAMIN B3	1500IU/5ML + 1MG/5ML + 1MG/5ML + 0.5MG/5ML + 20MG/5ML + 100 IU/5ML + 10MG/5ML	RENE INDUSTRIES LIMITEDPLOT 680 KAMULI- KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE,1.0X1.0X10 0.0 ML BOTTLE	01/07/2008

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2542	NDA/MAL/HDP/4 134	INDOCO REMEDIES LTD	STAR PHARMACEUTICAL S LTD	CITAL	DISODIUM HYDROGEN CITRATE	1.37G/5ML	INDOCO REMEDIES LTDB-20, MIDC, WALUJ, AURANGABAB 431136 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2004
2543	NDA/MAL/HDP/4 138	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYCLOX CAPSULES	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	ELYS CHEMICAL INDUSTRIES LTD ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER, 1.0X500.0 CAPSULE CONTAINER	01/07/1997



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2544	NDA/MAL/HDP/4 141	SANOFI 410 THALES	LABOREX UGANDA LIMITED	EPILIM 200	SODIUM VALPROATE	200MG	FISONS LTD (ALSO KNOWN AS SANOFI- AVENTIS)RIELL, SPAIN	SPAIN	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2001
2545	NDA/MAL/HDP/4 143	MODI NUNDIPHARMA PVT LTD	SURGIPHARM (U) LIMITED	TAM CONTIN 0.4	TAMSULOSIN HYDROCHLORIDE	0.4MG	MODI MUNDIPHARMA PVT. LTDMEERUT- MUZAFFARNAGAR ROAD, MODIPURAM – 250110 UTTAR PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2013

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2546	NDA/MAL/HDP/4 146	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOMPICLOX	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	MILAN LABORATORIES (INDIA ) PVT LTD PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTR A-410209,INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2011
2547	NDA/MAL/HDP/4 147	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	NIFEDI-DENK 20 RETARD	NIFEDIPINE	20MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2000

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2548	NDA/MAL/HDP/4 148	COSMOS LIMITED	ASTRA PHARMA (U) LIMITED	AMITRIPTYLINE TABLETS	AMITRIPTYLINE	25MG	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	01/07/1998
2549	NDA/MAL/HDP/4 150	TORRENT PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S LTD.	ANGIOPRIL-25	CAPTOPRIL	25MG	TORRENT PHARMACEUTICALS LTDINDRAD-382 721, DIST.MEHSANA,INDI A.AT:VILL.MANAKPU R,TEH.NALAGARH,DI ST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER	01/07/1997

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2550	NDA/MAL/HDP/4 165	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ZEFONE INJECTION	CEFTRIAZONE SODIUM	1G	SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ- BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA INJECTCARE PARENTERALS PVT. LTD.-PLOT130 SILVASSA ROAD GIDC VAPI 396195 GUJARAT, ZEISS	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2001
2551	NDA/MAL/HDP/4 171	MACK BROWN PHARMACEUTICAL S PVT LIMITED	SHURIK LTD	TOREX	MULTIINGREDIEN T	N/A	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

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2552	NDA/MAL/HDP/4 172	RENE INDUSTRIES	RENE INDUSTRIES LIMITED	KOF OFF EXPECTORANT	MULTI- INGREDIENT	MULTI- INGREDIENT	RENE INDUSTRIESPLOT 680 KAMULI KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X110.0 ML BOTTLE	01/07/2005
2553	NDA/MAL/HDP/4 173	ORGANON SOUTH AFRICA (PTY) LTD	SURGIPHARM (U) LIMITED	NASONEX	MOMETASONE FUROATE MONOHYDRATE	0.05%W/V	SCHERING PLOUGH LABO N.V,-INDUSTRY PARK 30, 2220 HEIST OPDENBERG BELGIUM	BELGIUM	NASAL SYSTEMIC METERED-DOSE LIQUIDS	1.0X1.0X120.0 METERED DOSE CANNISTER	01/07/2009

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2554	NDA/MAL/HDP/4 180	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	OSMOWIN	LACTULOSE	10G/15ML	G.S PHAMBUTOR PVT LTDG.S PHAMBUTOR PVT LTD B-172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE	01/07/2015
2555	NDA/MAL/HDP/4 182	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	SINAREST- FORTE	MULTI INGREDIENT	MULTI INGREDIENT	CENTAUR PHARMACEUTICALS LTD PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X50.0X4 .0 TABLET STRIP	01/07/2007

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2556	NDA/MAL/HDP/4 187	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	NORIGYNON	ESTRADIOL VALERATE +NORETHINDRON E ENANTHATE	5 MG+50 MG / ML	BAYER PHARMA A.GMULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE	01/07/1997
2557	NDA/MAL/HDP/4 188	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOPRAZ	PRAZICUANTEL	600MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X2.0X4. 0 TABLET BLISTER,1.0X1.0X4. 0 TABLET BLISTER	01/07/2013

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2558	NDA/MAL/HDP/4 209	AUROBINDOM PHARMA LIMITED	GITTOES PHARMACEUTICAL S LIMITED	POZINEG 1000	CEFEPIME	1000MG	AUROBINDO PHARMA LIMITED, UNIT IISURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELENGANA (STATE)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL + 1*1AMP WATER FOR INJECTION	01/07/2008
2559	NDA/MAL/HDP/4 241	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AMPICILLIN SODIUM FOR INJECTION BP	AMPICILLIN SODIUM	500MG	CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHUANG) CO. LTD WORKSHOP NO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA WORKSHOP 406 AND 407	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X500.0 MG VIAL	01/07/2011



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2560	NDA/MAL/HDP/4 275	F. HOFFMANN LA- ROCHE	LABOREX UGANDA LIMITED	AVASTIN 100MG/4ML	BEVACIZUMAB	100 MG/ 4ML	F.HOFFMANN-LA ROCHE LTD- GRENZACHERSTRASS E 124,CH- 4070 BASEL ROCHE DIAGNOSTICS GMBH- SANDHOFER STRASSE 116 D- 68305 MANNHEIM GERMANY	SWITZERLAND GERMANY	PARENTERAL ORDINARY VIALS	1.0X4.0 ML VIAL	01/07/2016
2561	NDA/MAL/HDP/4 276	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	FALCI CARE	ARTESUNATE	60MG	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 5 ML NACL + 1 ML SODIUM BICARBONATE	01/07/2013

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2562	NDA/MAL/HDP/4 277	NABIQASIM INDUSTRIES (PVT) LIMITED	JEET PHARMACEUTICAL S LIMITED	VIVIRON PLUS SYRUP	FERRIC AMMONIUM CITRATE +FOLIC ACID + PYRIDOXINE HCL + THIAMINE HCL + NICOTINAMIDE	50MG + 0.5MG + 2.2MG + 1.3MG +11MG	NABIQASIM INDUSTRIES (PVT) LTD-17/24,KORANGI INDUSTRIAL AREA, KORANGI, KARACHI- PAKISTAN.	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X90.0 ML BOTTLE,1.0X250.0 ML BOTTLE	01/07/2014
2563	NDA/MAL/HDP/4 279	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROTIM	TIMOLOL MALEATE	0.5% W/V	AUROLABNO. 1, SIVAGANGAI MAIN ROAD, VEERAPANJAN, MADURAI	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2016

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2564	NDA/MAL/HDP/4 280	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ABACAVIR SULFATE+LAMIVU DINE	ABACAVIR SULFATE + LAMIVUDINE	600 MG + 300 MG	MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD ,PLOT NO. 11, 12, & 13 INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III PITHAMPUR 454775, DIST DHAR -	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2013
2565	NDA/MAL/HDP/4 284	F. HOFFMANN LA- ROCHE	LABOREX UGANDA LIMITED	AVASTIN 400MG/4ML	BEVACIZUMAB	400MG/4ML	F.HOFFMANN-LA ROCHE LTD- GRENZACHERSTRASS E 124,CH- 4070 BASEL ROCHE DIAGNOSTICS GMBH- SANDHOFER STRASSE 116 D- 68305 MANNHEIM GERMANY	SWITZERLAND GERMANY	PARENTERAL ORDINARY VIALS	1.0X16.0 ML VIAL	01/07/2016

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2566	NDA/MAL/HDP/4 287	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANAXONE 1000	CEFTRIAZONE	1000MG	SANCE LABORATORIES PVT. LTD.VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT- 686573, KERALA, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL,1.0X50.0X10.0 ML VIAL	01/07/2010
2567	NDA/MAL/HDP/4 291	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	VITAMIN B COMPLEX INJECTION	VITAMIN B COMPLEX	10MG/2ML	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2008

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2568	NDA/MAL/HDP/4 292	F. HOFFMANN LA- ROCHE	LABOREX UGANDA LIMITED	HERCEPTIN 150MG	TRASTUZUMAB	150MG	ROCHE DIAGNOSTICS GMBH MANNHEIM- SANDHOFER STRASSE 116 -68305 MANNHEIM GERMANY.	GERMANY	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	01/07/2016
2569	NDA/MAL/HDP/4 303	PFIZER LABORATORIES (PTY)	LABOREX UGANDA LIMITED	SAYANA PRESS	MEDROXYPROGE STERONE ACETATE	104MG/0.65ML	PFIZER MANUFACTURING NV/NA, RIJKSWEG 12 2870, PUURS	BELGIUM	PARENTERAL ORDINARY I M PRE- FILLED SYRINGES	1.0X200.0X0.65 ML PRE- FILLED SYRINGE	01/07/2010

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2570	NDA/MAL/HDP/4 307	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	MIKACIN	AMIKACIN SULPHATE	500MG/2ML	ARISTO PHARMACEUTICALS PVT. LIMITED PLOT NO. 208, NEW INDUSTRIAL AREA NO.II, MANDIDEEEP PRADESH	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0X8.0X2.0 ML VIAL, 1.0X1.0X2.0 ML VIAL	01/07/2009
2571	NDA/MAL/HDP/4 309	HETERO DRUGS LTD	AIVEEN (U) LIMITED	LAMIVUDINE + ZIDOVDINE	LAMIVUDINE + ZIDOVDINE	150MG + 300MG	HETERO LABS LTD 22- 110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH HETERO LABS LTD (UNIT- V)SY.NO.438,439,44 0 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2010

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2572	NDA/MAL/HDP/4 312	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GONAL-F	FOLLITROPIN ALFA	75IU/IE	MERCK SERONO S.P.A-VIA DELLE MAGNOLIE,15.70026 MODUGNO (BA).ITALY MERCK SERONO S.A. (MSA) - 1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND	ITALY SWITZERLAND	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1 PRE FILLED SYRINGE OF WFI	01/07/2016
2573	NDA/MAL/HDP/4 313	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	AKUGABALIN	PREGABALIN 150MG CAPSULES	150MG	AKUMS DRUGS & PHARMACEUTICALS LTD.2, 3, 4, & 5, SEC- 6B, I.I.E., SIDCUL, RANIPUR, HARIDWAR-249403 (INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	07/01/2016

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2574	NDA/MAL/HDP/4 315	DENK PHARMA GMB H & CO. KG	BENLE CONSULT LIMITED	DESLORA-DENK 5	DESLORATIDINE	5MG	DENK PHARMA GMBH & CO.KG GOLLSTR 1,84529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016
2575	NDA/MAL/HDP/4 317	DENK PHARMA GMB H & CO. KG	BENLE CONSULT LIMITED	COLOSAR-DENK 50/12.5	LOSARTAN + HYDROCHLOROT HIAZIDE	50MG + 12.5MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER,1.0X2.0X14 .0 TABLET BLISTER	01/07/2011



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2576	NDA/MAL/HDP/4 318	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	AKUGABALIN	PREGABALIN	75 MG	AKUMS DRUGS & PHARMACEUTICALS LTD19, 20,21 SECTOR 6A IIE SIDCUL RANIPUR HARIDWAR 249 403	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	07/01/2016
2577	NDA/MAL/HDP/4 320	AFRICURE PHARMACEUTICAL S (INDIA) PRIVATELIMITED	ROYAL PHARMA 2011 LIMITED	HYOSCINE BUTYL BROMIDE	HYOSCINE BUTYL BROMIDE	10MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9- 12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2005

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2578	NDA/MAL/HDP/4 324	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PRASUSAFE 5	PRASUGREL	5MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1X3X10 TABLET BLISTER	01/07/2013
2579	NDA/MAL/HDP/4 325	AJANTA PHARMA LTD 31-0	ABACUS PHARMA (AFRICA) LIMITED	ACTINAC 100	ACECLOFENAC	100MG	AJANTA PHARMA LIMITED PLOT NO. M- 55-56-57, ISEZ, PHASE II, PITHAMPUR-454775, DISTRICT DHAR, MADHYA PRADESH STATE AJANTA PHARMA LIMITED B-4 5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST: AURANGABAD MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X2.0X10.0 TABLET BLISTER	01/07/2009

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2580	NDA/MAL/HDP/4 329	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGO-CPM	CHLORPHENIRAM INE MALEATE	2MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60 .0 ML BOTTLE	01/07/2010
2581	NDA/MAL/HDP/4 330	SPARSH BIO-TECH PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	FLUCLOXACILLIN CAPSULES	FLUCLOXACILLIN	250MG	SPARSH BIO-TECH PVT. LTD.-PLOT NO. 1, SURVEY NO. 242/243/244, VILLAGE LAKHABAVAD POST KHODIYAR COLONY DISTRICT, JAMNAGAR – 361006 GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE STRIP	01/07/2016

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2582	NDA/MAL/HDP/4 331	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	STEDNAC	ACECLOFENAC	100MG	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2010
2583	NDA/MAL/HDP/4 333	ZEE PHARMACEUTICAL S LTD	ZEE PHARMACEUTICAL S LIMITED	CARVIBERG	CARVEDILOL USP	6.25MG	THE MADRAS PHARMACEUTICALS1 37-B,OLD MAHABALI PURAM ROAD,KARAPAKKAM ,CHENNAI INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016

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2584	NDA/MAL/HDP/4 334	DENK PHARM GMBH&CO.KG	BENLE CONSULT LIMITED	LOSAR-DENK 50	LOSARTAN	50MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2011
2585	NDA/MAL/HDP/4 335	DAWA LIMITED	SUPER MEDIC LTD	CURAMOL SUSPENSION	PARACETAMOL	120MG/5ML	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2009

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2586	NDA/MAL/HDP/4 339	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	SERETIDE 125 EVOHALER	SALMETEROL XINAFOATE + FLUTICASONE PROPIONATE	25MCG/125MCG	GLAXO WELLCOME PRODUCTIONZONE INDUSTRIELLE NO.2 23 RUE LAVOISER 27000 EVREUX	FRANCE	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER	01/07/2007
2587	NDA/MAL/HDP/4 348	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	MEDICLOAMP SYRUP	CLOXACILLIN+AM PICILLIN	250MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

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2588	NDA/MAL/HDP/4 350	ACINO PHARMA AG	LABOREX UGANDA LIMITED	OLFEN-75	DICLOFENAC SODIUM	75MG/2ML	MERCKLE GMBH,LUDWIG MERCKLE STRASSE3 D-89143 BLAUBEUREN HAUPT PHARMA WULFING GMBH.BETHELNER LANDSTR. 18, 31028 GRONAU/LEINE	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE	01/07/1997
2589	NDA/MAL/HDP/4 352	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REQUIN SYRUP	QUININE HYDROCHLORIDE	100MG/5ML	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2001

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2590	NDA/MAL/HDP/4 356	ADCOCK INGRAM LIMITED	SURGIPHARM (U) LIMITED	FRESHEN	BISACODYL	5 MG	ADCOCK INGRAM LIMITED 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE  560099, KARNATAKA STATE, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X12.0 TABLET BLISTER	01/07/2016
2591	NDA/MAL/HDP/4 358	A.MENARINI INDUSTRIE FARMACEUTICHE S.R.I	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	LIOTON	HEPARIN SODIUM	1000I.U/G	A. MENARINI MANUFACTURING LOGICTICS AND SERVICESVIA 3 SETTE SANTI FLORENCE 50131 ITALY	ITALY	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE,1.0X15.0 G TUBE	01/07/2016



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2592	NDA/MAL/HDP/4 362	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	LEVOMAC 750	LEVOFLOXACIN HEMIHYDRATE	750MG	MACLEODS PHARMACEUTICALS LIMITED BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH - 174101 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2016
2593	NDA/MAL/HDP/4 365	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ACTINAC PLUS	ACECLOFENAC + PARACETAMOL	100 MG + 500 MG	AJANTA PHARMA LIMITED PLOT NO. M- 55-56-57, ISEZ, PHASE II, PITHAMPUR-454775, DISTRICT DHAR, MADHYA PRADESH STATE AJANTA PHARMA LIMITED B- 4/5/6, MIDC AREA, PAITHAN, 431 148 INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2009

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2594	NDA/MAL/HDP/4 366	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	CLOXISPA	CLOXACILLIN	250MG	SPARSH BIO-TECH LTD PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER,1.0X10 0.0X10.0 CAPSULE BLISTER	01/07/2004
2595	NDA/MAL/HDP/4 367	ASTRA ZENECA	MACNAUGHTON LIMITED	ATACAND 8MG	CANDESARTAN	8MG	ASTRA ZENECA AB, SODERTALJEGARTUN AYEGEN, SODERTALJE	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2010

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2596	NDA/MAL/HDP/4 375	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	ZITHROMAX	AZITHROMYCIN DIHYDRATE	200MG/5ML	HAUPT PHARMA LATINA S.R.L LATINA- SS 156KM 47,600- 04100,BORGO SAN,MICHELE	ITALY	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X30.0 ML BOTTLE,1.0X15.0 ML BOTTLE	01/07/1997
2597	NDA/MAL/HDP/4 379	LEBEN LABORATORIES PVT.LTD	MALIX PHARMA (U) LIMITED	SINURHON	MULTI- INGREDIENT	5MG/ 2MG/ 500MG / 30MG	LEBEN LABORATORIES PVT. LTD PLOT NO. L-4, PHASE-III, MIDC, AKOLA- 444 104 (MS).	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X12.0X40.0 TABLET BLISTER,1.0X1.0X6. 0X20.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER	01/07/2010

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2598	NDA/MAL/HDP/4 380	GLAXO WELLCOME (KENYA) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZINNAT SUSPENSION	CEFUROXIME AXETIL-	125MG/5ML	GLAXOSMITHKLINE UK LTD HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE, 1.0X50.0 ML BOTTLE	01/07/1998
2599	NDA/MAL/HDP/4 383	ZEE PHARMACEUTICAL S LTD	ZEE PHARMACEUTICAL S LIMITED	ZEEMYCIN - 150	CLINDAMYCIN HYDROCHLORIDE BP	150MG	THE MADRAS PHARMACEUTICALS 37-B, OLD MAHABALI PURAM ROAD, KARAPAKKAM , CHENNAI INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2016

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2600	NDA/MAL/HDP/4 388	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	TAZOBAK	PIPERACILLIN SODIUM + TAZOBACTAM SODIUM	4.0G + 0.5G	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA SWISS PARENTERALS LIMITED UNIT IIPLOT 402, 412-414, KERALA INDUSTRIAL ESTATE, GIDC, NEAR BAVLA, AHMEDABAD - 382220, GUJARAT - INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X4.5 G VIAL	01/07/2016
2601	NDA/MAL/HDP/4 389	PHARMACARE LTD	MEDICAL ACCESS (UGANDA) LIMITED	PREZISTA	DARUNAVIR	600MG	JANSSEN ORTHO LLC. STATE ROAD 933 KM 0.1 MARNEY WARD GURABO PUERTO RICO 00778	UNITED STATES	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2011

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2602	NDA/MAL/HDP/4 390	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROCOL	CHLORAMPHENIC OL	0.5%W/V	AUROLABNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA	INDIA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE	01/07/2016
2603	NDA/MAL/HDP/4 392	IND SWIFT LTD	PLANET PHARMACEUTICAL S UGANDA LTD	CAPLOR	CLOPIDOGREL	75MG	IND SWIFT LTDGBU JAWAHARPUR OFF NH-21 DERABASSI DIST MOHALI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011

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2604	NDA/MAL/HDP/4 394	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	NS	SODIUM CHLORIDE	0.9% W/V	ABACUS PARENTERAL DRUGS LTD PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE,  MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE, 1.0X250.0 ML BOTTLE	01/07/2010
2605	NDA/MAL/HDP/4 396	MYLAN LABORATORIES LIMITED (OTL)	KIMSY MEDS LTD	ABACAVIR SULPHATE	ABACAVIR SULFATE	300MG	MYLAN LABORATORIES LTD PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR - 454775; DIST; DHAR; MADHYA PRADESH; MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2007

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2606	NDA/MAL/HDP/4 398	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	SODIUM CHLORIDE	SODIUM CHLORIDE	0.9 % W/V	ACULIFE HEALTHCARE PVT. LTDVILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE,1.0X250.0 ML BOTTLE	01/07/1997
2607	NDA/MAL/HDP/4 399	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	GEFIL	COMPOUND MAGNESIUM TRISILICATE	ALUMINIUM HYDROXIDE & MAGNESIUM TRISILICATE 132 &	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED VANDALUR ROAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2005



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2608	NDA/MAL/HDP/4 400	COSMOS LTD	ASTRA PHARMA (U) LIMITED	ORAL REHYDRATION SALT (DTS)	ORAL REHYDRATION SALT	N/A	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X100.0X20.6 G SACHET,1.0X100.0X 10.3 G SACHET	01/07/1997
2609	NDA/MAL/HDP/4 401	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPICEPHIN	CEFTRIAXONE DISODIUM	ZG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X2.0 G VIAL + 2*5 ML OF WFI GLASS AMPOULES,1.0X2.0 G VIAL + 1*10ML GLASS AMPOULE OF WFI	01/07/2014

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2610	NDA/MAL/HDP/4 402	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICAL S LIMITED	CLOTRILIN	CLOTRIMAZOLE	100MG	LINCOLN PHARMACEUTICALS LTD10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI , KHATRAJ-382721, GHANDINAGAR ARAT, INDIA	INDIA	VAGINAL TABLETS	1.0X6.0 TABLET STRIP	01/07/2014
2611	NDA/MAL/HDP/4 404	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	FOLIGRAF	RECOMBINANT HUMAN FOLLICLE STIMULATING HORMONE	75I.U/ VIAL	BHARAT SERUMS AND VACCINES LIMITED,PLOT NO. K- 27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	01/07/2016

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2612	NDA/MAL/HDP/4 406	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	SATISFIL -100	SILDENAFIL	100MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	01/07/2011
2613	NDA/MAL/HDP/4 408	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	UNISTEN CREAM	CLOTRIMAZOLE	1%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/1997

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2614	NDA/MAL/HDP/4 410	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	M-KAST 4	MONTELUKAST	4MG	AUROBINDO PHARMA LTD UNIT VII (SEZ) APIICPLOT NO. S1 SURVEY NO. 411,425,434,435 & 458 GREEN INDUSTRIAL PARK POLEPALLY VILLAGE MAHABOBNAGAR DISTRICT ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
2615	NDA/MAL/HDP/4 411	ASTRAZENECA AG	MACNAUGHTON LIMITED	ATACAND PLUS	CANDESARTAN + HYDROCHLOROT HIAZIDE	16 MG + 12.5 MG	ASTRA ZENECA AB, SODERTALJEGARTUN AYEGEN, SODERTALJE	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2010

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2616	NDA/MAL/HDP/4 412	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	M-KAST 5	MONTELUKAST SODIUM	5MG	AUROBINDO PHARMA LTD UNIT VII (SEZ) APIICPLOT NO. S1 SURVEY NO. 411,425,434,435 & 458 GREEN INDUSTRIAL PARK POLEPALLY VILLAGE MAHABOBNAGAR DISTRICT ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
2617	NDA/MAL/HDP/4 413	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPICEPHIN	CEFTRIAZONE	1G	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL (+ 1 GLASS AMPOULE OF 10ML WFI)	01/07/2011

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2618	NDA/MAL/HDP/4 415	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	CATAFLAM 50MG TABLETS	DICLOFENAC POTASSIUM	50MG	NOVARTIS-- URUNLERI INSTABUL TURKEY NOVARTIS PHARMA SPA,- TORRE ANNUNZIATA ITALY	ITALY TURKEY	ORAL SOLID ORDINARY COATED TABLETS	10.0X10.0 TABLET BLISTER,1.0X2.0X10 .0 TABLET BLISTER	01/07/1997
2619	NDA/MAL/HDP/4 417	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPICEPHIN	CEFTRIAXONE SODIUM	500MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X0.5 G VIAL + 1*5 ML OF WFI GLASS AMPOULES	01/07/2014

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2620	NDA/MAL/HDP/4 418	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	VALORAN	CEFOTAXIME	1000MG	MEDOCHEMIE LIMITED (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL - CYPRUS.	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 VIAL CARTON	01/07/2009
2621	NDA/MAL/HDP/4 419	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIGONAL 75	HUMAN MENOPAUSAL GONADOTROPHI N	75IU/5ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL + 1 ML AMPOULE 0.9%W/V NAACL	01/07/2010

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2622	NDA/MAL/HDP/4 425	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REQUIN FC	QUININE	300MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2011
2623	NDA/MAL/HDP/4 468	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TOPRAZ 40	PANTOPRAZOLE SODIUM SESQUIHYDRATE	40MG	AUROBINDO UNIT XV PLOT NO. 17 A, E. BONANGI (VILLAGE), JAWAHARLAL NEHRU PHARMA CITY, PARAWADA MANDAL, VISAKHAPATNAM DIST, ANDHRA PRADESH -531021 INDIA AUROBINDOPHARM A LIMITED, UNIT VII, SEZ APIIC, PLOT NO.SI SURVEY NO. 425	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016



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2624	NDA/MAL/HDP/4 480	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	KIPEL 5	MONTELUKAST	5MG	MSN LABORATORIES PVT. LIMITED PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
2625	NDA/MAL/HDP/4 483	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	WORMOL SUSPENSION	MEBENDAZOLE	100MG/5ML	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE, 1.0X100.0 L BOTTLE	01/07/1997

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2626	NDA/MAL/HDP/4 519	ARISTO PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	S-AMLOSAFE 5	AMLODIPINE BESILATE	5MG	ARISTO PHARMACEUTICALS PVT LTD PLOT NO 208 NEW INDUSTRIAL AREA NO 11 MANDIDEEP	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X3.0X1. 0X3.0X10.0 TABLET BLISTER	01/07/2007
2627	NDA/MAL/HDP/4 522	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	S-AMLOSAFE 2.5	AMLODIPINE BESILATE	2.5 MG	ARISTO PHARMACEUTICALS PVT LTD PLOT NO 208 NEW INDUSTRIAL AREA NO 11 MANDIDEEP	INDIA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X3.0X1. 0X3.0X10.0 TABLET BLISTER	01/07/2007

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2628	NDA/MAL/HDP/4 523	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	BIGOMET SR 500	METFORMIN HYDROCHLORIDE	500MG	ARISTO PHARMACEUTICALS PVT. LIMITED PLOT NO. 208, NEW INDUSTRIAL AREA NO.II, MANDIDEEEP PRADESH	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008
2629	NDA/MAL/HDP/4 526	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AZ-500	AZITHROMYCIN	500MG	AGOG PHARMA LTD PLOT NO.33, SECTOR II, VASAI, TALUKA INDL CO-OP ESTATE LTD, GAURAI PADA, VASAI(E) DIST. T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER, 1.0X20.0X3 .0 TABLET BLISTER	01/07/2011

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2630	NDA/MAL/HDP/4 528	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	PIOSAFE MF 15/500	PIOGLITAZONE + METFORMIN	15 MG + 500 MG	ARISTO PHARMACEUTICALS PVT LIMITED PLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP- 462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008
2631	NDA/MAL/HDP/4 536	SEDICO PHARMACEUTICAL CO.	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FLUCAMOX	FLUCLOXACILLIN + AMOXICILLIN	250MG+250MG	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X4.0 CAPSULE STRIP	01/07/2004

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2632	NDA/MAL/HDP/4 546	KARNATAKA ANTIBIOTICS & PHARMACEUTICAL S LTD	TATA UGANDA LIMITED	CHLORAMPHENIC OL INJECTION IG	CHLORAMPHENIC OL SODIUM SUCCINATE	1G	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD #14, II PHASE PIA, BANGALORE 560058	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X100.0X1.0 G VIAL,1.0X50.0X1.0 G VIAL	01/07/1998
2633	NDA/MAL/HDP/4 553	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	ARTESUN	ARTESUNATE	30MG	GUILIN PHARMACEUTICAL CO. LTD.NO. 43 QILIDIAN ROAD, GUILIN 541004	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X30.0 MG VIAL + 1*0.5 ML SODIUM BICARBONATE	01/07/2011

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2634	NDA/MAL/HDP/4 556	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM 375	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	250MG + 125MG	INDCHEMIE HEALTH SPECIALTIES PVT. LTD-(UNIT 3 BETA LACTAM BLOCK) VILLAGE: THANA, TEHSIL: BADDI, DISTRICT: SOLAN HIMACHAL PRADESH -173205 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET STRIP	01/07/2005
2635	NDA/MAL/HDP/4 559	MSN LABORATORIES PRIVATE LIMITED,	METRO PHARMACEUTICAL S LIMITED	PREGASAFE 75	PREGABALIN	75MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2014

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2636	NDA/MAL/HDP/4 561	TORRENT PHARMACEUTICAL S LTD	KARURI PHARMACEUTICAL S LTD.	LORVAS SR	INDAPAMIDE	1.5MG	TORRENT PHARMACEUTICALS LTD. AHMEDABAD- MEHSANA HIGHWAY, TAL. KADI, DIST. MEHSANA, INDRAD 382 721, GUJARAT TORRENT PHARMACEUTICALS LTD VILLAGE: BHUD & MAKHNU MAJRA, TEHSIL: BADDI – 173205, DIST: SOLAN, HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2009
2637	NDA/MAL/HDP/4 568	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM 625	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	500MG + 125MG	INDCHEMIE HEALTH SPECIALTIES PVT. LTD-(UNIT 3 BETA LACTAM BLOCK) VILLAGE: THANA, TEHSIL: BADDI, DISTRICT: SOLAN HIMACHAL PRADESH -173205 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET STRIP	01/07/2005

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2638	NDA/MAL/HDP/4 571	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ASPICLOX	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	ASTRA LIFE CARE (INDIA) PVT.LTD PLOT NO. 57/P, SARKHEJ- BAVLA HIGHWAY, POST RAJODA- 382220, TALUKA BAVLA, AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE STRIP,1.0X1000.0 CAPSULE CONTAINER	01/07/1997
2639	NDA/MAL/HDP/4 575	FDC LTD	AIVEEN (U) LIMITED	PYRICORT EYE/EAR DROPS	DEXAMETHASON E+GENTAMICIN	0.1%+0.3%W/V	FDC LIMITED B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.☒	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2013



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2640	NDA/MAL/HDP/4 581	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM 1000	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	875MG + 125MG	INDCHEMIE HEALTH SPECIALTIES PVT. LTD-(UNIT 3 BETA LACTAM BLOCK) VILLAGE: THANA, TEHSIL: BADDI, DISTRICT: SOLAN HIMACHAL PRADESH -173205 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET STRIP	01/07/2005
2641	NDA/MAL/HDP/4 587	CIRON DRUGS AND PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	CIRATRO	ATROPINE	1MG/ML	CIRON DRUGS AND PHARMACEUTICALS PVT LTDN-118 M.I.D.C, TAAPUR,BOISAR,DIS T.THANE MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X1.0 ML AMPOULE	01/07/2008

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2642	NDA/MAL/HDP/4 588	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	FLUCAN 200	FLUCONAZOLE	200MG	LINCOLN PHARMACEUTICAL LIMITED TRIMAL ESTATE KHATRAJ KOLOL, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0 TABLET BLISTER	01/07/2011
2643	NDA/MAL/HDP/4 589	FEROZSONS LABORATORIES LTD	HEALTHCARE LTD.	LEFOXCIN-500	LEVOFLOXACIN HEMIHYDRATE	500MG	FEROZSONS LABORATORIES LTD MANGARH- NOWSHERA, (KHYBER PAKHTOONKHWA), PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2013

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2644	NDA/MAL/HDP/4 591	S KAGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	SILVER KANT	SILVER SULPHADIAZINE USP	1%W/W	S.KANT HEALTHCARE LTD1802-18-5 GIDC PHASE III, VAPI- 396195,GUJARAT INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2009
2645	NDA/MAL/HDP/4 592	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	PENTALINK 40	PANTOPRAZOLE	40MG	LINCOLN PHARMACEUTICAL LIMITEDTRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP,1.0X3.0X10.0 TABLET BLISTER	01/07/2008

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2646	NDA/MAL/HDP/4 593	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	ERYTHROKANT- 250	ERYTHROMYCIN STEARATE	250MG	S KANT HEALTHCARE LIMITED1802 – 1805, G.I.D.C., PHASE III, VAPI -396195 GUJARAT, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2011
2647	NDA/MAL/HDP/4 595	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	VAST-20	ATORVASTATIN	20MG	LINCOLN PHARMACEUTICAL LIMITEDTRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2010

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2648	NDA/MAL/HDP/4 598	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AZ-250	AZITHROMYCIN	250MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER	01/07/2011
2649	NDA/MAL/HDP/4 602	ELI-LILLY (SUISSE) SA	LABOREX UGANDA LIMITED	HUMALOG MIX 50	INSULIN LISPRO	100 .IU(50 I.U+50 I.U)	LILLY FRANCE SAFRANCE	FRANCE	PARENTERAL ORDINARY S C VIALS	1.0X3.0 ML VIAL,1.0X5.0 ML VIAL	01/07/2000

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2650	NDA/MAL/HDP/4 603	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	HALOXEN - 5	HALOPERIDOL	5MG	REMEDICA LIMITED LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
2651	NDA/MAL/HDP/4 605	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGODRYL SYRUP	BROMHEXINE HCL+DEXTROMET HORPHAN HBR+AMMONIU M CHLORIDE+MENT HOL	4MG/5ML+5MG/5 ML+50MG/5ML+2. 5MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60 .0 ML BOTTLE	01/07/2009

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

2652	NDA/MAL/HDP/4 606	INTAS PHARMACEUTICAL S LIMITED	NORVIK ENTERPRISES LIMITED	ROVAS 10	ROSUVASTATIN	10MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
2653	NDA/MAL/HDP/4 609	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYCORT	HYDROCORTISON E	1%W/W	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997

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2654	NDA/MAL/HDP/4 611	DAFRA PHARMA LTD	MULTIPHAR UGANDA LIMITED	DAFRACLAV	AMOXYCILLIN + POTASSIUM CLAVULANATE	200MG + 28MG	BILIM ILAC SAN. VE. TIC. A.S.CERKEZKOY ORGANIZE SANAYI BOLGESI, KARAAGAC, MH. 5. SK. NO. 6, KAPAKLI - TEKIRDAG 59510	TURKEY	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X70.0 ML BOTTLE	01/07/2011
2655	NDA/MAL/HDP/4 614	GALENTIC PHARMA LTD	VITACARE LIMITED	COMPOUND BENZOIC ACID OINTMENT	BENZOIC ACID + SALICYLIC ACID	6 %W/W + 3 %W/W	GALENTIC PHARMA( INDIA ) PVT LTDR- 673,MIDC TTC RABALE THANE- BELAPUR ROAD,NAVI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X25.0 G TUBE,1.0X500.0 G TUBE	01/07/2006



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2656	NDA/MAL/HDP/4 617	ASTRA ZENECA	MACNAUGHTON LIMITED	CRESTOR	ROSUVASTATIN	10MG	IPR PHARMACEUTICALS INC, LOT 17 INDUSTRIAL PARK PUERTO RICO, SAN ISIDRO, PUERTO RICO	PUERTO RICO	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2010
2657	NDA/MAL/HDP/4 619	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CHLORAMPHENIC OL SODIUM SUCCINATE	CHLORAMPHENIC OL SODIUM SUCCINATE	1G	SCOTT-EDIL PHARMACIA LTD (UNIT I)56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0X1.0 G VIAL	01/07/2009

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2658	NDA/MAL/HDP/4 620	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	MALANIL PAEDIATRIC TABLET	ATOVAQUONE + PROGUANIL	62.5 MG + 25.0 MG	GLAXO WELLCOME S.A ARANDAARANDA AVDA EXTREMADURA 3, 09400 ARANDA DE DUERO BURGOS	SPAIN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X12.0 TABLET BLISTER	01/07/2007
2659	NDA/MAL/HDP/4 622	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	CLOXAREN	CLOXACILLIN	250MG	RENE INDUSTRIESPLOT 680 KAMULI KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER	01/07/2007

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2660	NDA/MAL/HDP/4 623	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	LOPERAREN	LOPERAMIDE HYDROCHLORIDE	2MG	RENE INDUSTRIAL LTDRENE INDUSTRIES LTD, PLOT 680, KAMULI- KIREKA KAMPALA UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2007
2661	NDA/MAL/HDP/4 627	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	HYCORUM CREAM	HYDROCORTISON E	1%W/W	LABORATORY AND ALLIED LTD PLOT 209/10349- MOMBASA ROAD NAIROBI	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997

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2662	NDA/MAL/HDP/4 629	DAWA LIMITED	SUPER MEDIC LTD	ORACEF	CEFALEXIN MONOHYDRATE	125MG/5ML	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1X100 ML BOTTLE	01/07/2015
2663	NDA/MAL/HDP/4 634	DENK PHARMA GMB H &CO. KG	BENLE CONSULT LIMITED	LOSAR-DENK 100	LOSARTAN	100MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2011

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2664	NDA/MAL/HDP/4 641	YURIA PHARM LTD- UKRAINE	PHARMA VILLE LIMITED	RHEOSORBILACT	SORBITOL + SODIUM LACTATE + NACL + CALCIUM CHLORIDE + MAGNESIUM CHLORIDE	6G +1.9G +0.6G + 0.01G +0.03G +0.02	YURIA-PHARM LLC MANUFACTURING SITE NO. 1108, KOBZARSKA STREET, CHERKASY, 18030	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X200.0 ML BOTTLE,1.0X400.0 ML BOTTLE	01/07/2013
2665	NDA/MAL/HDP/4 645	ASTRA ZENECA	MACNAUGHTON LIMITED	CRESTOR	ROSUVASTATIN CALCIUM	20MG	IPR PHARMACEUTICALS INC,LOT 17 INDUSTRIAL PARK PUERTO RICO, SAN ISIDRO, PUERTO RICO	PUERTO RICO	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2010

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2666	NDA/MAL/HDP/4 646	YURIA PHARM LTD- UKRAINE	PHARMA VILLE LIMITED	LEFLOCIN	LEVOFLOXACIN	5MG/ML	YURIA-PHARM LLC MANUFACTURING SITE NO. 1108, KOBZARSKA STREET, CHERKASY, 18030	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X150.0 ML BOTTLE,1.0X1.0X10 0.0 ML BOTTLE	01/07/2013
2667	NDA/MAL/HDP/4 650	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	DUOTRAV	TRAVOPROST + TIMOLOL MALEATE	40MG/ML + 5MG/ML	ALCON COUVREUR NVRIJKSWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X1.0X2.5 ML VIAL	01/07/2010

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2668	NDA/MAL/HDP/4 657	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	VOLAR 300MG	GABAPENTIN	300MG	DAR AL DAWADAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2013
2669	NDA/MAL/HDP/4 658	PT SANBE FARMA	MEDVIN PHARMA LIMITED	MEROSAN 0.5	MEROPENEM	0.5G	PT SANBE FARMAJI LEUWIGAJAH I62 CIMINDI CIMAHI WEST JAVA INDONESIA	INDONESIA	PARENTERAL ORDINARY DRY VIALS	1.0X0.5 G VIAL	01/07/2014

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2670	NDA/MAL/HDP/4 661	YURIA PHARM LTD- UKRAINE	PHARMA VILLE LIMITED	FLUCONAZOLE-UF	FLUCONAZOLE	2MG/ML	YURIA-PHARM LLC MANUFACTURING SITE NO. 1108, KOBZARSKA STREET, CHERKASY, 18030	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X50.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2013
2671	NDA/MAL/HDP/4 666	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	ANTIPLEX	CLOPIDOGREL BISULFATE	30MG	DAR AL DAWANA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013



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2672	NDA/MAL/HDP/4 669	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	DICLOGESIC 100MG SUPPOSITORIES	DICLOFENAC SODIUM.	100MG	DAR AL DAWADAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	TOPICAL EXTERNAL ADULT SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP	01/07/2013
2673	NDA/MAL/HDP/4 670	MEDOPHARM PRIVATE LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	MEDOMOX 500	AMOXICILLIN	500MG	MEDOPHARM PVT LTD.NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2014

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2674	NDA/MAL/HDP/4 675	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	DICLOGESIC RETARD 100	DICLOFENAC SODIUM	100MG	DAR AL DAWADAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X6.0 CAPSULE BLISTER	01/07/2013
2675	NDA/MAL/HDP/4 678	: ALKEM LABORATORIES LIMITEDV	ABACUS PHARMA (AFRICA) LIMITED	ZOCEF-500	CEFUROXIME AXETIL	500MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2009

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2676	NDA/MAL/HDP/4 680	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANCEPH DS	CEPHALEXIN	125MG/5ML	SANCE LABORATORIES PVT. LTD.VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT- 686573, KERALA, INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2011
2677	NDA/MAL/HDP/4 690	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYPEN	PHENOXYMETHYL PENICILLIN	250MG	ELYS CHEMICAL INDUSTRIES LTDROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997

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2678	NDA/MAL/HDP/4 694	MERCK SHARP & DOHME INTAPHARMA	SURGIPHARM (U) LIMITED	ROTATEQ	ROTAVIRUS LIVE REASSORTANT VIRUS G1+G2+G3+G4 &P1	2.2M IU+2.8M IU+2.2M IU+2.0M IU	MERK & CO. INCSUMNEYTOWN PIKE, P.O BOX 4, WEST POINT, PENNSYLVANIA, U.S. 19486, USA	UNITED STATES	ORAL LIQUID ORDINARY EMULSIONS	1.0X10.0 ML BOTTLE	01/07/2011
2679	NDA/MAL/HDP/4 697	PT SAMBE FARMA	MEDVIN PHARMA LIMITED	SANBE CLANEKSI	AMOXICILLIN + CLAVULANIC ACID	1000 MG + 200 MG	PT SANBE FARMAJI LEUIGAJAH NO. 162 CIMINDI, INDONESIA	INDONESIA	PARENTERAL ORDINARY VIALS	1.0X6.0 VIAL CARTON	01/07/2011

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2680	NDA/MAL/HDP/4 700	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	MEDIZOLE	METRONIDAZOLE	125MG/5ML	MEDIPHARM INDUSTRIES (E.A) LTD PLOT 65, KAKAJJO ROAD, BWEYOGERERE	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2006
2681	NDA/MAL/HDP/4 701	AFRICURE PHARMACEUTICAL S (INDIA) PRIVATE LIMITED	ROYAL PHARMA 2011 LIMITED	MEBRONE 100 TABLETS	MEBENDAZOLE	100MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED PLOT 9- 12, DEWAN & SONS INDL. AREA, VEOOR, PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X6.0 TABLET BLISTER, 1.0X1000.0 TABLET CONTAINER	01/07/1997

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2682	NDA/MAL/HDP/4 702	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABTOL 20%W/V	MANNITOL	200MG/ML	ABACUS PARENTERAL DRUGS LTD.PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2011
2683	NDA/MAL/HDP/4 703	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABGYL	METRONIDAZOLE	500MG	ABACUS PARENTERAL DRUGS LTD.PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	01/07/2011

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2684	NDA/MAL/HDP/4 704	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	DICLOGESIC 12.5	DICLOFENAC SODIUM	12.5MG	DAR AL DAWADAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY BLISTER	01/07/2012
2685	NDA/MAL/HDP/4 705	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	DICLOGESIC-50	DICLOFENAC	50MG	DAR AL DAWADAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY BLISTER	01/07/2012

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2686	NDA/MAL/HDP/4 706	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	DICLOMOL GEL	DICLOFENAC DIETHYLAMINE	1.16%W/W	G,S PHARMBUTOR PVT LTD B-172 INDUSTRIAL AREA BEHROR 301701 RAJASTHAN	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G CONTAINER	01/07/2015
2687	NDA/MAL/HDP/4 707	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	DICLOMOL INJECTION	DICLOFENAC SODIUM	25MG/ML	WIN MEDICARE PVT LIMITEDMEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X3.0 ML AMPOULE	01/07/1998



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2688	NDA/MAL/HDP/4 710	COSMOS LTD	ASTRA PHARMA (U) LIMITED	MEDOPRESS TABLETS 250MG	METHYLDOPA	250MG	COSMOS LIMITED..RANGWE ROAD, OFF LUNGA LUNGA ROAD, INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1998
2689	NDA/MAL/HDP/4 712	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	MEFINAL-500	MEFENAMIC ACID	500MG	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009

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2690	NDA/MAL/HDP/4 715	BLUE CROSS LABARATORIES LIMITED	STAR PHARMACEUTICAL S LTD	MEFTAL FORTE	MEFENAMIC ACID + PARACETAMOL	500MG + 450MG	BLUE CROSS LABORATORIES LTDL- 17, VERNA INDUSTRIAL ESTATE,VERNA GOA- 403722	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X2.0X10.0 TABLET BLISTER	01/07/2008
2691	NDA/MAL/HDP/4 717	BLUE CROSS LABARATORIES LIMITED	STAR PHARMACEUTICAL S LTD	MEFTAL-SPAS	MEFENAMIC ACID + DICYCLOMINE HYDROCHLORIDE	250MG + 10MG	BLUE CROSS LABORATORIES LTDL- 17, VERNA INDUSTRIAL ESTATE,VERNA GOA- 403722	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X20.0 TABLET BLISTER,1.0X2.0X3. 0X10.0 TABLET BLISTER,1.0X10.0X3 .0X10.0 TABLET BLISTER	01/07/2008

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2692	NDA/MAL/HDP/4 718	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	ACNOTIN 20	ISOTRETINOIN	20MG	MEGA LIFE SCIENCES PUBLIC COMPANY LIMITED384 SOIB PATTANA 3 RD BANGPOO INDUSTRIAL ESTATE SAMUTPRAKARN 10280	THAILAND	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2011
2693	NDA/MAL/HDP/4 719	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	ACNOTIN 10	ISOTRETINOIN	10MG	MEGA LIFE SCIENCES PUBLIC COMPANY LIMITED384 SOIB PATTANA 3 RD BANGPOO INDUSTRIAL ESTATE SAMUTPRAKARN 10280	THAILAND	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2011

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2694	NDA/MAL/HDP/4 721	PT SAMBE FARMA	MEDVIN PHARMA LIMITED	MEGABAL	MECOBALAMIN	5000MCG	PT SANBE FARMA,UNIT 1JI INDUSTRI NO.9 LEUWIGAJAH CIMINDI CIMAH WEST JAVA,INDONESIA	INDONESIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	01/07/2011
2695	NDA/MAL/HDP/4 723	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	MEGYL SUSPENSION	METRONIDAZOLE BENZOATE	200MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/1997

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2696	NDA/MAL/HDP/4 725	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	MEGYL TABLET	METRONIDAZOLE	200MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X250.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	01/07/1997
2697	NDA/MAL/HDP/4 726	MACK BROWN PHARMACEUTICAL S PVT LIMITED	SHURIK LTD	ADB MIN MULTIPOWER	MULTI- INGREDIENT	MULTI- INGREDIENT	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X300.0 ML BOTTLE	01/07/1997

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2698	NDA/MAL/HDP/4 738	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	CILOXAN	CIPROFLOXACIN	0.3%W/V	ALCON COUVREUR NVRIJKSWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/1997
2699	NDA/MAL/HDP/4 739	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	MERO	MEROPENEM	1G	SWISS PARENTERALS LIMITED (UNIT-2) PLOT NO. 402, 412- 414 KERALA INDUSTRIAL ESTATE, GIDC, NEAR BAVLA, AHMEDABAD,38222 0, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2011

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2700	NDA/MAL/HDP/4 744	DAFRA PHARMA N.V/S.A	MULTIPHAR UGANDA LIMITED	MERONIA 500	MEROPENEM	500MG	DEMO SA21ST KM NATIONAL ROAD, ATHENS, LAMIA 14568 KRYONERI, ATHENS	GREECE	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL	01/07/2013
2701	NDA/MAL/HDP/4 748	MEDICAL UNION PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	ACICONE-S CHEWABLE TABLET	MAGALDRATE+SI METHICONE	720MG+25MG	MEDICAL UNION PHARMA .COABU- SULTAN ISMAILIA EGYPT	EGYPT	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X5.0X4.0 TABLET BLISTER	01/07/2006

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2702	NDA/MAL/HDP/4 749	PT SANBE FARMA	MEDVIN PHARMA LIMITED	MEROSAN	MEROPENEM	1G	PT SANBE FARMAJI LEUWIGAJAH 162 CIMINDI CIMAH WEST JAVA INDONESIA	INDONESIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2012
2703	NDA/MAL/HDP/4 751	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	FEROL	FERROUS SULPHATE	200MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER,1.0X100.0X 10.0 TABLET BLISTER	01/07/2009



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2704	NDA/MAL/HDP/4 757	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	METFORMIN- DENK 500	METFORMIN	500MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/1998
2705	NDA/MAL/HDP/4 758	DENK PHARMA GMB H & CO. KG	BENLE CONSULT LIMITED	METFORMIN DENK 1000	METFORMIN	1000MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER	01/07/2011

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2706	NDA/MAL/HDP/4 759	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	CIPRODAR	CIPROFLOXACIN	500MG	DAR AL DAWADAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2009
2707	NDA/MAL/HDP/4 766	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOBEN SUSPENSION	MEBENDAZOLE	100MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2001

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2708	NDA/MAL/HDP/4 769	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOBEX	MEBENDAZOLE	100MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER,1.0X100.0X 10.0 TABLET BLISTER	01/07/2009
2709	NDA/MAL/HDP/4 774	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FERROFOL VIT-Z	FERROUS SULPHATE+FOLIC ACID+ASCORBIC ACID+THIAMINE MONONITRATE+R IBOTLAVINE+PYRI DOXINE HCL+NICOTINAMI DE+ZINC	150MG+0.5MG+50 MG+2MG+2MG+1 MG+10MG+25MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X6.0 CAPSULE BLISTER	01/07/2014

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2710	NDA/MAL/HDP/4 775	SKAGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	CIPROKANT-500	CIPROFLOXACIN	500MG	S KANT HEALTH CARE LTD PLOT 1802 - 1805	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010
2711	NDA/MAL/HDP/4 781	CYANO PHARMA(P)	RENE PHARMACY LTD	CYANO IRON TABLETS	FERROUS SULPHATE	200MG	CYANO PHARMA(P)115-C IND ESTATE POLO GROUND INDORE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10. 0X10.0 TABLET BLISTER	01/07/2001

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2712	NDA/MAL/HDP/4 784	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	D50	GLUCOSE INTRAVENOUS INFUSION	50%W/V	ABACUS PARENTERAL DRUGS LIMITEDBLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2011
2713	NDA/MAL/HDP/4 788	JASSEN-CILAG (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	DAKTARIN ORAL GEL	MICONAZOLE NITRATE	20MG/G	SPECPHARM HOLDINGS 15TH ROAD HALFWAY HOUSE	SOUTH AFRICA	ORAL TOPICAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/1997

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2714	NDA/MAL/HDP/4 789	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	DALACIN C	CLINDAMYCIN HYDROCHLORIDE	300MG	FAREVA AMBOISE - ZONE INDUSTRIELLE, 29 ROUTE DES INDUSTRIES, 37530 POCE SUR CISSE, FRANCE	FRANCE	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CARTON,1.0X2.0X8. 0 CAPSULE STRIP	01/07/1997
2715	NDA/MAL/HDP/4 790	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	DALACIN C	CLINDAMYCIN HYDROCHLORIDE	150MG	FAREVA AMBOISE - ZONE INDUSTRIELLE, 29 ROUTE DES INDUSTRIES, 37530 POCE SUR CISSE, FRANCE	FRANCE	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X8.0 CAPSULE STRIP,1.0X100.0 CAPSULE CARTON	01/07/1997

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2716	NDA/MAL/HDP/4 792	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	DALACIN C	CLINDAMYCIN PHOSPHATE	150MG/ML	PFIZER GLOBAL MANUFACTURING BELGIUM NVRIJKSWEG 12, 2870 PUURS - BELGIUM	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X4.0 ML VIAL,1.0X2.0 ML VIAL	01/07/1997
2717	NDA/MAL/HDP/4 794	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	DALADOL	DICLOFENAC SODIUM + PARACETAMOL	50MG+500MG	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2012

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2718	NDA/MAL/HDP/4795	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	DAROXIME	CEFUROXIME	500MG	DAR AL DAWADAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL-HUSSEIN STREET. AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BOTTLE	01/07/2010
2719	NDA/MAL/HDP/4796	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	DARROWS SOLUTION (HALF STRENGTH)	POTASSIUM CHLORIDE+SODIUM CHLORIDE+SODIUM LACTATE	0.13%+0.20%+0.30%	ABACUS PARENTERAL DRUGS LTD PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2011



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2720	NDA/MAL/HDP/4 800	DAWA LIMITED	SUPER MEDIC LTD	DAWAVITE SYRUP	MULTI- INGREDIENT	MULTI- INGREDIENT	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2009
2721	NDA/MAL/HDP/4 801	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	DAZEL KIT	FLUCONAZOLE + AZITHROMYCIN + SECNIDAZOLE	150MG + 1G + 1G	AJANTA PHARMA LIMITED PAITHANMANUFACT URING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2009

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2722	NDA/MAL/HDP/4 804	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	CLAVODAR	AMOXICILLIN + CLAVULANIC	200MG + 28MG /5ML	DAR AL DAWANA'UR PLANT AMMAN	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X70.0 ML BOTTLE	01/07/2012
2723	NDA/MAL/HDP/4 806	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOFER	FERROUS SULPHATE+FOLIC ACID	200MG + 0.25MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10 0.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2009

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2724	NDA/MAL/HDP/4 807	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOFORMIN	METFORMIN	500MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2011
2725	NDA/MAL/HDP/4 809	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOCORT SKIN CREAM	HYDROCORTISON E	0.1%W/W	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2013

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2726	NDA/MAL/HDP/4 811	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOGYL	METRONIDAZOLE	200MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER,1.0X100.0X 10.0 TABLET BLISTER	01/07/2009
2727	NDA/MAL/HDP/4 812	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOMETROL SUSPENSION	METRONIDAZOLE BENZOATE	125MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2001

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2728	NDA/MAL/HDP/4 813	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOMETROL TABLETS (THANE)	METRONIDAZOLE	200MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X10 0.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER,10.0X1 0.0 TABLET BLISTER	01/07/1998
2729	NDA/MAL/HDP/4 815	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	FERROLIC-LF	FERROUS SULPHATE +FOLIC ACID	200MG+0.4MG	LABORATORY & ALLIED LTD PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2014

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2730	NDA/MAL/HDP/4 817	CYANO PHARMA(P)	RENE PHARMACY LTD	METOCLOPRAMID E TABLETS	METOCLOPRAMI DE	10MG	CYANO PHARMA(P)115-C IND ESTATE POLO GROUND INDORE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2001
2731	NDA/MAL/HDP/4 818	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	FERROUS SULPHATE	FERROUS SULPHATE	200MG	LABORATORY & ALLIED LTD PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1997

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2732	NDA/MAL/HDP/4 819	FDC LIMITED	AIVEEN (U) LIMITED	ELECTRAL 21.8G	ORAL REHYDRATION SALT	21.8G	FDC LIMITED B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.☐	INDIA	ORAL LIQUID ORDINARY UNIT DOSE POWDERS	1.0X21.8 G SACHET	01/07/2000
2733	NDA/MAL/HDP/4 821	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	METPURE-XL 50	METOPROLOL	50MG	EMCURE PHARMACEUTICALS LIMITED LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI- BRAHMANA JAMMU ,181133	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2009

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2734	NDA/MAL/HDP/4 823	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	METRIS INFUSION	METRONIDAZOLE	5MG/ML	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTDVILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/1997
2735	NDA/MAL/HDP/4 826	UNIQUE PHARMACEUTICAL S LTD	PLANET PHARMACEUTICAL S UGANDA LTD	METROGYL DENTA GEL	METRONIDAZOLE + CHLORHEXIDINE	1%W/W + 0.25%W/W	UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)-216-219 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X20.0 G TUBE	01/07/2004



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2736	NDA/MAL/HDP/4 828	UNIQUE PHARMACEUTICAL S LABORATORIES	PLANET PHARMACEUTICAL S UGANDA LTD	METROGYL GEL	METRONIDAZOLE	1%W/W	UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)-304-308 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH	INDIA	TOPICAL EXTERNAL EMULSION GELS	1.0X30.0 G TUBE (ALUMINIUM TUBE),1.0X30.0 G TUBE (LAMINATED TUBE)	01/07/2001
2737	NDA/MAL/HDP/4 830	UNIQUE PHARMACEUTICAL S LABORATORIES	PLANET PHARMACEUTICAL S UGANDA LTD	METROGYL INJECTION	METRONIDAZOLE	5MG/ML	UNIQUE PHARMACEUTICAL LABORATORIES, (A DIVISION OF J.B CHEMICALS & PHARMACEUTICALS LTD PLOT NO 4, PHASE IV, GIDC INDUSTRIAL AREA, PANOLI 394 116 UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/1997

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2738	NDA/MAL/HDP/4 832	UNIQUE PHARMACEUTICAL S LABORATORIES	PLANET PHARMACEUTICAL S UGANDA LTD	METROGYL SUSPENSION	METRONIDAZOLE	200MG/5ML	UNIQUE PHARMACEUTICAL LABORATORIES PLOT NO. 215-219, G.I.D.C. INDUSTRIAL AREA, PANOLI — 394 116, GUJARAT, INDIA. J.B. CHEMICALS AND PHARMACEUTICALS LTD .128/1, GIDC, ANKLESHWAR 393 002, GUJARAT	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/1997
2739	NDA/MAL/HDP/4 834	AUROBINDO PHARMA LTD UNIT VII	GITTOES PHARMACEUTICAL S LIMITED	FINAGEN	FINASTERIDE	5MG	AUROBINDO PHARMA LIMITED, UNIT III SURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELENGANA (STATE)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2004

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2740	NDA/MAL/HDP/4 836	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	METRON	METRONIDAZOLE	200MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X 10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2009
2741	NDA/MAL/HDP/4 838	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	METRONIDAZOLE	METRONIDAZOLE BENZOATE	125MG/5ML	MEDICAMEN BIOTECH LTDSP- 1192, A &B, PHASE -IV, INDUSTRIAL AREA BHIWADI -301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2014

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2742	NDA/MAL/HDP/4 839	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	ANOMEX	ZINC OXIDE+LIDOCAIN E+HYDROCORTIS ONE+ALLANTOIN	5%W/W+3%W/W+ 0.25%W/W+0.5% W/W	BLISS GVS PHARMA LTD PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA- INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY BLISTER,1.0X2.0X5. 0 SUPPOSITORY BLISTER	01/07/2007
2743	NDA/MAL/HDP/4 841	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROMETRO FC	METRONIDAZOLE	200MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9- 12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007

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2744	NDA/MAL/HDP/4 854	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	METROREN FC	METRONIDAZOLE	200MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2014
2745	NDA/MAL/HDP/4 855	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICAL S LTD	ASCORIL EXPECTORANT	SALBUTAMOL SULPHATE + BROMHEXINE HYDROCHLORIDE + GUAIFENESIN + MENTHOL	(2MG + 4MG + 100MG + 1MG)/10ML	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE, 1.0X100.0 ML BOTTLE	01/07/2000

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2746	NDA/MAL/HDP/4 856	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	METROREN	METRONIDAZOLE	200MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X20.0X1 0.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2001
2747	NDA/MAL/HDP/4 858	RENE INDUSTRIES	RENE INDUSTRIES LIMITED	METROREN SUSPENSION	METRONIDAZOLE BENZOATE	200MG/5ML	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2001

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2748	NDA/MAL/HDP/4 863	MEDICAL UNION PHARMACUITICALS	KARURI PHARMACEUTICAL S LTD.	MICONAZ ORAL GEL	MICONAZOLE	2%W/W	MEDICAL UNION PHARMA .COABU- SULTAN ISMAILIA EGYPT	EGYPT	ORAL TOPICAL GELS AND SOLS	1.0X20.0 G TUBE	01/07/2003
2749	NDA/MAL/HDP/4 865	MEDICAL UNION PHARMACUITICALS	KARURI PHARMACEUTICAL S LTD.	MICONAZ CREAM	MICONAZOLE NITRATE	2%W/W	MEDICAL UNION PHARMA .COABU- SULTAN ISMAILIA EGYPT	EGYPT	VAGINAL CREAMS	1.0X20.0 G TUBE	01/07/2003

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2750	NDA/MAL/HDP/4 867	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	MICONA ORAL GEL	MICONAZOLE	20MG	CENTAUR PHARMACEUTICALS PVT LTD -PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X40.0 G TUBE,1.0X20.0 G TUBE	01/07/2003
2751	NDA/MAL/HDP/4 868	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	FLUCANIR	FLUCONAZOLE	2MG/ML	ACULIFE HEALTHCARE PVT LTDVILLAGE SACHANA, TALUKA, VIRAMGAM, DIST. AHMEDABAD 382150, GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2011



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2752	NDA/MAL/HDP/4 872	DAWA LIMITED	SUPER MEDIC LTD	MICLOCIN CREAM	MICONAZOLE NITRATE + CLOBETASOL PROPRIONATE + GENTAMICN	2%W/W+0.5%W/ W+0.1W/W	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2013
2753	NDA/MAL/HDP/4 873	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	FLUCAS	FLUCONAZOLE	200MG	ASTRA LIFE CARE (INDIA) PVT.LTD PLOT NO. 57/P, SARKHEJ- BAVLA HIGHWAY, POST RAJODA- 382220, TALUKA BAVLA, AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0 CAPSULE BLISTER	01/07/2011

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2754	NDA/MAL/HDP/4 874	SANOFI-AVENTIS	LABOREX UGANDA LIMITED	CLEXANE	ENOXAPARIN SODIUM	100MG/ML	SANOFI WINTHROP INDUSTRIE180 RUE JEAN JAURE'S BP 94702, MAISONS- ALFORT CEDEX	FRANCE	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X2.0X0.6 ML PRE FILLED SYRINGE	01/07/2009
2755	NDA/MAL/HDP/4 875	MARIE STOPE UGANDA LIMITED	MARIE STOPE UGANDA LIMITED	MISOCLEAR	MISOPROSTOL	200MCG	ACME FORMULATION PVT LTD,ACME FORMULATION PVT LTD ROPAR ROAD NALAGARH DIST SOLAN HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2011

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2756	NDA/MAL/HDP/4 876	SANOFI-AVENTIS	LABOREX UGANDA LIMITED	CLEXANE	ENOXAPARIN SODIUM	100MG/ML	SANOFI WINTHROP INDUSTRIE180 RUE JEAN JAURE'S BP 94702, MAISONS- ALFORT CEDEX	FRANCE	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X2.0X0.8 ML PRE FILLED SYRINGE	01/07/2009
2757	NDA/MAL/HDP/4 877	SANOFI-AVENTIS	LABOREX UGANDA LIMITED	CLEXANE	ENOXAPARIN SODIUM	100MG/ML	SANOFI WINTHROP INDUSTRIE180 RUE JEAN JAURE'S BP 94702, MAISONS- ALFORT CEDEX	FRANCE	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X2.0X0.4 ML PRE FILLED SYRINGE	01/07/2009

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2758	NDA/MAL/HDP/4 880	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	MISOPROST 200	MISOPROSTOL	200MCG	CIPLA LTD .CIPLA GOA UNIT 8 L-147 TO L-147/1 L-147-3 TO L-138 VERNA INDUSTRIAL ESTATE VERNA GOA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER,1.0X7.0X4. 0 TABLET BLISTER,1.0X15.0X4 .0 TABLET BLISTER	01/07/2014
2759	NDA/MAL/HDP/4 891	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	ASPEC TABLET	ASPIRIN+PARACE TAMOL+CAFFEINE ANHYDROUS	150MG+250MG+3 00MG	REGAL PHARMACEUTICALS LTDOFF BABA DOGO RD, RUARAKA, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X10 0.0 TABLET CONTAINER	01/07/1997

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2760	NDA/MAL/HDP/4 895	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	CLOMIFERT	CLOMIPHENE	50MG	DAR AL DAWADAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2010
2761	NDA/MAL/HDP/4 903	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	CMT-TABLETS	MAGNESIUM TRISILICATE+DRIE D ALUMINIUM HYDROXIDE+PEPP ERMINT OIL	250MG+120MG+0. 003ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2008

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2762	NDA/MAL/HDP/4 904	NOVO NORDISK	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	MIXTARD 30	INSULIN HUMAN	100 I.U./ML	NOVO NORDISK PRODUCTION SAS45 AVENUE D'ORLEANS, 28000 CHARTRES, FRANCE NOVO NORDISK PHARMANOVO ALLE	DENMARK FRANCE	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL	01/07/1997
2763	NDA/MAL/HDP/4 905	XEPA-SOUL PATTINSON	DELMAW ENTERPRISES LIMITED	AVORAX CREAM	ACYCLOVIR	5%W/W	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE	01/07/1997

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2764	NDA/MAL/HDP/4 906	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	AVORAX TABLETS	ACYCLOVIR	200MG	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X5.0 TABLET STRIP	01/07/1997
2765	NDA/MAL/HDP/4 907	XEPA-SOUL PATTINSON	DELMAW ENTERPRISES LIMITED	AVORAX TABLETS	ACYCLOVIR	400MG	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X5.0 TABLET STRIP	01/07/1997

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2766	NDA/MAL/HDP/4 908	NOVO NORDISK	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MIXTARD 30 PENFILL	BIPHASIC ISOPHANE INSULIN (HUMAN)	100 I.U./ML	NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDAAV. "C", 1413, DISTRITO INDUSTRIAL - 390404 004 MONTES CLAROS, MINAS GERAIS - BRAZIL NOVO NORDISK A/S NOVO ALLE DK-2880 BAGSVAERD	DENMARK BRAZIL	PARENTERAL ORDINARY CARTRIDGES	1.0X1.5 ML FLEXPEN,1.0X5.0X3. 0 ML FLEXPEN	01/07/1997
2767	NDA/MAL/HDP/4 909	AXA PARENTERALS LTD	VITACARE LIMITED	AXAGYL	METRONIDAZOLE	0.5%W/V	AXA PARENTERAL LIMITEDPLOT NO.936,937&939, VILL. KISHANPUR, JAMALPUR,ROORKEE 247667, DISTT. HARIDWAR (UTTARAKHAND) INDIA.	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2015



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2768	NDA/MAL/HDP/4 910	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	FLUZOL	FLUCONAZOLE	200MG	ABACUS PARENTERAL DRUGS LIMITED BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2011
2769	NDA/MAL/HDP/4 911	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	MOFILET-500	MYCOPHENOLAT E MOFETIL	500MG	EMCURE PHARMACEUTICALS LIMITED LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI- BRAHMANA JAMMU ,181133	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2008

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2770	NDA/MAL/HDP/4 915	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	FOGYL-S TABLETS	METRONIDAZOLE	200MG	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED VANDALUR ROAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/1997
2771	NDA/MAL/HDP/4 916	FREDUN PHARMACEUTICAL S LTD	PLANET PHARMACEUTICAL S UGANDA LTD	NEOPROFANE 200 TABLETS	IBUPROFEN	200MG	FREDUN PHARMACEUTICALS LTD14,15,16 ZORBIAN INDUSTRIAL COMPLEX VEOOR PALGHAR EAST INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	10.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	01/07/2001

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2772	NDA/MAL/HDP/4 917	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL EVILINE FORTE SUSPENSION	MAGNESSION HYDROXIDE +ALUMINIUM HYDROXIDE+SIME THICONE	400MG/5ML+400 MG/5ML+40MG/5 ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X120.0 ML BOTTLE	01/07/2010
2773	NDA/MAL/HDP/4 918	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	FOGYL SUSPENSION	METRONIDAZOLE BENZOATE	200MG/5ML	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED VANDALUR ROAD	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/1997

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2774	NDA/MAL/HDP/4 919	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL FUSIDIC ACID- B CREAM	FUSIDIC ACID+BETAMETH ASONE 17 VALERATE	2%,W/W,+0.1% W/W	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2008
2775	NDA/MAL/HDP/4 920	LEBEN LABORATORIES LTD	MALIX PHARMA (U) LIMITED	FOLIBEN	FOLIC ACID	5MG	LEBEN LAB PVT LTDL4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X20.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2011

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2776	NDA/MAL/HDP/4 922	KOPRAN LIMITED	TATA UGANDA LIMITED	CIPROQUIN-500	CIPROFLOXACIN	500MG	KOPRAN LIMITEDVILLAGE- SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	10.0X10.0 TABLET BLISTER	01/07/1999
2777	NDA/MAL/HDP/4 924	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	MULTIVIT TABLET	MULTIVITAMIN	MULTI- INGREDIENT	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2001

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2778	NDA/MAL/HDP/4 926	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	FOLIC ACID	FOLIC ACID	5MG	LABORATORY & ALLIED LTD PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER	01/07/1997
2779	NDA/MAL/HDP/4 927	NORVATIS PHARMA AG-SWITZERLAND	LABOREX UGANDA LIMITED	AZOPT	BRINZOLAMIDE	10MG/ML	ALCON COUVREUR NVRIJKSWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML BOTTLE	01/07/2009

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2780	NDA/MAL/HDP/4 929	MARTINDALE AND AURUM PHARMACEUTICAL	LABOREX UGANDA LIMITED	MORPHINE INJECTION	MORPHINE	15MG/ML	MARTINDALE PHARMACEUTICAL LIMITED BAMPTON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/1997
2781	NDA/MAL/HDP/4 932	MARTINDALE AND AURUM PHARMACEUTICAL	LABOREX UGANDA LIMITED	MORPHINE INJECTION	MORPHINE	10MG/ML	MARTINDALE PHARMACEUTICAL LIMITED BAMPTON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/1997

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2782	NDA/MAL/HDP/4 933	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	AZUDOX	DOXYCYCLINE HYDROCHLORIDE	100MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD PLOT NO. M444B, STRETCHER ROAD, NTINDA, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CONTAINER,1.0X10. 0 CAPSULE BLISTER,1.0X500.0 CAPSULE CONTAINER,1.0X25 0.0 CAPSULE CONTAINER,1.0X10 00.0 CAPSULE CONTAINER	01/07/1997
2783	NDA/MAL/HDP/4 934	FREDUN PHARMACEUTICAL S LTD	PLANET PHARMACEUTICAL S UGANDA LTD	FOLIFRED	FOLIC ACID	5MG	FREDUN PHARMACEUTICALS LTD14,15,16 ZORBIAN INDUSTRIAL COMPLEX VEOR PALGHAR EAST INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997



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2784	NDA/MAL/HDP/4 936	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	COMBIFEN	IBUPROFEN + PARACETAMOL	400MG + 500MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2011
2785	NDA/MAL/HDP/4 937	JASSEN-CILAG (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	MOTILIUM	DOMPERIDONE	10MG	JANSSEN- CILAG DOMAINE DE MAIGREMONT, 27100 VAL DE REUIL - FRANCE	FRANCE	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X20.0 TABLET BLISTER, 1.0X30.0 TABLET BLISTER	01/07/1997

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2786	NDA/MAL/HDP/4 939	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	FOLIREN	FOLIC ACID	5MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2005
2787	NDA/MAL/HDP/4 940	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	FOLON	FOLIC ACID	5MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2006

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2788	NDA/MAL/HDP/4 943	ASTRAZENECA	MACNAUGHTON LIMITED	NOLVADEX	TAMOXIFEN	20MG	ASTRAZENECA UK LIMITED ASTRAZENECA UK LIMITED SILK ROAD BUSINESS PARK, MACCLES FIELD,CHESHIRE SK 10 2NA,	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/1997
2789	NDA/MAL/HDP/4 944	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	BENA EXPECTORANT	DIPHENHYDRAMINE HCL + AMMONIUM CHLORIDE + SODIUM CITRATE	14MG + 135MG + 57.5MG	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X120.0 ML BOTTLE	01/07/1997

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2790	NDA/MAL/HDP/4 946	ESAPHARM SRL	BYAMA KA PHARMACEUTICAL COMPANY LTD	MOVATE	CLOBETASOL	0.05%W/W	ESAPHARMA SRL VIA DE GASPERI, 13- 20066 MELZO (MILAN) ITALY	ITALY	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	01/07/1999
2791	NDA/MAL/HDP/4 949	JOHNSON&JOHNS ON PTY LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	BENYLIN DRY COUGH DM	DEXTROMETHOR PHAN HYDROBROMIDE	15MG/ML	JOHNSON&JOHNSO N PTY LTD.EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997

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2792	NDA/MAL/HDP/4 951	JOHNSON&JOHNS ON PTY LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	BENYLIN ORIGINAL	DIPHENHYDRAMINE HYDROCHLORIDE + AMMONIUM CHLORIDE	12.5 MG/5ML + 125 MG/5ML	JOHNSON&JOHNSO N PTY LTD.EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE,1.0X2.5 L BOTTLE	01/07/1997
2793	NDA/MAL/HDP/4 952	JOHNSON&JOHNS ON PTY LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	BENYLIN WITH CODEINE	DIPHENHYDRAMINE HCL + AMMONIUM CHLORIDE + CODEINE PHOSPHATE	12.5MG/5ML +125MG/5ML +10MG/5ML	JOHNSON&JOHNSO N PTY LTD.EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE	01/07/1997

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2794	NDA/MAL/HDP/4 953	MEGA LIFSCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	NAT-B	MULTI- INGREDIENT	MULTI- INGREDIENT	MEGA LIFE SCIENCES PUBLIC COMPANY LIMITED384 SOIB PATTANA 3 RD BANGPOO INDUSTRIAL ESTATE SAMUTPRAKARN 10280	THAILAND	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2009
2795	NDA/MAL/HDP/4 955	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	COMPOUND SODIUM LACTATE INFU.	COMPOUND SODIUM LACTATE	MULTI INGREDIENT	ACULIFE HEALTHCARE PVT. LTDVILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/1997

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2796	NDA/MAL/HDP/4 956	UNIQUE PHARMACEUTICAL S LABORATORIES	PLANET PHARMACEUTICAL S UGANDA LTD	CONTRAPAQUE 350	IOHEXOL	350MG	UNIQUE PHARMACEUTICAL LABORATORIES, (A DIVISION OF J.B CHEMICALS & PHARMACEUTICALS LTD PLOT NO 4, PHASE IV, GIDC INDUSTRIAL AREA, PANOLI 394 116	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL	01/07/2010
2797	NDA/MAL/HDP/4 957	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICAL S LTD	MUMFER	IRON (111) POLYMALTOSE COMPLEX + FOLIC ACID	100MG + 500MCG	GLENMARK PHARMACEUTICALS LTD PLOT E PLOT NO. E-37, 39, MIDC AREA, SATPUR, NASIK - 422 007, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2004

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2798	NDA/MAL/HDP/4 958	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BENZOSED	MIDAZOLAM	1MG/ML	TROIKAA PHARMACEUTICALS LTD .SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X5.0 ML VIAL	01/07/2011
2799	NDA/MAL/HDP/4 959	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	CONTUS PAEDIATRIC LINCTUS	CHLORPHENIRAM INE / PHENYLEPHRINE / DXTROMETHOR PHAN	1MG/ 5MG/ 10MG	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X50.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2011



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2800	NDA/MAL/HDP/4 962	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	BETAD	BETAMETHASONE DIPROPIONATE	0.05%W/W	S.KANT HEALTHCARE LTD PLOT 1802, 1805, GIDC PHASE III VAPI 39179, GUJARAT	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE, 1.0X1.0X15.0 G TUBE	01/07/2010
2801	NDA/MAL/HDP/4 964	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	CONTUS PLUS PAEDIATRIC SUSPENSION	CHLORPHENAMIN E+PHENYLEPHRIN E+PARACETAMOL	IMG+5MG+160MG	STEDMAN PHARMACEUTICALS PVT LIMITED NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X50.0 ML BOTTLE, 1.0X100.0 ML BOTTLE	01/07/2011

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2802	NDA/MAL/HDP/4 965	BETA HEALTHCARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	BETAFEN SYRUP	IBUPROFEN	100MG/5ML	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2001
2803	NDA/MAL/HDP/4 966	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	CONTUS-650	CHLORPHENIRAM INE + PHENYLEPHRINE + PARACETAMOL	2MG + 5MG + 650MG	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X50.0X1 .0X6.0 TABLET BLISTER, 1.0X1.0X10.0 TABLET BLISTER	01/07/2010

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2804	NDA/MAL/HDP/4 968	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	FRUSEMIDE INJECTION	FUROSEMIDE	10MG/ML	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2008
2805	NDA/MAL/HDP/4 969	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	BENZATHINE PENICILLIN	BENZATHINE PENICILLIN	2.4 M.U	CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHUANG) CO. LTD WORKSHOP NO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA WORKSHOP 406 AND 407	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X2.4 MU VIAL	01/07/2001

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2806	NDA/MAL/HDP/4 971	AFRICURE PHARMACEUTICAL S (INDIA) PRIVATE LIMITED	AFRICURE PHARMACEUTICAL S U LIMITED	FRUSEMIDE TABLETS	FUROSEMIDE	40MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED PLOT 9- 12, DEWAN & SONS INDL. AREA, VEOOR, PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP, 1.0X1000.0 TABLET CONTAINER	01/07/1997
2807	NDA/MAL/HDP/4 972	JOHNSON & JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	COOLMINT LISTERINE	MENTHOL + ALCOHOL 95%	0.02% + 4.58ML	JOHNSON & JOHNSON PTY LTD. EDMS BPK241 MAIN ROAD /HOOFWEG 241, RETREAT 7945, SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY LIQUIDS	1.0X250.0 ML CONTAINER, 1.0X50 0.0 ML CONTAINER	01/07/2001

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2808	NDA/MAL/HDP/4 973	MERCK	UNITED HEALTHCARE DISTRIBUTORS LTD	PERGOVERIS	FOLLITROPIN ALFA/LUTROPIN ALFA	150 I.U/75 I.U	MERCK SERONO S.A. (MSA) -1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND	ITALY SWITZERLAND	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 ML VIAL + 1*1ML VIAL OF WFI	01/07/2014
2809	NDA/MAL/HDP/4 974	COSMOS LTD	ASTRA PHARMA (U) LIMITED	FRUSEMIDE TABLETS BP 40MG	FUROSEMIDE	40MG	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	01/07/1998

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2810	NDA/MAL/HDP/4975	FREDUN PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	FRUSINA TABLETS	FUROSEMIDE	40MG	FREDUN PHARMACEUTICALS LTD14,15,16 ZORBIAN INDUSTRIAL COMPLEX VEOOR PALGHAR EAST INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER,1.0X10.0 TABLET BLISTER	01/07/1997
2811	NDA/MAL/HDP/4976	MEGA LIFSCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	PERGLIM 2	GLIMEPIRIDE	2MG	INVENTIA HEALTHCARE PVT. LTD .FI – FI /1 ADDITIONAL AMBERNATH(EAST) – 421 506,MAHARASHTRA DIST. THANE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2015

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2812	NDA/MAL/HDP/4 979	CIRON DRUGS & PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	FUROSEMIDE	FUROSEMIDE	10MG/ML	CIRON DRUGS AND PHARMACEUTICALS PVT LTDN-118 M.I.D.C, TAAPUR,BOISAR,DIS T.THANE MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE	01/07/2010
2813	NDA/MAL/HDP/4 982	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSMAG TABLETS	MAGNESIUM TRISILICATE	370MG	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X100.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	01/07/1998

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2814	NDA/MAL/HDP/4 983	PT SAMBE FARMA	MEDVIN PHARMA LIMITED	PELASTIN	IMIPENEM + CILASTATIN	500MG + 500MG	PT SANBE FARMAJI LEUWIGAJAH I62 CIMINDI CIMAH WEST JAVA INDONESIA	INDONESIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2011
2815	NDA/MAL/HDP/4 998	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	HYAN	LEVONORGESTRE L	0.03MG	MYLAN LABORATORIES LIMITED..PLOT NO.20 & 21, PHARMEZ, SARKHEJ- BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL- SANAND, AHMEDABAD, GUJARAT, INDIA 382213 MYLAN LABORATORIES LIMITED.-PLOT NO. 1606-1609	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X28.0 TABLET BLISTER	01/07/2006



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2816	NDA/MAL/HDP/4 999	UNIQUE PHARMACEUTICAL LABORATORIES	PLANET PHARMACEUTICAL S UGANDA LTD	PAMIDOL*370	IOPAMIDOL	755.3MG/ML	UNIQUE PHARMACEUTICAL LABORATORIES, (A DIVISION OF J.B CHEMICALS & PHARMACEUTICALS LTD PLOT NO 4, PHASE IV, GIDC INDUSTRIAL AREA, PANOLI 394 116	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL,1.0X1.0X100.0 ML VIAL	01/07/2010
2817	NDA/MAL/HDP/5 002	ELI-LILLY EXPORT SA	LABOREX UGANDA LIMITED	HUMALOG MIX 25	INSULIN LISPRO + INSULIN LISPRO PROTAMINE	25I.U+75I.U	LILLY FRANCE SAFRANCE	FRANCE	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE	01/07/2000

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2818	NDA/MAL/HDP/5004	GLAXOSMITHKLINE LIMITED LIKONI	BETA HEALTHCARE UGANDA LIMITED	COFTA TABLETS	MULTI-INGREDIENT	N/A	GLAXOSMITHKLINE LIMITED - 78392-00507, VIWANDANI LIKONI ROAD NAIROBI KENYA BETA HEALTHCARE INTERNATIONAL LTD PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY LOZENGES	1.0X100.0 TABLET CARTON,1.0X50.0 TABLET CARTON,1.0X150.0 TABLET CARTON	01/07/1997
2819	NDA/MAL/HDP/5005	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	COLD GO	PARACETAMOL+PHENYLEPHRINE HYDROCHLORIDE +CHLORPHENIRAMINE MALEATE+CAFFEINE	325MG+10MG+2MG+30MG	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X1.0X4.0 TABLET BLISTER	01/07/2010

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2820	NDA/MAL/HDP/5 008	UNIMED INDIA	ASTRA PHARMA (U) LIMITED	COLDAFEX	MULTI- INGREDIENT	MULTI- INGREDIENT	UNIMED INDIA86,MAROL COOPORATIVE ESTATE, M.V ROAD ANDHERE(E)MUMBA I 400059	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2005
2821	NDA/MAL/HDP/5 010	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	ZARIN CREAM	MICONAZOLE NITRATE	2%W/W	XEPA-SOUL PATTINSON (MALAYSIA) SDA BHD1-5, CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997

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2822	NDA/MAL/HDP/5011	UNIMED INDIA	ASTRA PHARMA (U) LIMITED	COLDAFEX TABLETS	MULTI-INGREDIENT	MULTI-INGREDIENT	UNIMED INDIA86,MAROL COOPORATIVE ESTATE, M.V ROAD ANDHERE(E)MUMBA I 400059	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X4.0 TABLET STRIP,1.0X10.0X10.0 TABLET BLISTER	01/07/1997
2823	NDA/MAL/HDP/5014	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	VERMOREX SUSPENSION	MEBENDAZOLE	100MG/5ML	UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)216-219 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH J.B CHEMICALS & PHARMACEUTICALS LTD128/1 GIDC ANKLESHWAR 393 022 GUJARAT INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/1998

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2824	NDA/MAL/HDP/5015	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	COLDCAP CAPSULES	PHENYLEPHRINE HYDROCHLORIDE +CHLORPHENIRAMINE	5MG+4MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X500.0 CAPSULE CONTAINER,1.0X1000.0 CAPSULE CONTAINER,1.0X8.0X12.0 CAPSULE BLISTER,1.0X10.0X10.0 CAPSULE BLISTER,1.0X12.0 CAPSULE BLISTER,1.0X10.0 CAPSULE BLISTER	01/07/1997
2825	NDA/MAL/HDP/5017	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	COLDCAP SYRUP	PARACETAMOL + CHLORPHENIRAMINE MALEATE + PSEUDOEPHEDRINE HYDROCHLORIDE	120MG/5ML + 2MG/5ML + 10MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997

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2826	NDA/MAL/HDP/5 018	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	VENTOLIN	SALBUTAMOL	100MCG	GLAXO WELLCOME PRODUCTION.ZONE INDUSTRIELLE NO.2 23, RUE LAVOISIER 27000 EVREUX,FRANCE.	FRANCE	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER	01/07/1997
2827	NDA/MAL/HDP/5 019	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	COLOSPASMIN FORTE	MEBEVERINE	135MG	EGYPTIAN INT.PHARMACEUTIC AL INDUSTRIES CO (E.I.P.C.O)-EGYPTIAN INT.PHARMACEUTIC AL INDUSTRIES CO (E.I.P.C.O)	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X20.0 TABLET BLISTER	01/07/2011

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2828	NDA/MAL/HDP/5 021	BAYER SCHERING PHARMA FRANCE	SURGIPHARM (U) LIMITED	COMBINATION 3	ETHINYL ESTRADIOL+ LEVONORGESTRE L+FERROUS FUMARATE	0.03MG+0.15MG+ 75MG	BAYER PHARMA AG - 13353 BERLIN GERMANY BAYER WEIMAR GMBH UND CO. KG,-WEIMAR DEBEREINERSTRASSE 20, 99427 WEIMAR GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X100.0X28.0 TABLET BLISTER	01/07/2011
2829	NDA/MAL/HDP/5 028	THE MENTHOLATUM COMPANY LTD TWY	HARLEYS UGANDA LIMITED	DEEP HEAT SPRAY	MULTI- INGREDIENT	MULTI- INGREDIENT	COLEP LAUPHEIM GMBH & CO KG- FOCKESTRASSE 12, 88471, LAUPHEIM	GERMANY	TOPICAL EXTERNAL PRESSURISED AEROSOLS	1.0X150.0 ML CANNISTER	01/07/1997

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2830	NDA/MAL/HDP/5 030	PFIZER LAB LTD	LABOREX UGANDA LIMITED	SOLU-MEDROL	METHYLPREDNIS OLONE HEMISUCCINATE	125MG/2ML	PFIZER GLOBAL MANUFACTURING BELGIUM NVRIJKSWEG 12, 2870 PUURS - BELGIUM	BELGIUM	PARENTERAL ORDINARY DRY VIALS	1.0X2.0 ML VIAL,1.0X8.0 ML VIAL	01/07/1997
2831	NDA/MAL/HDP/5 031	THE MENTHOLATUM COMPANY LTD	HARLEYS UGANDA LIMITED	DEEP HEAT RUB	MULTI- INGREDIENT	MULTI- INGREDIENT	THE MENTHOLATUM COMPANY LTD, TWYFORD,1 REDWOOD AVENUE, PEEL PARK CAMPUS EAST KILBRIDE, G74 SCOTLAND	UNITED KINGDOM	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X35.0 G TUBE,1.0X67.0 G TUBE,1.0X100.0 G TUBE	01/07/1997



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2832	NDA/MAL/HDP/5 032	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	DELATED DRY COUGH SYRUP (NON DROWSY)	DEXTROMETHOR PHAN	7.5MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2004
2833	NDA/MAL/HDP/5 033	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	MEBFIL TABLETS	MEBENDAZOLE	100MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDAL UR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/1997

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

2834	NDA/MAL/HDP/5 035	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	MEBENDAZOLE	MEBENDAZOLE	100MG/5ML	MEDICAMEN BIOTECH LTD - SP- 1192 A&B PHASE IV INDUSTRIAL AREA BHIWADI 301019 DIST. ALWAR (RAJASTHAN) - INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2014
2835	NDA/MAL/HDP/5 036	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	DEPO PROGESTIN	MEDROXYPROGE STERONE ACETATE	150MG	PT HARSEN LABORATORIES, JL RAYA - JL RAYA BOGOR, KM 24.6, JAKARTA TIMUR 13750	INDONESIA	PARENTERAL ORDINARY VIALS	1.0X20.0 VIAL CARTON, 1.0X25.0X 1.0 ML VIAL	01/07/2010

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

2836	NDA/MAL/HDP/5037	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	MDOPAKANT-250	METHYLDOPA	250MG	S KANT HEALTHCARE LTD (1802-1805 GIDC PHASE III, VAPI-396195 GUJARAT, INDIA)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X5.0X10.0 TABLET BLISTER	01/07/2011
2837	NDA/MAL/HDP/5038	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	M-CAM TABLETS	MELOXICAM	15MG	UNICHEM LABORATORIES LIMITED UNICHEM LABORATORIES LIMITED. UNIT II, VILLAGE BHATAULI KALAN, BADDI, DIST. SOLAN PIN CODE 173 205, HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X5.0X10.0 TABLET BLISTER	01/07/2002

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2838	NDA/MAL/HDP/5 040	PFIZER LABORATORIES (PTY) LTD BELGIUM	LABOREX UGANDA LIMITED	DEPO-MEDROL	METHYLPREDNIS OLONE ACETATE	40MG/ML	PFIZER GLOBAL MANUFACTURING BELGIUM NVRIJKSWEG 12, 2870 PUURS - BELGIUM	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL,1.0X2.0 ML VIAL,1.0X5.0 ML VIAL	01/07/1997
2839	NDA/MAL/HDP/5 041	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	MAXITROL	DEXAMETHASON E/NEOMYCIN/POL YMYXIN B	0.1%W/W +0.1%W/W+6000 I.U	ALCON COUVREUR NVRIJKSWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC OINTMENTS	1.0X3.5 G TUBE	01/07/1997

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

2840	NDA/MAL/HDP/5 042	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSATRIM DS TABLETS	CO-TRIMOXAZOLE	960MG	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X50 0.0 TABLET CONTAINER,1.0X10 0.0 TABLET CONTAINER	01/07/1998
2841	NDA/MAL/HDP/5 043	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	MAXITROL	DEXAMETHASON E/NEOMYCIN/POL YMYXIN B	0.1%W/W+3500I.U /ML+6000I.U/ML	ALCON COUVREUR NVRIKSWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/1997

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

2842	NDA/MAL/HDP/5 044	PFIZER LABORATORIES (PTY) LTD BELGIUM	LABOREX UGANDA LIMITED	DEPO-PROVERA	MEDROXYPROGE STERONE ACETATE	150MG/ML	PFIZER GLOBAL MANUFACTURING BELGIUM NVRIJKSWEG 12, 2870 PUURS - BELGIUM	BELGIUM	PARENTERAL ORDINARY I M VIALS	1.0X3.5 ML VIAL,1.0X1.0 ML VIAL	01/07/1997
2843	NDA/MAL/HDP/5 049	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	GIZLAN PLUS 300/12.5	IRBESARTAN/HYD ROCHLOROTHIAZI DE	300MG/12.5MG	DAR AI DAWANA UR PLANT,AMMAN,JOR DAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

2844	NDA/MAL/HDP/5 050	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	MAXIDEX	DEXAMETHASON E	0.1%W/V	ALCON COUVREUR NVRIJKSWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/1997
2845	NDA/MAL/HDP/5 053	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	DERMX	ECONAZOLE/ TRIAMCINOLONE/ GENTAMYCIN	1%/0.1%/0.1%	S KANT HEALTH CARE LTD PLOT 1802 - 1805	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2011

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2846	NDA/MAL/HDP/5 055	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	DERMOVATE	CLOBETASOL PROPIONATE	0.05%W/W	GLAXOSMITHKLINE HARMIRE GLAXOSMITHKLINE HARMIRE ROAD BARNARD CASTLE DURHAM	UNITED KINGDOM	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE,1.0X25.0 G TUBE	01/07/1997
2847	NDA/MAL/HDP/5 064	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	MANNITOL INFUSION	MANNITOL	20%W/V	ACULIFE HEALTHCARE PVT. LTDVILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2011



## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

2848	NDA/MAL/HDP/5065	N.V. ORGANON	SURGIPHARM (U) LIMITED	MARVELON	DESOGESTREL/ETHINYLESTRADIOL	150MG/30MG	N.V. ORGANONKLOOSTER STRAAT 6, 5349 AB OSS, THE NETHERLAND	NETHERLANDS	ORAL SOLID ORDINARY TABLETS	1.0X100.0X1.0X28.0 TABLET BLISTER	01/07/2015
2849	NDA/MAL/HDP/5068	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	DEXAMETHASONE SODIUM PHOSPHATE	DEXAMETHASONE SODIUM PHOSPHATE	8MG/2ML	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	CHINA INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2010

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2850	NDA/MAL/HDP/5070	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	LOMOH-60	ENOXAPARIN SODIUM	60MG/0.6ML	EMCURE PHARMACEUTICALS LTD PLOT NO. P-1 ITBT PARK PHASE II MIDC HINJWADI PUNE 411057	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X1.0 ML PRE-FILLED SYRINGE	01/07/2009
2851	NDA/MAL/HDP/5071	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	LOMOH-40	ENOXAPARIN SODIUM	40MG/0.4ML	EMCURE PHARMACEUTICALS LTD PLOT NO. P-1 ITBT PARK PHASE II MIDC HINJWADI PUNE 411057	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X1.0 ML PRE-FILLED SYRINGE	01/07/2009

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2852	NDA/MAL/HDP/5 073	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	DEXONA EYE/EAR DROP	DEXAMATHASON E SODIUM PHOSPHATE+NEO MYCIN SULPHATE	0.35%W/V+0.1%W /V	AHLCON PARENTERALS (INDIA) LTDSP-917- 918, PHASE-III BHIWADI-301019, ALWAR, RAJASTHAN	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE,1.0X2.5 ML BOTTLE	01/07/1997
2853	NDA/MAL/HDP/5 074	ZYDUS LIFSCIENCES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DEXONA INJECTION	DEXAMETHASON E DISODIUM PHOSPHATE	4MG/ML	SAKAR HEALTH CARE PVT LTD-10/13 CHONGODAR SARKHEJ BAVLA ROAD DIST AHEMABAD 382213 GUJARATI	INDIA	PARENTERAL ORDINARY VIALS	1.0X6.0X2.0 ML VIAL,16.0X6.0X2.0 ML VIAL	01/07/1997

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2854	NDA/MAL/HDP/5 076	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	DEXTRACIN EYE DROPS	DEXAMETHASON E + NEOMYCIN	0.1MG + 0.5MG	XEPA-SOUL PATTINSON (MALAYSIA) SDA BHD1-5, CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA	MALAYSIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/1997
2855	NDA/MAL/HDP/5 078	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICAL S LIMITED	GLANDIN E2 VAGINAL	DINOPROSTONE	3MG	NABIQASIM INDUSTRIES (PVT) LIMITED17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN	PAKISTAN	VAGINAL TABLETS	1.0X1.0 TABLET STRIP	01/07/2006

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

2856	NDA/MAL/HDP/5079	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	GLEMONT CT 5	MONTELUKAST	5MG	GLENMARK PHARMACEUTICALS LTD .VILLAGE KISHANPURA, BADDI-NALAGARH ROAD, TEHSIL BADDI, DISTRICT SOLAN HP 173205	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
2857	NDA/MAL/HDP/5080	GENO PHARMACEUTICALS PVT LTD	HARLEYS UGANDA LIMITED	LOBAK	DICLOFENAC/PARACETAMOL/CHLORZOXAZONE	50MG/325MG/250MG	GENO PHARMACEUTICALS LTD-PHARMACEUTICAL COMPLEX, TIVIM INDUSTRIAL ESTATE, P.O. KARASWADA, MAPUSA, GOA 403526	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2011

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2858	NDA/MAL/HDP/5 086	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	GLIFIL M FORT	GLIBENCLAMIDE + METFORMIN HYDROCHLORIDE	5MG+500MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDAL UR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
2859	NDA/MAL/HDP/5 092	MICRO LABS LTD 92 SIPCOT	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DIAPRIDE	GLIMEPIRIDE	2MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011

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2860	NDA/MAL/HDP/5 095	MICRO LABS LTD	LABOREX UGANDA LIMITED	DIAPRIDE PLUS	GLIMEPIRIDE + METFORMIN	1MG + 500MG	MICRO LABS LTD 92 SIPCOT 92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
2861	NDA/MAL/HDP/5 096	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	SCABION	CROTAMITON + SULPHUR	10 G + 2G/100G	ATCO LABS LTD,B-18, S.I.T.E, KARACHI	PAKISTAN	TOPICAL EXTERNAL OINTMENTS	1.0X60.0 ML BOTTLE	01/07/2003

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2862	NDA/MAL/HDP/5099	COSMOS LTD	ASTRA PHARMA (U) LIMITED	GLUCOMET	METFORMIN	500MG	COSMOS LIMITED-RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X2.0X14.0 TABLET BLISTER,1.0X4.0X14.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/2005
2863	NDA/MAL/HDP/5100	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	L-GENTA	GENTAMICIN	0.3%W/V	LINCOLN PHARMACEUTICALS LTD-TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA	INDIA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL	01/07/2005



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2864	NDA/MAL/HDP/5 102	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE 500MG	METFORMIN	500MG	NKUNZI PHARMACEUTICALS (PTY) LTD.259 DAVIDSON ROAD CNR PEDDIE STREET, WADEVILLE EST. 1 GERMISTON 1422 MERCK SANTÉ2, RUE DU PRESOIR VERT F 45400, SEMOY	FRANCE SOUTH AFRICA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X500.0 TABLET CONTAINER,1.0X6.0 X15.0 TABLET BLISTER,1.0X30.0 TABLET BLISTER	01/07/2010
2865	NDA/MAL/HDP/5 103	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE 1000MG	METFORMIN	1000MG	NKUNZI PHARMACEUTICALS (PTY) LTD -259 DAVIDSON ROAD, WADEVILLE, EXT 1, GERMINSTON, SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X15.0 TABLET BLISTER	01/07/2010

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2866	NDA/MAL/HDP/5 104	NOVO NORDISK PHARMA GULF FZ- LC	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	LEVEMIR FLEXPEN	INSULIN DETEMIR	100 I.U./ML	NOVO NORDISK PRODUCTION SAS45 AVENUE D'ORLEANS, 28000 CHARTRES, FRANCE NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDAAV. "C", 1413, DISTRITO INDUSTRIAL - 390404 004 MONTES CLAROS, MINAS GERAIS - BRAZIL NOVO NORDISK A/S NOVO ALLE DK-2880 BAGSVAERD	DENMARK BRAZIL FRANCE	PARENTERAL ORDINARY PRE- FILLED PENS	1.0X5.0X3.0 ML PREFILLED PEN	01/07/2014
2867	NDA/MAL/HDP/5 106	ESAPHARM SRL	BYAMAKA PHARMACEUTICAL COMPANY LTD	LEMONVATE CREAM	CLOBETASOL PROPIONATE	0.05%W/W	ESAPHARMA SRLVIA DE GASPERI, 13- 20066 MELZO (MILAN) ITALY	ITALY	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	01/07/2003

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2868	NDA/MAL/HDP/5 107	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	INDOREN CAPSULES	INDOMETHACIN	25MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER, 1.0X1000.0 CAPSULE CONTAINER	01/07/2000
2869	NDA/MAL/HDP/5 109	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	LEBASMA ORAL SOLUTION	SALBUTAMOL	2MG/5ML	LEBEN LAB PVT LTD L4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2011

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2870	NDA/MAL/HDP/5 110	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	GLUCOSE INFUSION BP	DEXTROSE	5%W/V	ACULIFE HEALTHCARE PVT. LTDVILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X250.0 ML BOTTLE,1.0X500.0 ML BOTTLE	01/07/1997
2871	NDA/MAL/HDP/5 111	FREDUN PHARMACEUTICAL S LTD	PLANET PHARMACEUTICAL S UGANDA LTD	LAXAFRED	BISACODYL	5MG	FREDUN PHARMACEUTICALS LIMITED,14,15,16 - ZORABIAN INDUSTRIAL COMPLEX, VEOOR, PALGHAR (E), THANE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET BLISTER	01/07/1997

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2872	NDA/MAL/HDP/5 112	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	DICLOMOL SR TABLETS	DICLOFENAC SODIUM	100MG	WIN MEDICARE PVT LIMITEDMEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH -INDIA	INDIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1998
2873	NDA/MAL/HDP/5 115	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	INDOS-25	INDOMETHACIN	25MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1000.0 CAPSULE CONTAINER,20.0X5. 0 CAPSULE BLISTER,1.0X10.0X1 0.0 CAPSULE BLISTER	01/07/2000

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2874	NDA/MAL/HDP/5 117	VENUS REMEDIES LIMITED	HARLEYS UGANDA LIMITED	LASTINEM	IMIPENEM + CILASTATIN	500MG + 500MG	VENUS REMMEDIESUNIT II HILLTOP INDUSTRIAL ESTATES JHARMAJRI EPIP PHASE 1 BHOTOLI KALA BADDI INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	01/07/2011
2875	NDA/MAL/HDP/5 119	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	KONTRAC 200	MISOPROSTOL	200MCG	FOURRTS INDIA LABORATORIES PVT. LIMITEDVANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X2.0 TABLET STRIP,1.0X10.0X10. 0 TABLET BLISTER	01/07/2009

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2876	NDA/MAL/HDP/5 120	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	GLYFORMIN 500 TABLETS	METFORMIN	500MG	REMEDICA LIMITED LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER	01/07/1999
2877	NDA/MAL/HDP/5 121	UNIQUE PHARMACEUTICAL S LABORATORIES	PLANET PHARMACEUTICAL S UGANDA LTD	DICLORAN GEL	DICLOFENAC DIETHYLAMMONI UM	1%W/W	UNIQUE PHARMACEUTICALS LABS ( A DIV OF J.B CHEMICALS & PHARMACEUTICAL LTD)-304-308 ,GIDC , PANOLI 394116	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X50.0 G TUBE,1.0X20.0 G TUBE	01/07/1997

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2878	NDA/MAL/HDP/5 122	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	KOFAREST SYRUP	SALBUTAMOL SULPHATE/AMBR OXOL SULPHATE/GUAFFE NESIN/MENTHOL	2MG+30MG+100M G+5MG/10ML	CENTAUR PHARMACEUTICALS LTD PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2007
2879	NDA/MAL/HDP/5 124	GLAXOSMITHKLINE LTD BELGIUM	UNITED HEALTHCARE DISTRIBUTORS LTD	INFANRIX-HEXA	DIPHThERIA TOXOID+TETANU S TOXOID+PERTUSS IS TOXOID(Pt)+FILA MENTOUS HAEMAGGLUTINI N(FHA)+PERTACTI N(69KDA OMP)+HBSAG PURIFIED,INACTIV ATED POLIO VIRUS TYPE I+INACTIVATED POLIO VIRUS TYPE	MIN 30 I.U+MIN 40 I.U+25MG+25MG+ 8MG+10MG,40DU +8DU+32DU+10M G	GLAXOSMITHKLINE BOILOGICALSS.A RUE DE L'INSTITUT 89 B- 1330 RIXENSART	BELGIUM	PARENTERAL ORDINARY COMBINATION PACK VIALS	1.0X1.0 PACK CARTON (DTPA- HBV-IPV IN PREFILLED SYRINGE + 2 NEEDLES+FREEZE DRIED HIB IN A VIAL)	01/07/2013



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2880	NDA/MAL/HDP/5 125	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	GLYGESIC FORTE RHUMETIC CREAM	MULTI INGREDIENT	N/A	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1998
2881	NDA/MAL/HDP/5 128	MERCK (PTY) LTD	ABACUS PHARMA (AFRICA) LIMITED	GOFEN 400 CLEARCAP	IBUPROFEN	400MG	MEGA LIFESCIENCES LTD.384 PATTANA 3 ROAD BANGPOO INDUSTRIAL ESTATE SUMUTPRAKAN	THAILAND	ORAL SOLID ORDINARY CAPSULES	6.0X1.0X10.0 CAPSULE BLISTER	01/07/2009

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2882	NDA/MAL/HDP/5 129	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICAL S LIMITED	KLEEN ENEMA	DISODIUM BISPHOSPHATE/ SODIUM PHOSPHATE	19.2G+7.2G/ 120ML	NABIQASIM INDUSTRIES (PVT) LIMITED17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN	PAKISTAN	RECTAL SYSTEMIC ENEMA LIQUIDS	1.0X135.0 ML BOTTLE	01/07/2006
2883	NDA/MAL/HDP/5 130	UNIQUE PHARMACEUTICAL S LTD	PLANET PHARMACEUTICAL S UGANDA LTD	DICLORAN MS GEL	DICLOFENAC+ME THYL SALICYLATE+MEN THOL	1%W/W+10%W/W +5%W/W	UNIQUE PHARMACEUTICALS LABS ( A DIV OF J.B CHEMICALS & PHARMACEUTICAL LTD)-304-308 ,GIDC , PANOLI 394116	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/2005

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2884	NDA/MAL/HDP/5 131	NOVO NORDISK	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	INSULATARD	ISOPHANE INSULIN (HUMAN)	100 I.U./ML	NOVO NORDISK PRODUCTION SAS45 AVENUE D'ORLEANS, 28000 CHARTRES, FRANCE NOVO NORDISK PHARMANOVO ALLE	DENMARK FRANCE	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL	01/07/1997
2885	NDA/MAL/HDP/5 133	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GONAL-F PEN 900IU/1.5ML(66M CG/1.5ML)	FOLLITROPIN ALFA	66MCG/1.5ML	MERCK SERONO SPA (BARI)-VIA DELLE MAGNOLIE, 15 (LOC FRAZ ZONA INDUSTRIALE) 70026, MODUGNO, BARI MERCK SERONO S.A. (MSA) - 1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND	ITALY SWITZERLAND	PARENTERAL ORDINARY PRE- FILLED PENS	1.0X1.0 CARTRIDGE PREFILLED PEN + 20 NEEDLES FOR INJECTION,1.0X1.0 CARTRIDGE PREFILLED PEN + 8 NEEDLES FOR INJECTION.	01/07/2015

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2886	NDA/MAL/HDP/5 134	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	GOODMORNING COUGH TABLETS	MULTIINGREDIEN T	N/A	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CARTON	01/07/1997
2887	NDA/MAL/HDP/5 135	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	KETOZ	KETOCONAZOLE	2%W/W	SK ANT HEALTHCARE LTD1802-1805 GIDC PHASE III, VAPI- 396195 GUJARAT, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X30.0 G TUBE	01/07/2010

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2888	NDA/MAL/HDP/5 136	BETA HEALTHCARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	GOODMORNING LUNG TONIC	MULTIINGREDIEN T	N/A	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X50.0 ML BOTTLE	01/07/1997
2889	NDA/MAL/HDP/5 139	NOVO NORDISK	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	INSULATARD HM PENFILL	ISOPHANE INSULIN (HUMAN)	100I.U/ML	NOVO NORDISK PRODUCTION SAS45 AVENUE D'ORLEANS, 28000 CHARTRES, FRANCE NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDAAV. "C", 1413, DISTRITO INDUSTRIAL - 390404 004 MONTES CLAROS, MINAS GERAIS - BRAZIL NOVO NORDISK PHARMANOVO ALLE	DENMARK BRAZIL FRANCE	PARENTERAL ORDINARY CARTRIDGES	1.0X5.0X3.0 ML PREFILLED PEN,1.0X5.0X1.5 ML PREFILLED PEN	01/07/1997

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2890	NDA/MAL/HDP/5 140	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	DIFLUCAN	FLUCONAZOLE	200MG	FAREVA AMBOISE - ZONE INDUSTRIELLE, 29 ROUTE DES INDUSTRIES, 37530 POCE SUR CISSE, FRANCE	FRANCE	ORAL SOLID ORDINARY CAPSULES	1.0X7.0 CAPSULE BLISTER	01/07/1997
2891	NDA/MAL/HDP/5 142	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	INTAMINE CREAM	MEPYRAMINE MALEATE	2%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE,1.0X400.0 G TUBE	01/07/1997

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2892	NDA/MAL/HDP/5 143	ASTRA ZENECA	MACNAUGHTON LIMITED	BETALOC ZOK - 25MG	METOPROLOL	25MG	ASTRA ZENECA ABGARTUNAVGEN SE 151 58 SODAERTAJJE SWEDEN	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER	01/07/2011
2893	NDA/MAL/HDP/5 146	ASTRA ZENECA	MACNAUGHTON LIMITED	BETALOC ZOK - 100MG	METOPROLOL	100MG	ASTRA ZENECA ABSE- 151 85 SODERTALJE, SWEDEN (GARTUNAVAGEN & SNACKVIKEN)	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2011

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2894	NDA/MAL/HDP/5 147	ASTRA ZENECA	MACNAUGHTON LIMITED	BETALOC ZOK - 50MG	METOPROLOL	50MG	ASTRA ZENECA ABGARTUNAVGEN SE 151 58 SODAERTAJJE SWEDEN	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2011
2895	NDA/MAL/HDP/5 149	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	GRAVINATE SYRUP	DIMENHYDRINAT E	12.5MG/4ML	SEARLE COMPANY LTD - F-319, S.I.T.E., OPP. KESC POWER STATION, KARACHI	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/1997



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2896	NDA/MAL/HDP/5 150	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICAL S LTD	KETO PLUS SHAMPOO	KETOCONAZOLE + ZINC PYRITHIONE	2%W/W + 1%W/W	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL LIQUID SOAPS/WASHES	1.0X60.0 ML BOTTLE	01/07/2003
2897	NDA/MAL/HDP/5 153	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	GRAVINATE TABLETS	DIMENHYDRINAT E	50MG	SEARLE PAKISTAN LTD..F-319, S.I.T.E., OPP. KESC POWER STATION, KARACHI	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997

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2898	NDA/MAL/HDP/5 154	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	BETASIL PAEDIATRIC SYRUP	IPECACUANHA TINCTURE	0.5ML	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X50.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1997
2899	NDA/MAL/HDP/5 155	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	BETAVEL	MULTI- INGREDIENT	N/A	NEM LABORATORIES PVT LTD133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997

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2900	NDA/MAL/HDP/5 157	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	BETAVEL N	BETAMETHASONE +NEOMYCIN SULPHATE	1MG+5MG	NEM LABORATORIES PVT LTD133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL CREAMS	1.0X3.0 G TUBE,1.0X15.0 G TUBE	01/07/1997
2901	NDA/MAL/HDP/5 161	AFRICURE PHARMACEUTICAL S (INDIA) PRIVATELIMITED	ROYAL PHARMA 2011 LIMITED	GRISEOSIM-500	GRISEOFULVIN	500MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9- 12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

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2902	NDA/MAL/HDP/5 164	COSMOS LTD	ASTRA PHARMA (U) LIMITED	BROMSAL EXPECTORANT	SALBUTAMOL SULPHATE+BROM HEXINE HYDROCHLORIDE +GUAIFENESIN+M ENTHOL	1MG+2MG+50MG+ 0.5MG	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2010
2903	NDA/MAL/HDP/5 165	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	GRISEOFULVIN 500 TABLETS	GRISEOFULVIN	500MG	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER	01/07/2003

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2904	NDA/MAL/HDP/5 167	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	BRUSTAN TABLETS	IBUPROFEN + PARACETAMOL	400MG + 325MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED INDUSTRIAL AREA 3, A.B. ROAD, DEWAS 455001, MADHYA PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER, 2.0X10.0 TABLET BLISTER	01/07/1998
2905	NDA/MAL/HDP/5 169	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GVGYL SUPPOSITORY	METRONIDAZOLE BP	500MG	BLISS GVS PHARMA LTD PLOT.NO 10, SURVEY NO 38/1, DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST. THANE, MAHARASHTRA- INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY BLISTER	01/07/2007

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2906	NDA/MAL/HDP/5 170	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	CANDITRAL CAPSULE	ITRACONAZOLE	100MG	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0 CAPSULE STRIP, 1.0X10.0X1.0X4.0 CAPSULE STRIP	01/07/2000
2907	NDA/MAL/HDP/5 171	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	KETAMAX-50	KETAMINE	50MG/ML	TROIKAA PHARMACEUTICALS LIMITED C-1 SARA INDUSTRIAL ESTATE, SELAQUI, DEHRADUN- 248197, UTTARAKHAND, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	01/07/2011

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2908	NDA/MAL/HDP/5 176	BAYER AG	SURGIPHARM (U) LIMITED	CANESTEN	CLOTRIMAZOLE	100MG	BAYER AG D-51368 LEVERKUSEN GERMANY	GERMANY	VAGINAL TABLETS	1.0X6.0 TABLET STRIP	01/07/1997
2909	NDA/MAL/HDP/5 177	YURIA PHARM LTD	PHARMA VILLE LIMITED	ISONIAZID	ISONIAZID	100MG/5ML	YURIA-PHARM LLC MANUFACTURING SITE NO. 1108, KOBZARSKA STREET, CHERKASY, 18030	UKRAINE	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2013

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2910	NDA/MAL/HDP/5 179	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFIX 200MG CAPSULES	CEFIXIME TRIHYDRATE	200MG	PHARMA INTERNATIONAL CO.,AL-QASTAL AREA, AIRPORT ROAD, 11941, AMMAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X8.0 CAPSULE BLISTER	01/07/2007
2911	NDA/MAL/HDP/5 180	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	ISORYN DROPS ( PAEDRIATRIC)	EPHEDRINE HYDROCHLORIDE	5MG/ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	NASAL TOPICAL DROPS	1.0X15.0 ML BOTTLE	01/07/1997



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2912	NDA/MAL/HDP/5 182	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	ISORYN DROPS (ADULT)	EPHEDRINE HYDROCHLORIDE	10MG/ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	NASAL TOPICAL DROPS	1.0X15.0 ML BOTTLE	01/07/1997
2913	NDA/MAL/HDP/5 183	PHARCO B PHARMACEUTICAL S	WIDE SPECTRUM ENTERPRISES (U) LIMITED	GYNOZOL VAGINAL CAPSULES	MICONAZOLE NITRATE	400MG	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT, P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	VAGINAL SUPPOSITORIES	1.0X3.0 CAPSULE BLISTER	01/07/2000

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2914	NDA/MAL/HDP/5 184	PHARCO PHARMACEUTICAL S	WIDE SPECTRUM ENTERPRISES (U) LIMITED	GYNOZOL VAGINAL CREAM	MICONAZOLE NITRATE	2%W/W	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT, P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	VAGINAL CREAMS	1.0X40.0 G TUBE	01/07/2000
2915	NDA/MAL/HDP/5 186	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ISOTROY 250	ISOFLURANE	250ML	TROIKAA PHARMACEUTICALS LTDTHOL VILLAGE, DIST. MEHSANA- 382728, GUJARAT, INDIA	INDIA	OTHER SYSTEMIC LIQUID INHALATIONS	1.0X250.0 ML BOTTLE	01/07/2014

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2916	NDA/MAL/HDP/5 187	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	HEALIT SKIN OINTMENT	BACITRACIN+POL YMYXIN B SO4+NEOMYCIN+ LIDOCAINE	500UNITS+5000UN ITS+3.5MG+40MG/ G	ATCO LABORATORIES PVT LTDB-18,S.I.T.E KARACHI, PAKISTAN	PAKISTAN	TOPICAL EXTERNAL OINTMENTS	1.0X10.0 G TUBE	01/07/2007
2917	NDA/MAL/HDP/5 188	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	ITRAZ CAPSULES	ITRACONAZOLE	100MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X5.0 CAPSULE BLISTER,1.0X6.0X10 .0 CAPSULE BLISTER	01/07/2009

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2918	NDA/MAL/HDP/5 200	COSMOS LTD	ASTRA PHARMA (U) LIMITED	HYDRALAZINE TABLETS B.P 25MG.	HYDRALAZINE HYDROCHLORIDE	25MG	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1998
2919	NDA/MAL/HDP/5 201	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM BENDAZOLE	MEBENDAZOLE	100MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X250.0 TABLET CONTAINER,1.0X50 0.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1997

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2920	NDA/MAL/HDP/5 205	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM-VENT	SALBUTAMOL	4MG	KAMPALA PHARMACEUTICALS INDUSTRIES PLOT NO M44B STRETCHER ROAD INTINDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER, 1.0X100.0 TABLET CARTON, 1.0X250.0 TABLET JAR, 1.0X500.0 TABLET JAR, 1.0X1000.0 TABLET CONTAINER	01/07/1997
2921	NDA/MAL/HDP/5 207	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	DIGOXIN TABLETS	DIGOXIN	0.25MG	NEM LABORATORIES PVT. LIMITED 133 KRISHNA IND. ESTATE, VASAI (E), THANE - 401 210, MAHARASHTRA - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X1000.0 TABLET CONTAINER	01/07/2013

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2922	NDA/MAL/HDP/5 211	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	DINAC GEL	DICLOFENAC	1%W/W	S KANT HEALTHCARE LTD1802-1805 GIDC PHASE III VAPI 396 195 GUJARAT	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE	01/07/2009
2923	NDA/MAL/HDP/5 214	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	NIRMET	METRONIDAZOLE	500MG/100ML	ACULIFE HEALTHCARE PVT. LTDVILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2010

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2924	NDA/MAL/HDP/5 215	J.B CHEMICALS & PHARMACEUTICAL S LTD	PLANET PHARMACEUTICAL S UGANDA LTD	METROGYL TABLETS	METRONIDAZOLE	200MG	J.B. CHEMICALS AND PHARMACEUTICALS LTD .128/1, GIDC, ANKLESHWAR 393 002, GUJARAT GLOBELA PHARMA PVT.LTD.357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X20.0X5 .0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X5.0 X2.0X10.0 TABLET BLISTER	01/07/2001
2925	NDA/MAL/HDP/5 221	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	DICLOFENAC SODIUM	DICLOFENAC SODIUM	75MG/3ML	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X3.0 ML AMPOULE,1.0X10.0 X3.0 ML AMPOULE	01/07/2006

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2926	NDA/MAL/HDP/5 222	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	EMTRICITABINE+T ENOFOVIR DF	EMTRICITABINE/T ENOFOVIR	200MG/300MG	MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD ,PLOT NO. 11, 12, & 13 INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III PITHAMPUR 454775, DIST DHAR -	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	07/07/2008
2927	NDA/MAL/HDP/5 224	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	EMTRICITABINE+T ENOFOVIR DISOPROXIL FUMERATE	EMTRICITABINE/T ENOFOVIR DISOPROXIL FUMERATE	200MG/300MG	AUROBINDO PHARMA LTD UNIT IIIAUROBINDO PHARMA LTD UNIT III SURVEY NO. 313 BACHUPALLY VILLAGE QUTHUBULLAPUR MANDAL RANGA REDDY DISTRICT (A.P)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2009



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2928	NDA/MAL/HDP/5 226	HETERO DRUGS LTD	AIVEEN (U) LIMITED	EMTRICITABINE+T ENOFOVIR DISOPROXIL FUMERATE	EMTRICITABINE+T ENOFOVIR DISOPROXIL FUMERATE	200MG/300MG	HETERO LABS LTD (UNIT- V)SY.NO.438,439,44 0 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA HETERO DRUGS LTDUNIT-111 NO 22- 110 I.D.A JEEDIMETTA HYDRABAD 500055	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2013
2929	NDA/MAL/HDP/5 228	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	DICLOGENTA	DICLOFENAC SODIUM+GENTA MICIN SULPHATE	1MG/ML+3MG/ML	CENTAUR PHARMACEUTICALS PVT LTD -PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2009

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2930	NDA/MAL/HDP/5 231	INTAS, PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	ENAPRIL 10	ENALAPRIL MALEATE	10MG	INTAS PHARMACEUTICALS LTD PLOT 457/458, SARKHEJ BAVLA HIGHWAY MATODA 382 210 TAL: SANAND, AHMEDABAD, INDIA INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
2931	NDA/MAL/HDP/5 232	INTAS, PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	ENAPRIL-5	ENALAPRIL MALEATE	5MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2006

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2932	NDA/MAL/HDP/5 233	CADILA PHARMACEUTICAL S LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	ENVAS 10 MG TABLETS	ENALAPRIL	10MG	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997
2933	NDA/MAL/HDP/5 234	CADILA PHARMACEUTICAL S LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	ENVAS 5MG TABLETS	ENALAPRIL MALEATE	5MG	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997

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2934	NDA/MAL/HDP/5 235	UNIQUE PHARMACEUTICAL S LABORATORIES	PLANET PHARMACEUTICAL S UGANDA LTD	DICLORAN DELAYED-RELEASE TABLETS	DICLOFENAC SODIUM	50MG	UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)-216-219 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH GLOBELA PHARMA PVT.LTD.357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID RETARD ENTERIC- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,5.0X2.0 X10.0 TABLET BLISTER	01/07/1997
2935	NDA/MAL/HDP/5 243	IND SWIFT LTD	PLANET PHARMACEUTICAL S UGANDA LTD	EZO 20	ESOMEPRAZOLE MAGNESIUM	20MG	IND-SWIFT- LTD,GLOBAL BUSINESS UNIT, JAWAHARPUR, OFF NH-21 DERABASSI	INDIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013

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2936	NDA/MAL/HDP/5 245	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	FABUTAS-40	FEBUXOSTAT	40MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
2937	NDA/MAL/HDP/5 248	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM-AMPI	AMPICILLIN	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE CONTAINER,1.0X10 0.0 CAPSULE CONTAINER,1.0X10 00.0 CAPSULE CONTAINER,1.0X50 0.0 CAPSULE CONTAINER,1.0X25 0.0 CAPSULE CONTAINER	01/07/1997

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2938	NDA/MAL/HDP/5 249	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	ENCIFER	IRON SUCROSE	100MG/5ML	SAMRUDH PHARMACEUTICALS PVT LTDJ-174, J-168 & J-168/1, MIDC, TARAPUL, BOISAR, DIST THANE-401506 EMCURE PHARMACEUTICALS LTD PLOT NO. P-1 ITBT PARK PHASE II MIDC HINJWADI PUNE 411057	INDIA	PARENTERAL ORDINARY INFUSION AMPOULES	1.0X5.0X5.0 ML AMPOULE	01/07/2013
2939	NDA/MAL/HDP/5 250	PHARCO PHARMACEUTICAL S	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCOLIN SYRUP	SALBUTAMOL + AMMONIUM CHLORIDE	2MG/5ML +100MG/5ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT, P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/1998

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2940	NDA/MAL/HDP/5 255	GLAXOSMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ENO LEMONFRUIT SALT	MULTI- INGREDIENT	MULTI- INGREDIENT	GLAXO SMITH KLINE LTDLIKONI RD, INDUSTRIAL AREA,NAIROBI KENYA	KENYA	ORAL LIQUID ORDINARY EFFERVESCENT POWDERS/GRANU LES	1.0X8.0X4.5 G SACHET,1.0X10.0X4 .5 G SACHET,1.0X48.0X4 .5 G SACHET,1.0X4.0X4. 5 G SACHET,1.0X24.0X4 .5 G SACHET	01/07/1997
2941	NDA/MAL/HDP/5 256	ORGANON SOUTH AFRICA (PTY) LTD	SURGIPHARM (U) LIMITED	DIPROFOS INJECTION	BETAMETHASONE DISODIUM PHOSPHATE + BETAMETHASONE DIPROPIONATE	2MG + 5MG/ML	SCHERING-PLOUGH LABO N.V-- INDUSTRIE PARK 30, ZONE A 2220 HEIST- OP-DEN-BERG	BELGIUM	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE	01/07/2001

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2942	NDA/MAL/HDP/5 260	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	ERYMYCIN	ERYTHROMYCIN ESTOLATE	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997
2943	NDA/MAL/HDP/5 263	ORGANON SOUTH AFRICA (PTY) LTD	SURGIPHARM (U) LIMITED	DIPROSALIC OINTMENT	BETAMETHASONE + SALICYLIC ACID	0.5 %W/W + 0.3 %W/W	SCHERING-PLOUGH LABO N.V-- INDUSTRIE PARK 30, ZONE A 2220 HEIST- OP-DEN-BERG	BELGIUM	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 MG TUBE	01/07/2001



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2944	NDA/MAL/HDP/5 269	INTAS, PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	DIVAA OD 500	DIVALPROEX	500MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2010
2945	NDA/MAL/HDP/5 271	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	ERYTHYL SYRUP	ERYTHROMYCIN ETHYL SUCCINATE	125MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

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2946	NDA/MAL/HDP/5 272	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	DIX	DIGOXIN	0.25MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2011
2947	NDA/MAL/HDP/5 279	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DOSIN	DOXAZOCIN	2MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2011

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2948	NDA/MAL/HDP/5 281	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	EFAVIRENZ+EMTRICITABINE+TENOFVIR DISOPROXIL	EFAVIRENZ + EMTRICITABINE + TENOFVIR DISOPROXIL FUMARATE	600MG +200MG + 300MG	AUROBINDO PHARMA LTD UNIT VIISEZ SURVEY NO. 411/P,425/P, 434/P, 435/P AND 458/P PLOT NO S1 ( PART) SPECIAL ECONOMIC ZONE GREEN INDUSTRIAL PARK POLEPALLY VILLAGRE ANDHRA PRADESH 509302	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2015
2949	NDA/MAL/HDP/5 282	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	DORFEN	ACECLOFENAC	100MG	TRIVENI FORMULATIONS LIMITED -PLOT NO 52-54,62-64 ALEAP INDUSTRIAL ESTATE SURAMPALLI (V) VIJAYAWADA A.P	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014

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2950	NDA/MAL/HDP/5 283	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	IBUMEX GEL	IBUPROFEN	5%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL EMULSION GELS	1.0X25.0 G TUBE	01/07/2001
2951	NDA/MAL/HDP/5 284	HETERO LABS LTD	AIVEEN (U) LIMITED	EFAVIRENZ+EMTR ICITABINE+TENOF OVIR	EFAVIRENZ + EMTRICITABINE + TENOFVIR	600MG + 200MG + 300MG	HETERO LABS LTD(UNIT V).JADCHERLA (M),MAHABOBNAG AR DIST, ANDHRA PRADESH,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2012

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2952	NDA/MAL/HDP/5 287	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	EFAVIRENZ + LAMIVUDINE + TENOFVIR DISOPROXIL FUMERATE	EFAVIRENZ + LAMIVUDINE + TENOFVIR DISOPROXIL FUMERATE	600MG + 300MG + 300MG	AUROBINDO PHARMA LIMITED (SEZ, UNIT – VII), SURVEY NO.411, 425, 434, 435 & 458, APIIC, PLOT NO. SI GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHERLA MANDAL, MAHABOOB NAGAR DISTRICT, HYDERABAD, ANDHRA PRADESH 500090, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2014
2953	NDA/MAL/HDP/5 288	REGAL PHARMAEUICALS LTD	REGAL PHARMA (U) LTD	IBUMEX SUSPENSION	IBUPROFEN	100MG/5ML	REGAL PHARMAEUICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	100.0 ML BOTTLE,60.0 ML BOTTLE,1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/1997

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2954	NDA/MAL/HDP/5 290	ORGANON SOUTH AFRICA (PTY) LTD	SURGIPHARM (U) LIMITED	ELOCOM CREAM	MOMETASONE FUROATE	0.1%W/W	SCHERING-PLOUGH LABO N.V-- INDUSTRIE PARK 30,B-2220 HEIST-OP- DEN-BERG,BELGIUM	BELGIUM	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2000
2955	NDA/MAL/HDP/5 291	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	IBUMEX TABLET	IBUPROFEN	200MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	10.0X10.0 TABLET BLISTER,1.0X20.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER	01/07/1997

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2956	NDA/MAL/HDP/5 292	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	DOMI 10	DOMPERIDONE	10MG	LINCOLN PHARMACEUTICAL LIMITEDTRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2011
2957	NDA/MAL/HDP/5 294	ORGANON SOUTH AFRICA (PTY) LTD	SURGIPHARM (U) LIMITED	ELOCOM OINTMENT	MOMETASONE FUROATE	0.1%W/W	SCHERING-PLOUGH LABO N.V-- INDUSTRIE PARK 30,B-2220 HEIST-OP- DEN-BERG,BELGIUM	BELGIUM	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/2000

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2958	NDA/MAL/HDP/5 295	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	DOXY	DOXYCYCLINE	100MG	LABORATORY & ALLIED LTD-PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X280.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER	01/07/2000
2959	NDA/MAL/HDP/5 297	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELOGYL	METRONIDAZOLE	200MG	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997



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2960	NDA/MAL/HDP/5 298	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELOGYL	METRONIDAZOLE	200MG/5ML	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/1997
2961	NDA/MAL/HDP/5 299	PHARMA INTERNATIONAL.C O	OMAB UGANDA LIMITED	KENAZOLE	KETOCONAZOLE	20MG/ML	PHARMA INTERNATIONAL COMPANY „AL- QASTAL INDUSTRIAL AREA/AMMAN	JORDAN	TOPICAL EXTERNAL LIQUID SOAPS/WASHES	1.0X100.0 ML BOTTLE	01/07/2014

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2962	NDA/MAL/HDP/5 300	CADILA PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	DOLAC	KETOROLAC TROMETHAMINE	30MG	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2015
2963	NDA/MAL/HDP/5 302	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	IBUGO-COMBI	IBUPROFEN + PARACETAMOL + CAFFEINE	200MG + 325MG + 30MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER,1.0X10.0X1 0.0 CAPSULE BLISTER,1.0X100.0X 10.0 CAPSULE BLISTER	01/07/2014

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2964	NDA/MAL/HDP/5 305	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	IBUGO - 200	IBUPROFEN	200MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2008
2965	NDA/MAL/HDP/5 307	USV PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DUOTROL	GLYBURIDE + METFORMIN HYDROCHLORIDE	5MG + 500MG	FREDUN PHARMACEUTICALS LIMITED--14,15,16 ZORABIAN INDUSTRIAL COMPLEX PALAGHAR (EAST), DIST THANE 401 404 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

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2966	NDA/MAL/HDP/5 311	ABBOTT HEALTHCARE PRODUCTS B.V.	HARLEYS UGANDA LIMITED	DUPHASTON TABLETS	DYDROGESTERON E	10MG	ABBOTT BIOLOGICALS B.V ABBOTT BIOLOGICALS B.V VEERWEG 12 8121 AA OLST	NETHERLANDS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X20.0 TABLET BLISTER	01/07/2001
2967	NDA/MAL/HDP/5 312	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	DOXYCYCLINE	DOXYCYCLINE	100MG	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0 CAPSULE CONTAINER	01/07/2005

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2968	NDA/MAL/HDP/5 316	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DYNAPAR	DICLOFENAC SODIUM + PARACETAMOL	50MG + 500MG	TROIKAA PHARMACEUTICALS LTD .SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
2969	NDA/MAL/HDP/5 317	MACK BROWN	SHURIK LTD	DR MAC'S COUGH FORMULA	TERBUTALINE SULPHATE+BROM HEXINE HYDROCHLORIDE +GUAIFENESIN+M ENTHOL	2.5MG+8.0MG+10 0MG+5MG	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2003

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2970	NDA/MAL/HDP/5 318	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DYNAPAR AQ (1ML)	DICLOFENAC SODIUM	75MG/ML	TROIKAA PHARMACEUTICALS LTD .SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE	01/07/2009
2971	NDA/MAL/HDP/5 320	LEBEN LABORATORIES PVT.LTD	MALIX PHARMA (U) LIMITED	INDOL	INDOMETHACIN	25MG	LEBEN LAB PVT LTDL4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X10. 0X10.0 CAPSULE BLISTER,1.0X100.0X 10.0 CAPSULE BLISTER	01/07/2010

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2972	NDA/MAL/HDP/5 321	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	IBUGESIC COLD & SINUS	IBUPROFEN/PSEU DOEPHEDRINE	200MG/30MG	DAR AL DAWANA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY GELATIN-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2012
2973	NDA/MAL/HDP/5 323	STEDMAN PHARMACEUTICALS LTD	VEERAM HEALTHCARE (U) LIMITED	DREZ	IODINATED POVIDONE + METRONIDAZOLE	1.0% W/V + 5.0% W/V	STEDMAN PHARMACEUTICALS PVT LTD...C-4, SIDCO PHARMACEUTICAL COMPLEX ALATHUR, THIRUPORUR	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X60.0 ML CONTAINER,1.0X30. 0 ML CONTAINER,1.0X10 0.0 ML CONTAINER,1.0X50 0.0 ML CONTAINER	01/07/2010

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2974	NDA/MAL/HDP/5 324	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	IBUFIL 400	IBUPROFEN	400MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDAL UR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1998
2975	NDA/MAL/HDP/5 326	UNIQUE PHARMACEUTICAL S LABORATORIES	PLANET PHARMACEUTICAL S UGANDA LTD	ECODAX G CREAM	ECONAZOLE NITRATE + GENTAMYCIN + BECLAMETASONE	1%+0.1%+0.025%	UNIQUE PHARMACEUTICAL LABORATORIESPLOT NO. 215-219, G.I.D.C. INDUSTRIAL AREA,PANOLI — 394 116, GUJARAT, INDIA.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE,1.0X100.0 G TUBE	01/07/1997



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2976	NDA/MAL/HDP/5 327	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	IBUFIL 200	IBUPROFEN	200MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDAL UR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997
2977	NDA/MAL/HDP/5 329	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	IBUFEN TABLETS	IBUPROFEN	200MG	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/1997

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2978	NDA/MAL/HDP/5 330	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	DREZ-V	MICONAZOLE + METRONIDAZOLE	2.0%W/W + 1.0%W/W	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/2011
2979	NDA/MAL/HDP/5 333	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	IBUFEN	IBUPROFEN	200MG	KPI ( KAMPALA PHARMACEUTICAL INDUSTRIES LTD PLOT M444 B STRETCHER ROAD NTINDA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X100.0X10.0 TABLET BLISTER,500.0 TABLET CONTAINER,1000.0 TABLET CONTAINER,250.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1997

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2980	NDA/MAL/HDP/5 338	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	HYDROSIL TABLETS	ALUMINIUM HYDROXIDE+MAG NESIUM HYDROXIDE+SIME THICONE	200MG+200MG+2 0MG	XEPA-SOUL PATTINSON (MALAYSIA) SDA BHD1-5, CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X20.0 TABLET BLISTER	01/07/1997
2981	NDA/MAL/HDP/5 341	LABORATORY&ALLI ED LTD	HARLEYS UGANDA LIMITED	HYDOPA	METHYLDOPA	250MG	LABORATORY & ALLIED LTD PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997

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2982	NDA/MAL/HDP/5 346	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFUTIL 500	CEFUROXIME AXETIL	500MG	PHARMA INTERNATIONAL COMPANY MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET CONTAINER	01/07/2014
2983	NDA/MAL/HDP/5 347	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	CEFUTIL 250	CEFUROXIME AXETIL	250MG	PHARMA INTERNATIONAL COMPANY MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2014

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2984	NDA/MAL/HDP/5 348	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	CELEPID 20	INTRAVENOUS FAT EMULSION	20%W/V	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTDVILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X250.0 ML BOTTLE,1.0X500.0 ML BOTTLE	01/07/2005
2985	NDA/MAL/HDP/5 352	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICAL S LTD	MUMFER	IRON(111) POLYMALTOSE COMPLEX	50MG/5ML	GLENMARK PHARMACEUTICALS LTD PLOT E PLOT NO. E-37, 39, MIDC AREA, SATPUR, NASIK - 422 007, MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X150.0 ML BOTTLE	01/07/2005

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2986	NDA/MAL/HDP/5 356	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	BURNNEM	MULTI- INGREDIENT	N/A	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/1997
2987	NDA/MAL/HDP/5 358	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	CADISTIN EXPECTORANT	CHLORPHENIRAM INE MALEATE + GUAIFENESIN + AMMONIUM CHLORIDE + SODIUM CITRATE + LEVOMENTHOL + TERPIN HYDRATE + TOLU BALSAM + VASAKA SYRUP	(2MG + 80MG + 100MG + 44MG + 0.8MG + 4MG + 6MG + 0.133ML)/5ML	SAKAR HEALTHCARE PVT LTD SAKAR HEALTHCARE PVT LTD, BLOCK NO 10- 13, M.N. DESA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE, 1.0X60.0 ML BOTTLE	01/07/1997

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2988	NDA/MAL/HDP/5 361	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	CALFIC	MULTI- INGREDIENT	N/A	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997
2989	NDA/MAL/HDP/5 362	ASTRA ZENECA	MACNAUGHTON LIMITED	CASODEX 150MG	BICALUTAMIDE	150MG	ASTRAZENECA MACCLESFIELDCHES HIRE	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	2.0X14.0 TABLET STRIP	01/07/2001

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2990	NDA/MAL/HDP/5 363	ASTRA ZENECA	MACNAUGHTON LIMITED	CASODEX 50MG	BICALUTAMIDE	50MG	BULK CORDEN PHARMA GMBHOTT HAHN STRASSE ,68723 GERMANY ASTRA ZENECA UK LIMITEDASTRAZENECA UK LIMITED SILK ROAD BUSINESS PARK, MACCLES FIELD,CESHIRE SK 10 2NA,	UNITED KINGDOM GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/1997
2991	NDA/MAL/HDP/5 366	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	CEFIM	CEFIXIME	400MG	HILTON PHARMA (PVT) LTD PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X5.0 CAPSULE STRIP	01/07/2005



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2992	NDA/MAL/HDP/5 367	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	CEFIM	CEFIXIME	100MG/5ML	HILTON PHARMA (PVT) LTD PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE, 1.0X30.0 ML BOTTLE	01/07/2005
2993	NDA/MAL/HDP/5 368	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	CEFIX 100MG/5ML DRY SUSPENSION	CEFIXIME	100MG/5ML	PHARMA INTERNATIONAL CO. AMMAN JORDAN PLANT AL-QARTAL MARKETING DEPARTMENT ALBUJAH COMPLEX, ALJUBAIHA	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE, 1.0X30.0 ML BOTTLE	01/07/2007

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2994	NDA/MAL/HDP/5 370	COSMOS LTD	ASTRA PHARMA (U) LIMITED	HYOSCINE BUTYLBROMIDE	HYOSCINE N- BUTYLBROMIDE	10 MG	COSMOS LIMITED RANGWA ROAD, OFF LUNGA LUNGA ROAD, INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X1000.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2010
2995	NDA/MAL/HDP/5 377	JOHNSON&JOHNS ON PTY LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	BENYLIN FOUR FLU LIQUID	DIPHENHYDRAMINE + PARACETAMOL + PSEUDOEPHEDRINE	25MG/20ML + 1G/20ML + 45MG/20ML	JOHNSON&JOHNSON PTY LTD.EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2001

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

2996	NDA/MAL/HDP/5 379	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ZOLANAS-30	LANSOPRAZOLE	30MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER,1.0X10.0X1 0.0 CAPSULE BLISTER	01/07/2008
2997	NDA/MAL/HDP/5 380	CIRON DRUGS & PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	CIROZEP	DIAZEPAM	5MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD .N- 118,M.I.D.C, TARAPUR,BOISAR, DIST.THANE-401506, MAHARASHTRA,INDI A.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE	01/07/2013

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2998	NDA/MAL/HDP/5 381	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	ADIFLAM GEL	DICLOFENAC DIETHYLAMINE	1.16%W/W	LEBEN LABORATORIES PVT. LTD PLOT NO. L-4, PHASE-III, MIDC, AKOLA- 444 104 (MS).	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/2008
2999	NDA/MAL/HDP/5 386	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	UDIHEP TABLETS	URSODEOXYCHOL IC ACID	150MG	WIN- MEDICARE LTDMODIPURAM - 250 110,UTTAR PRAADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2001

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3000	NDA/MAL/HDP/5 388	IPCA LABORATOIES LTD	MEDVIN PHARMA LIMITED	LARINATE-60	ARTESUNATE	60MG	IPCA LABORATORIES LTD,- SEJAVTA,RATLAM 457-002 REG.OFF.48 KANDIVLI IND.ESTATE MUMBAI 400067	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 1*5 ML SODIUM CHLORIDE INJECTION + 1*1 ML AMPOULE OF SODIUM BICARBONATE INJECTION	01/07/2011
3001	NDA/MAL/HDP/5 389	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LUMARTEM	ARTEMETHER + LUMEFANTRINE	20MG + 120 MG	CIPLA LTD., PATALGANGA UNIT I & UNIT II PLOT NO. A- 33(UNIT-I), A-42( UNIT-II), MIDC PATALGANGA, 410220 DISTRICT RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X24.0 TABLET BLISTER,1.0X1.0X6. 0 TABLET BLISTER,1.0X30.0X6 .0 TABLET BLISTER,1.0X1.0X12 .0 TABLET BLISTER,1.0X1.0X18 .0 TABLET BLISTER,1.0X30.0X1 2.0 TABLET BLISTER,1.0X30.0X1 8.0 TABLET BLISTER,1.0X30.0X2 4.0 TABLET BLISTER	01/07/2011

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3002	NDA/MAL/HDP/5 391	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	NITROFURANTOIN	NITROFURANTOI N	100MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2008
3003	NDA/MAL/HDP/5 392	DENK PHARMA GMB H & CO. KG	BENLE CONSULT LIMITED	AMLO-DENK 10	AMLODIPINE MESILATE MONOHYDRATE	10MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2008

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3004	NDA/MAL/HDP/5 393	DENK PHARMA GMB H & CO. KG	BENLE CONSULT LIMITED	AMLO-DENK 5	AMLODIPINE MESILATE MONOHYDRATE	5MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2008
3005	NDA/MAL/HDP/5 394	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	FINAZOL	ALBENDAZOLE	400MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDAL UR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	01/07/2007

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3006	NDA/MAL/HDP/5 395	MICRO LABS LTD	LABOREX UGANDA LIMITED	OFLOX	OFLOXACIN	200MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
3007	NDA/MAL/HDP/5 400	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	ALBEN SUSPENSION	ALBENDAZOLE	400MG/10ML	PANACEA BIOTEC LTD MALPUR, BADDI, TEHSIL, NALAGARH, DIST. SOLAN (H.P) – 173 205	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	01/07/1999



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3008	NDA/MAL/HDP/5 404	INTAS, PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	HIFENAC P	ACECLOFENAC + PARACETAMOL	100 MG + 500 MG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI- 248197, DEHRADUN (UTTARAKHAND)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
3009	NDA/MAL/HDP/5 406	INTAS, PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	HIFENAC SR	ACECLOFENAC	200 MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2007

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3010	NDA/MAL/HDP/5 407	THEMIS PHARMACEUTICAL S	STAR PHARMACEUTICAL S LTD	E MAL-75	ALPHA-BETA ARTEETHER	75MG/ML	THEMIS MEDICARE LTD SECTOR 6A, PLOT NO. 16 TO 18, IIE, BHEL HARIDWA, UTTARAKHAND	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X3.0X1.0 ML AMPOULE	01/07/2013
3011	NDA/MAL/HDP/5 410	MEDICAL UNION PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	UNICTAM 1500	AMPICILLIN + SULBACTAM	1000 MG + 500 MG	MEDICAL UNION PHARMACEUTICALS LTD - ABU SULTAN, CR 13363 ISMAILIA, EGYPT	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	01/07/2009

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3012	NDA/MAL/HDP/5 414	ACINO PHARMA AG	LABOREX UGANDA LIMITED	XYLO-ACINO 0.1%	XYLOMETAZOLINE	0.1 % W/V	MERCKLE GMBH,LUDWIG MERCKLE STRASSE3 D-89143 BLAUBEUREN	GERMANY	NASAL TOPICAL DROPS	1.0X1.0X10.0 ML BOTTLE	01/07/2007
3013	NDA/MAL/HDP/5 415	CENTAUR PHARMACEUTICAL S PVT. LTD	GITTOES PHARMACEUTICAL S LIMITED	SINAREST	OXYMETAZOLINE	0.05%W/V	CENTAUR PHARMACEUTICALS PVT LTD -PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	NASAL TOPICAL DROPS	1.0X10.0 ML BOTTLE	01/07/2009

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3014	NDA/MAL/HDP/5 416	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	CIPROX	CIPROFLOXACIN	0.2%W/V	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTDVILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2005
3015	NDA/MAL/HDP/5 417	PHARMA INTERNATIONAL.C O	OMAB UGANDA LIMITED	CIPROPHARM	CIPROFLOXACIN	500MG	PHARMA INTERNATIONAL COMPANYMAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2007

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3016	NDA/MAL/HDP/5418	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	PAEDIATRIC CO-TRIMOXAZOLE	CO-TRIMOXAZOLE	240MG/5ML	MACLEODS PHARMACEUTICALS LTD(BLOCK N2)VILLAGE THEDA,P.O LODHI MAJRA,TEHSIL BADDI,HIMACHAL PRADESH 174101	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2005
3017	NDA/MAL/HDP/5419	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGO-CPM	CHLORPHENIRAMINE	4MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER	01/07/2005

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3018	NDA/MAL/HDP/5 423	HETERO LABS LTD	AIVEEN (U) LIMITED	EFAVIRENZ+LAMI VUDINE+TENOF VIR	EFAVIRENZ+LAMI VUDINE+TENOF VIR	600MG/300MG/30 0MG	HETERO LABS LTD. UNIT (V) .S.NO.439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA. HETERO DRUGS LTDUNIT-111 NO 22-110 I.D.A JEEDIMETTA HYDRABAD 500055	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER,1.0X90. 0 TABLET JAR,1.0X100.0 TABLET JAR	01/07/2013
3019	NDA/MAL/HDP/5 425	ROYAL GROUP	HARLEYS UGANDA LIMITED	PARACETAMOL	PARACETAMOL	500MG	HEBEI (JIHENG GRP) PHARMACEUTICALS CO.LTD-INDIA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014

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3020	NDA/MAL/HDP/5 427	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	NIRCIP	CIPROFLOXACIN	200MG/100MG	ACULIFE HEALTHCARE PVT. LTDVILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2010
3021	NDA/MAL/HDP/5 428	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	CIPFIL 500	CIPROFLOXACIN	500MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDAL UR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007

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3022	NDA/MAL/HDP/5 429	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	CIPRO-500	CIPROFLOXACIN	500MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10 0.0 TABLET CARTON	01/07/2006
3023	NDA/MAL/HDP/5 434	MEDIPHARM (EA) LTD	MEDIPHARM INDUSTRIES (E.A) LTD	ORALYTE CO- PACK	DT ZINC-20 + ORAL REHYDRATION SALTS (ORS)	20G	MEDIPHARM INDUSTRIES( EA) LTD PLOT 65 KAKAJJO ROAD BWEYOGERERE P.O.BOX 6218,KAMPALA,UGA NDA AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY OTHER SPECIAL FORMS	1.0X2.0X20.5 G SACHET + 1.0*10.0 TABLET BLISTER	01/07/2016



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3024	NDA/MAL/HDP/5 435	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	PIC	PARACETAMOL+I BUPROFEN+CAFF EINE	500MG+200MG+3 OMG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X25.0X4.0 TABLET STRIP	01/07/2015
3025	NDA/MAL/HDP/5 439	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENIRON SYRUP	VITAMIN B6 + FERROUS GLUCONATE + VITAMIN B1 + VITAMIN C + VITAMIN B2	2MG/5ML + 200MG/5ML + 2MG/5ML + 20MG/5ML + 2MG/5ML	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2001

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3026	NDA/MAL/HDP/5 441	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL NASATAB TABLETS	PARACETAMOL+C HLORPHENIRAMI NE+PSEUDOEPHE DRINE	500MG+4MG+60M G	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X100.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2008
3027	NDA/MAL/HDP/5 442	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	CHLORAMPHENIC OL OPHTHALMIC OINTMENT USP 1%	CHLORAMPHENIC OL	1%W/W	NEM LABORATORIES PVT LTD133 KRISHNA INDUSTRIAL ESTATE VASAI (E) DIST THANE 401 210 MAHARASHTRA	INDIA	OPHTHALMIC OINTMENTS	1.0X20.0X3.5 G TUBE	01/07/2013

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3028	NDA/MAL/HDP/5 444	ORGANON SOUTH AFRICA (PTY) LTD	SURGIPHARM (U) LIMITED	AERIUS TABLETS	DESLORATIDINE	5MG	SCHERING PLOUGH LABO NV-INDUSTRIE PARK 30, ZONE A, 2220, HEIST OP-DEN- BERG	BELGIUM	ORAL SOLID ORDINARY TABLETS	1.0X2.0X15.0 TABLET BLISTER	01/07/2001
3029	NDA/MAL/HDP/5 445	ESKAYEF PHARMACEUTICAL S LTD	SWASTIK PHARMACEUTICAL LTD	AZITHRAX 500	AZITHROMYCIN DIHYDRATE	500 MG	ESKAYEF BANGLADESH LTD- 400, TONGI INDUSTRIAL AREA, SQUIB ROAD TONGI- GAZIPUR BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X6.0 TABLET BLISTER,1.0X1.0X3. 0 TABLET BLISTER	01/07/2014

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3030	NDA/MAL/HDP/5 447	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	DICLOFENAC	DICLOFENAC SODIUM	50MG	TRIVENI FORMULATION LTD PLOT NO.52,53,54,63,62,6 4, ALEAP INDUSTRIAL ESTATE SURAMPALI, AP-INDIA – 521212	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CARTON,1.0X10.0X 10.0 TABLET BLISTER	01/07/2012
3031	NDA/MAL/HDP/5 449	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	CLOFENAC 50	DICLOFENAC SODIUM	50MG	HOVID BERHAD (CHEMOR SITE)-LOT 56442, 71/2, JALAN IPOH/CHEMOR 31200, PERAK. MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010

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3032	NDA/MAL/HDP/5 457	RAJESHI PLASTICS	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	FALCIMON 100/270 B/L	ARTESUNATE+AM ODIAQUINE	100MG+270MG	CIPLA LTD UNIT IIA- 42 MIDC PATALGANGA DISTRICT RAIGAD MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X25.0X3 .0 TABLET BLISTER,1.0X25.0X6 .0 TABLET BLISTER	01/07/2014
3033	NDA/MAL/HDP/5 458	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	FALCIMON 50/135 B/L	ARTESUNATE+AM ODIAQUINE	50MG+135MG	CIPLA LTD UNIT IIA- 42 MIDC PATALGANGA DISTRICT RAIGAD MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER,1.0X25.0X3 .0 TABLET BLISTER	01/07/2014

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3034	NDA/MAL/HDP/5 460	GUILIN PHARMACEUTICAL S CO.LTD	TRIDEM PHARMA UGANDA LIMITED	ASAQ GPSC	ARTESUNATE+AM ODIAQUINE	50MG+135MG	GUILIN PHARMACEUTICALS CO. LTDNO 43 QULIDIAN ROAD GUILIN GUANGXI CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0X20.0 TABLET BLISTER,1.0X25.0X3 .0 TABLET BLISTER,1.0X25.0X6 .0 TABLET BLISTER	01/07/2011
3035	NDA/MAL/HDP/5 464	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	CO-METHER	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	AGOG PHARMA LTDPLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X4.0 TABLET BLISTER,1.0X3.0X8. 0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,2.0X6.0 TABLET BLISTER,4.0X6.0 TABLET BLISTER,1.0X1.0X24 .0 TABLET BLISTER,1.0X1.0X6. 0 TABLET BLISTER,1.0X1.0X12 .0 TABLET BLISTER 1.0X30.0X6	01/07/2007

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3036	NDA/MAL/HDP/5 467	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMSIDAR	SULFADOXINE/PY RIMETHAMINE	525MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CARTON,1.0X250.0 TABLET CONTAINER,1.0X50 0.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	01/07/1997
3037	NDA/MAL/HDP/5 469	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	NIMOTOP	NIMODIPINE	0.2MG/ML	SOLUPHARM GMBH INDUSTRIESTRASSE 3, 34212 MELSUNGEN BAYER PHARMA AG 51368 LEVERKUSEN GERMANY	GERMANY	PARENTERAL ORDINARY I V VIALS	1.0X50.0 ML VIAL	01/07/2009

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3038	NDA/MAL/HDP/5 471	MICRO LABS LTD	LABOREX UGANDA LIMITED	AVAS 40	ATORVASTATIN	40MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
3039	NDA/MAL/HDP/5 472	CLARIS OTSUKA LIMITED	REDDYS PHARMA LIMITED	NS	SODIUM CHLORIDE	0.9%W/V	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTDVILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X250.0 ML BOTTLE,1.0X500.0 ML BOTTLE,1.0X100.0 ML BAG	01/07/2007



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3040	NDA/MAL/HDP/5 473	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TROYPOFOL	PROPOFOL	1%W/V	TROIKAA PHARMACEUTICALS LTD .C-1 SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL	01/07/2012
3041	NDA/MAL/HDP/5 474	PHARMA INTERNATIONAL.C O	OMAB UGANDA LIMITED	CEFODOX	CEFPODOXIME PROXETIL	200MG	PHARMA INTERNATIONAL CO.AMMAN JORDAN PLANT AL-QARTAL MARKETING DEPARTMENT ALBUJAH COMPLEX, ALJUBAIHA	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2005

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3042	NDA/MAL/HDP/5 476	ACINO PHARMA AG	LABOREX UGANDA LIMITED	MESPORIN 1000MG I.V	CEFTRIAXONE	1000MG	LABESFAL LABORATORIESALMI RO S.A ZONA INDUSTRIAL DO LAGEDO, 3465-157, SANTIAGO DE BESTERIOS PORTUGAL	PORTUGAL	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL + 10 ML WFI	01/07/2002
3043	NDA/MAL/HDP/5 478	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	BECORT 50	BECLOMETHASON E DIPROPIONATE	50MCG/ACTUATIO N	CIPLA LTD.- PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X1.0X200.0 METERED DOSE CANNISTER	01/07/2010

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3044	NDA/MAL/HDP/5 479	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	RANFERON 12 CAPSULES	MULTI- INGREDIENT	MULTI- INGREDIENT	SUN PHARMACEUTICAL INDUSTRIES LIMITED,INDUSTRIAL AREA NO.3, A.B.ROAD DEWAS,455001 MADHYA PRADESH INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X30.0 CAPSULE BLISTER	01/07/1997
3045	NDA/MAL/HDP/5 482	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGO-LIN	SALBUTAMOL	2MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2010

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3046	NDA/MAL/HDP/5 483	GUILIN PHARMACEUTICAL S CO.LTD	TRIDEM PHARMA UGANDA LIMITED	ASAQ GPSC	ARTESUNATE + AMODIAQUINE	25 MG + 67.5 MG	GUILIN PHARMACEUTICALS CO. LTDNO 43 QULIDIAN ROAD GUILIN GUANGXI CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0X20.0 TABLET BLISTER,1.0X25.0X3 .0 TABLET BLISTER,1.0X25.0X6 .0 TABLET BLISTER	01/07/2011
3047	NDA/MAL/HDP/5 486	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	FOSEAL 400	SEVELAMER HCL	400MG	EMCURE PHARMACEUTICALS LIMITEDPLOT NO. P- 2. ITBT PARK, PHASE II, MIDC, HINJWADI PUNE 411057, MHARASHTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X6.0X10 .0 TABLET BLISTER	01/07/2009

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3048	NDA/MAL/HDP/5 489	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	CORBIS-5	BISOPROLOL	5MG	UNICHEM LABORATORIES LIMITED UNIT IIVILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2008
3049	NDA/MAL/HDP/5 495	AGOG PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	AGOCAL TABLETS	CALCIUM LACTATE	300MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2001

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3050	NDA/MAL/HDP/5 496	ASTRAZENECA AG	MACNAUGHTON LIMITED	ATACAND 16MG	CANDESARTAN CILEXETIL	16MG	ASTRA ZENECA ABSE- 151 85 SODERTALJE, SWEDEN (GARTUNAVAGEN & SNACKVIKEN)	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2010
3051	NDA/MAL/HDP/5 497	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	EXPEN	BENZYL PENICILLIN	1MU	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X1.0 MU VIAL,1.0X10.0X1.0 MU VIAL,1.0X100.0X1.0 MU VIAL	01/07/2011

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3052	NDA/MAL/HDP/5 591	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	SWISSCILLIN	AMPICILLIN	500MG	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL	01/07/2011
3053	NDA/MAL/HDP/5 619	CADILA PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S LTD.	RABELOX 20	RABEPRAZOLE SODIUM	20MG	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X1.0X10.0 TABLET STRIP	01/07/2006

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3054	NDA/MAL/HDP/5644	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	FORTIFIED PROCAINE PENICILLIN	FORTIFIED PROCAINE PENICILLIN	4 MEGA UNITS	CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHUANG) CO. LTD WORKSHOP NO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA WORKSHOP 406 AND 407	CHINA	PARENTERAL ORDINARY VIALS	1.0X4.0 MU VIAL	01/07/2001
3055	NDA/MAL/HDP/5648	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD	TATA UGANDA LIMITED	CLOXACILLIN SODIUM	CLOXACILLIN SODIUM	500MG	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD #14, II PHASE PIA, BANGALORE 560058	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X500.0 MG VIAL	01/07/2010



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3056	NDA/MAL/HDP/6032	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	MET XL 100	METOPROLOL SUCCINATE	100MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/03/2019
3057	NDA/MAL/HDP/6034	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOXIN -250 DT	AMOXICILLIN TRIHYDRATE	250 MG	MILAN LABS PVT LTD63-67 JAWAHAR CO.OP. INDUSTRIAL ESTATE KAMOTHE,NAVI MUMBAI	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER	01/07/2016

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3058	NDA/MAL/HDP/6 036	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	OFLOTECH-O	OFLOXACIN + ORNIDAZOLE	200MG + 500MG	AKUMS DRUGS & PHARMACEUTICALS LTD19-20,21, SECTOR 6-4, SIDCUL, IIE, RANIPUR HARIDWAR-249403	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	27/03/2019
3059	NDA/MAL/HDP/6 037	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AVIT	VITAMIN A	200,000 IU	OLIVE HEALTHCARE197/2, ATHIYAWAD DABHEL VILLAGE DAMAN 396210 (U.T)	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X30.0 CAPSULE BLISTER,1.0X10.0X1 0.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE JAR	01/07/2017

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3060	NDA/MAL/HDP/6 040	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	U-TRYP	ULINASTATIN	100,000 I.U	BHARAT SERUMS AND VACCINES LIMITED,PLOT NO. K- 27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	01/07/2017
3061	NDA/MAL/HDP/6 041	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	CANDIZOL	CLOTRIMAZOLE	100MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	VAGINAL TABLETS	1.0X6.0 PESSARY STRIP	01/07/2017

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3062	NDA/MAL/HDP/6 050	MICRO LABS LTD	LABOREX UGANDA LIMITED	ITACARE	ITRACONAZOLE	100MG	MICRO LABS LTD 92 SIPCOT 92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER,1.0X10.0 CAPSULE BLISTER	01/07/2017
3063	NDA/MAL/HDP/6 057	BROOKES PHARMACEUTICAL LABORATORIES L	HARLEYS UGANDA LIMITED	CORAM 5MG	AMLODIPINE BESYLATE	5MG	BROOKES PHARMACEUTICALS LABORATORIES (PAKISTAN) LTD PLOT 58 SECTOR 15 KORANGI INDUSTRIAL AREA, KARACHI-PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2009

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3064	NDA/MAL/HDP/6 059	RESONANT PHARMACEUTICAL S PVT LTD	SHREEJI PHARMACEUTICAL S LIMITED	NEUROZONE	MECOBALAMIN + PREGABALIN	750MCG + 75MG	ACME FORMULATION PVT LTD. ROPAR ROAD NALAGARH DIST SOLAN (H.P) -174 101	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2017
3065	NDA/MAL/HDP/6 065	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	PROXYREN	PIROXICAM	20MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2017

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3066	NDA/MAL/HDP/6067	RENE PHARMACY(R) LTD..	RENE PHARMACY LTD	DIAZEPAM	DIAZEPAM	5MG	NEM LABORATORIES PVT LTD133 KRISHNA INDUSTRIAL ESTATE VASAI (E) DIST THANE 401 210 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017
3067	NDA/MAL/HDP/6070	DEVA HOLDING A.S	SHREEJI PHARMACEUTICALS LIMITED	VAZKOR	AMLODIPINE BESILATE	10MG	DEVA HOLDING A.S CERKEZKOY ORGANIZE SANAYI BOLGESI, KARAAGAC MAH., ATATURK CAD., NO.: 32 KAPAKLI TEKIRDAG	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X9.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	01/07/2017

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3068	NDA/MAL/HDP/6 071	DEVA HOLDING A.S	SHREEJI PHARMACEUTICAL S LIMITED	VAZKOR	AMLODIPINE BESILATE	5MG	DEVA HOLDING A.SCERKEZKOY ORGANIZE SANAYI BOLGESI, KARAAGAC MAH., ATATURK CAD., NO.: 32 KAPAKLI TEKIRDAG	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X9.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2017
3069	NDA/MAL/HDP/6 075	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OLOHISTINE	OLOPATADINE HYDROCHLORIDE	1MG/ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2017

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3070	NDA/MAL/HDP/6 076	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	FALCI CARE	ARTESUNATE	30MG	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X30.0 MG VIAL + 1*5 ML OF 0.9%W/V NACL AMPOULE + 1*1 ML OF 5%W/V NAHCO3 AMPOULE	01/07/2017
3071	NDA/MAL/HDP/6 078	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TIMOLOL MALEATE	TIMOLOL MALEATE	5MG/ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2017



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3072	NDA/MAL/HDP/6 079	ADCOCK INGRAM LIMITED	SURGIPHARM (U) LIMITED	ALLERGEX	CHLORPHENIRAM INE MALEATE	4MG	ADCOCK INGRAM LIMITED 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE  560099, KARNATAKA STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3073	NDA/MAL/HDP/6 080	EXPHAR SA	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	FEBRILEX JUNIOR	PARACETAMOL+C HLORPHENIRAMI NE MALEATE	125MG+1MG/5ML	GRACURE PHARMACEUTICAL LTDE-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X150.0 ML BOTTLE	01/07/2017

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3074	NDA/MAL/HDP/6 081	TIANJIN MNCHIP TECHNOLOGIES CO.,LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	ANTALGEX T	PARACETAMOL/T RAMADOL HYDROCHLORIDE	325MG/37.5MG	GRACURE PHARMACEUTICAL LTDE-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2017
3075	NDA/MAL/HDP/6 082	EXPHAR SA	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	CROMSOL	SODIUM CROMOGLYCAT	2%W/V	AHLCONPARENTERA LS (INDIA) LIMITEDSP- 918, PHASE-III, BHIWADI-301019, RAJASTHAN (INDIA) TEL: +91-1493- 305300 (30 LINES) FAX: +91-1493- 221045, 305345	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2017

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

3076	NDA/MAL/HDP/6 086	UNOSOURCE PHARMA LTD	MEDVIN PHARMA LIMITED	ACEWEL-P	ACECLOFENAC+P ARACETAMOL	100MG+500MG	AKUMS DRUGS & PHARMACEUTICALS LTD19, 20,21 SECTOR 6A IIE SIDCUL RANIPUR HARIDWAR 249 403	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2017
3077	NDA/MAL/HDP/6 092	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPOTCLAV 1000	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	875 MG + 125 MG	SPARSH BIO-TECH PVT. LIMITEDPLOT NO. 1;SURVEY NO. 242/243/244,LAKHA BAVAD,JAMNAGAR- 361 006, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017

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3078	NDA/MAL/HDP/6 093	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPOTCLAV 625	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	500 MG + 125 MG	SPARSH BIO-TECH PVT. LIMITED PLOT NO. 1; SURVEY NO. 242/243/244, LAKHA BAVAD, JAMNAGAR- 361 006, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2017
3079	NDA/MAL/HDP/6 094	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPOTCLAV 375	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	250 MG + 125 MG	SPARSH BIO-TECH PVT. LTD PLOT NO. 1; SURVEY NO. 242/243/244, LAKHABAVAD, JAMNAGAR-361 006, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2017

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3080	NDA/MAL/HDP/6095	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	DIPGEN	BETAMETHASONE DIPROPIONATE + GENTAMICIN SULFATE	0.64 MG/G + 1 MG/G	S KANT HEALTHCARE LTD1802-1805 GIDC PHASE III VAPI 396 195 GUJARAT	INDIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE,1.0X15.0 G TUBE	01/07/2017
3081	NDA/MAL/HDP/6099	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	HARIPIL-60	ARTESUNATE	60MG	PSYCHOTROPICS INDIA LTD PLOT NO. 12 & 12A, INDUSTRIAL PARK-II, PHASE-1, VILLAGE SALEMPUR, MEHDOOD-2 HARIDWAR-249403, UTTARAKHAND INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 1*5 ML OF 0.9% W/V NACL GLASS AMPOULE + 1*1 ML OF 5%W/V NAHCO3 GLASS AMPOULE	01/07/2017

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3082	NDA/MAL/HDP/6 101	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TELPRESS-H 40/12.5	TELMISARTAN + HYDROCHLOROT HIAZIDE	40MG + 12.5MG	PSYCHOTROPICS INDIA LTD PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3083	NDA/MAL/HDP/6 102	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TELPRESS 80	TELMISARTAN	80MG	PSYCHOTROPICS INDIA LTD PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017

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3084	NDA/MAL/HDP/6 103	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	OZACE MD 5	OLANZAPINE	5MG	PSYCHOTROPICS INDIA LTD PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017
3085	NDA/MAL/HDP/6 105	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	AZOPIL 200	AZITHROMYCIN	200MG/5ML	PSYCHOTROPICS INDIA LTD PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND KESAR PHARMA PVT LTD PLOT SURVEY NO. 50/2. VILLAGE BILSHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1X15 ML BOTTLE	01/07/2017

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3086	NDA/MAL/HDP/6 106	SQUARE PHARMACEUTICAL S LTD	GAMA PHARMACEUTICAL S (U) LIMITED	TREVOX 500	LEVOFLOXACIN HEMIHYDRATE	500MG	SQUARE PHARMACEUTICALS LTDKALIAKOIR	BANGLADESH	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2017
3087	NDA/MAL/HDP/6 107	SQUARE PHARMACEUTICAL S LTD	GAMA PHARMACEUTICAL S (U) LIMITED	SULPREX	IPRATROPIUM BROMIDE+SALBU TAMOL SULPHATE	500MCG/2.5ML+2. 5MG/2.5ML	SQUARE PHARMACEUTICALS LIMITEDKALIAKOIR GAZIPUR – 1750, BANGLADESH	BANGLADESH	LUNG ADMINISTRATION LIQUID FOR INHALATION	1.0X10.0 AMPOULE CARTON	01/07/2017



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3088	NDA/MAL/HDP/6108	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	TREVOX 750	LEVOFLOXACIN HEMIHYDRATE	750MG	SQUARE PHARMACEUTICALS LTD ( DHAKA UNIT KALIAKOIR GAZIPUR)	BANGLADESH	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.09X10.0 TABLET Blister	29/03/2017
3089	NDA/MAL/HDP/6114	FDC LTD	AIVEEN (U) LIMITED	ZOXAN	CIPROFLOXACIN	0.3% W/V	FDC LIMITED B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.☒	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	01/07/2005

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3090	NDA/MAL/HDP/6 115	I-CARE PHARMA LTD	SUPER MEDIC LTD	TIZOL	TINIDAZOLE	500MG	MEDICO REMEDIES PVT LTD.,8 & 9 DEWAN AND SONS, UDYOG NAGAR, PALGHAR, DIST. THANE-401404, MAHARSHITRA	INDIA	ORAL SOLID ORDINARY TABLETS	1X4 TABLE STRIP	01/07/1997
3091	NDA/MAL/HDP/6 117	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	GRAN-DENK	GRANISETRON HYDROCHLORIDE	1MG/ML	SIEGFRIED HAMELN GMBHLANGES FELD 13,31789 HAMELN SOLUPHARM GMBH INDUSTRIESTRASSE 3, 34212 MELSUNGEN	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X5.0 ML AMPOULE,1.0X5.0X 3.0 ML AMPOULE	01/07/2017

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3092	NDA/MAL/HDP/6 118	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	L-TRIM DS	SULPHAMETHOX AZOLE + TRIMETHOPRIM	800MG + 160MG	LEBEN LABORATORIES PVT. LTD PLOT NO. L-4, PHASE-III, MIDC, AKOLA- 444 104 (MS).	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017
3093	NDA/MAL/HDP/6 120	NATIONAL HEALTHCARE PVT LTD	VITACARE LTD	KMINE	KETAMINE HYDROCHLORIDE	50MG/ML	NATIONAL HEALTHCARE PVT LTD-CHHATAPIPRA 3 BARA NEPAL	NEPAL	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	01/07/2017

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3094	NDA/MAL/HDP/6 121	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LTD	DEXİREN	DEXKETOPROFEN TROMETAMOL	25MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş3. ORGANİZE SANAYİ BÖLGESİ KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2017
3095	NDA/MAL/HDP/6 126	MEDICAL UNION PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	DERMOTRACIN	NEOMYCIN SULPHATE + BACITRACIN	165,000 IU + 12,500 IU	MEDICAL UNION PHARMACEUTICAL CO.PLANT: ABU- SULTAN, ISMAILIA, EGYPT	EGYPT	TOPICAL EXTERNAL PRESSURISED AEROSOLS	1.0X150.0 ML CANNISTER	01/07/2016

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3096	NDA/MAL/HDP/6 127	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	INTELENCE	ETRAVIRINE	25MG	JANSSEN-CILAG S.P.A.VIA C. JANSSEN BORGIO S. MICHELE 04100 LATINA	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET BOTTLE	01/07/2016
3097	NDA/MAL/HDP/6 129	VIIV HEALTHCARE UK LTD-	UNITED HEALTHCARE DISTRIBUTORS LTD	TRIUMEQ	DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE	50MG + 600MG + 300MG	GLAXOSMITHKLINE PHARMACEUTICALS SAGRUNWALDZKA 189 STREET, 60-322 POZNANA GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS)PRIORY STREET, WARE HERTFORDSHIRE SG12 0DJ, UK	UNITED KINGDOM POLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2016

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3098	NDA/MAL/HDP/6 132	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	KETOVID	KETOCONAZOLE	2%W/W	HOVID BHD 121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	TOPICAL EXTERNAL LIQUID SOAPS/WASHES	1.0X120.0 ML BOTTLE	01/07/2016
3099	NDA/MAL/HDP/6 134	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	ZAMADOL P	TRAMADOL HYDROCHLORIDE +ACETAMINOPHE N	37.5MG+325MG	MACLEODS PHARMACEUTICALS LIMITED BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH - 174101 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016

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3100	NDA/MAL/HDP/6 135	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TRIXONE-S	CEFTRIAZONE SODIUM+SULBAC TAM	1000MG+500MG	ZEISS PHARMA LIMITED-IGC,SIDCO, PHASE II, SAMBA, JAMMU - 184121,(J&K)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL	01/07/2016
3101	NDA/MAL/HDP/6 137	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	LUPRODEX	LEUPROLIDE ACETATE	3.75MG	BHARAT SERUMS AND VACCINES LIMITED,PLOT NO. K- 27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X1.0 ML VIAL + 1*2ML GLASS AMPOULE OF DILUENT (EACH ML CONTAINS 50MG OF D-MANNITOL AND WFI TO Q.S) + 1 DISPOSABLE SYRINGE, 2 NEEDLES AND 2 ALCOHOL SWABS	01/07/2016

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3102	NDA/MAL/HDP/6 141	UNOSOURCE PHARMA LTD	MEDVIN PHARMA LIMITED	ACEWEL	ACECLOFENAC	100MG	AKUMS DRUGS & PHARMACEUTICALS LTD19, 20,21 SECTOR 6A IIE SIDCUL RANIPUR HARIDWAR 249 403	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2016
3103	NDA/MAL/HDP/6 142	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOCARB	ACTIVATED CHARCOAL	0.25GM	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET BOTTLE,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2016



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3104	NDA/MAL/HDP/6 143	IESUS GROUP	SHREEJI PHARMACEUTICAL S LIMITED	CONTRACTUBEX	EXTRACT CEPAE FLUID +HEPARIN SODIUM+ALLANT OIN	10G+5000 I.U+1G/100G	MARCYRL PHARMACEUTICAL INDUSTRIES.EL OBOUR CITY CAIRO	EGYPT	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE	01/07/2016
3105	NDA/MAL/HDP/6 158	DEVA HOLDING A.S	SHREEJI PHARMACEUTICAL S LIMITED	DESEFIN	CEFTRIAZONE SODIUM	1G	DEVA HOLDING A.S.CERKEZKOY ORGANIZE SANAYI BOLGESI, KARAAGAC MAH., ATATURK CAD., NO.: 32 KAPAKLI TEKIRDAG	TURKEY	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2016

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3106	NDA/MAL/HDP/6 167	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	AKUROSE	IRON SUCROSE	20MG/ML	AKUMS DRUGS & PHARMACEUTICALS LTD. -PLANT III,PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL,RANIPUR, 249 403	INDIA	PARENTERAL ORDINARY INFUSION AMPOULES	1.0X5.0X5.0 ML AMPOULE	07/01/2016
3107	NDA/MAL/HDP/6 169	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	INTELENCE	ETRAVIRINE	100MG	JANSSEN-CILAG S.P.A.VIA C. JANSSEN BORGIO S. MICHELE 04100 LATINA	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET BOTTLE	01/07/2016

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3108	NDA/MAL/HDP/6 170	SQUARE PHARMACEUTICAL S LTD	GAMA PHARMACEUTICAL S (U) LIMITED	ALACOT 0.1% EYE DROPS	OLOPATADINE HYDROCHLORIDE	0.1%W/V	SQUARE PHARMACEUTICALS LIMITED-KALIAKOIR GAZIPUR – 1750, BANGLADESH	BANGLADESH	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	07/01/2016
3109	NDA/MAL/HDP/6 176	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	G-GLUTAMIN	VITAMIN B1 +B6+B12 WITH L- GLUTAMIC ACID	100MG+50MG+10 0MCG+50MG	BLISS GVS PHARMA LTD PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA- INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2010

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3110	NDA/MAL/HDP/6 179	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	ON.SETRON-DENK 4MG ODT	ONDANSETRON	4MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X6.0 TABLET BLISTER	01/07/2016
3111	NDA/MAL/HDP/6 181	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	AZINOWEL-500	AZITHROMYCIN	500MG	AKUMS DRUGS AND PHARMACEUTICALS LTDPLANT-1 PLOT NO.19, 20&21 SECTOR-6A, 11E, SIDCUL, RAHIPUR DISTT; HARIDWAR, 249403, (UTTRAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0 TABLET BLISTER	01/07/2016

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3112	NDA/MAL/HDP/6 182	SQUARE PHARMACEUTICAL S LTD	GAMA PHARMACEUTICAL S (U) LIMITED	ALARID	KETOTIFEN FUMARATE	0.025%W/V	SQUARE PHARMACEUTICALS LTD DHAKA UNIT KALIAKOIR GAZIPUR	BANGLADESH	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2016
3113	NDA/MAL/HDP/6 184	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ATOXIA 60MG	ETORICOXIB	60MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTDP.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL- RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016

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3114	NDA/MAL/HDP/6 185	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	DOLOFORTE DENK	TRAMADOL HYDROCHLORIDE + PARACETAMOL	37.5MG + 325MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2016
3115	NDA/MAL/HDP/6 186	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ATOXIA 90MG F.C. TABLETS	ETORICOXIB	90MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTDP.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL- RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016

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3116	NDA/MAL/HDP/6 187	ALLY PHARMA OPTIONS PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	FLOXCIP	CIPROFLOXACIN HYDROCHLORIDE	500MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328 - 1330, VILLAGE MANPURA. TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH, 174101 - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X10X10 TABLET BLISTER	01/07/2016
3117	NDA/MAL/HDP/6 188	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	GIZLAN 150	IRBESARTAN	150MG	DAR AI DAWANA UR PLANT,AMMAN,JOR DAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016

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3118	NDA/MAL/HDP/6 189	UNEEED GLOBAL GROUP LIMITED	ABACUS PHARMA (AFRICA) LIMITED	WORMEE-4	ALBENDAZOLE	400MG	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0 TABLET BLISTER	01/07/2016
3119	NDA/MAL/HDP/6 190	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	D-LYTE	ANHYDROUS GLUCOSE+SODIU M CHLORIDE+TRISO DIUM CITRATE+POTASSI UM CHLORIDE, ANHYD ROUS GLUCOSE+SODIU M CHLORIDE+TRISO DIUM CITRATE+POTASSI UM CHLORIDE ANHYD	2.7MG+0.52MG+0. 58MG+0.30MG PER 200ML SACHET, 6.75MG+1. 30MG+1.45MG+0. 75MG PER 500ML SACHET, 13.5MG+2. 60MG+2.90MG+1. 50MG PER 1000ML SACHET	AGOG PHARMA LTD PLOT NO.33, SECTOR II, VASAI, TALUKA INDL CO-OP ESTATE LTD, GAURAI PADA, VASAI(E) DIST. T HANE INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X500.0 ML SACHET, 1.0X1000.0 ML SACHET, 1.0X200.0 ML SACHET	01/07/2015



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3120	NDA/MAL/HDP/6 191	AMOUN PHARMACEUTICAL S COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	KAPRON AMPOULE	TRANEXAMIC ACID	500MG/5ML	AMOUN PHARMACEUTICAL CO. S.A.E-1ST INDUSTRIAL ZONE A, PLOTS NO. 1B,2,3,4,5 BLOCK 13015, EL- OBOUR CITY, KALYOUBIA CAIRO EGYPT	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X6.0X5.0 ML AMPOULE	01/07/2016
3121	NDA/MAL/HDP/6 201	SPARSH BIO-TECH PVT.LTD.	ABACUS PHARMA (AFRICA) LIMITED	SPAMOXIFLOX	AMOXICILLIN TRIHYDRATE + FLUCLOXACILLIN SODIUM	250MG + 250MG	SPARSH BIO-TECH PVT. LIMITED PLOT NO. 1; SURVEY NO. 242/243/244, LAKHA BAVAD, JAMNAGAR- 361 006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE STRIP	01/07/2016

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3122	NDA/MAL/HDP/6 207	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	GO!GEL	DICLOFENAC DIETHYLAMINE+ METHYL SALICYLATE	1.16%W/W + 10%W/W	S KANT HEALTHCARE LTD PLOT NO. 1802- 1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT.	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/2016
3123	NDA/MAL/HDP/6 211	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	CLOFAINS	PARACETAMOL/D ICLOFENAC SODIUM	500MG/50MG	MILAN LABORATORIES (INDIA ) PVT LTD PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTR A-410209,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016

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3124	NDA/MAL/HDP/6 217	INDIAN IMMUNOLOGICALS LTD	TATA UGANDA LIMITED	ELOVAC -B	HEPATITIS B (RDNA)	20MCG/ML	HUMAN BIOLOGICALS INSTITUTE (A DIVISION OF INDIAN IMMUNOLOGICALS LTD) RAKSHAPURAM GACHIBOWLI POST HYDERABAD 500032	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0X1.0 ML VIAL (1 DOSE VIAL)	01/07/2016
3125	NDA/MAL/HDP/6 218	ASTRA ZENECA	MACNAUGHTON LIMITED	FORXIGA	DAPAGLIFLOZIN	10MG	ASTRAZENECA PHARMACEUTICALS LP4601 HIGHWAY 62 EAST, MOUNT VERNON, IN 47620- 1500 - UNITED STATES OF AMERICA	UNITED STATES	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2016

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3126	NDA/MAL/HDP/6 220	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	METHYLDOPA	METHYLDOPA	250MG	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
3127	NDA/MAL/HDP/6 223	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROPROST- RT	LATANOPROST	0.005%W/V	AUROLAB.SIVAGANG AI MAIN ROAD, VEERAPANJAN, MADURAI 625 020 TAMIL INDIA	INDIA	OPHTHALMIC DROPS	1.0X2.5 ML BOTTLE	01/07/2016

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3128	NDA/MAL/HDP/6 227	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ISONIAZID	ISONIAZID	300MG	MYLAN LABORATORIES LIMITED.PLOT NO. H- 12 & H-13 MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD. – 431136, MAHARASHTRA STATE, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2016
3129	NDA/MAL/HDP/6 228	CACHET PHAMACUITICALS PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	ACINET	AMOXICILLIN + POTASSIUM CLAVULANATE	500 MG + 125 MG	INDCHEMIE HEALTH SPECIALITIES PVT. LTDVILLAGE-THANA, BADDI, DIST. SOLAN, HIMACHAL PRADESH- 173 205.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X2.0X7. 0 TABLET BLISTER	01/07/2016

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3130	NDA/MAL/HDP/6 229	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	CO-FLUAMPICIL CAPSULES BP 500MG	FLUCLOXACILLIN SODIUM + AMPICILLIN TRIHYDRATE	250MG +250MG	SPARSH BIO-TECH PVT. LIMITED PLOT NO. 1; SURVEY NO. 242/243/244, LAKHA BAVAD, JAMNAGAR- 361 006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE STRIP	01/07/2016
3131	NDA/MAL/HDP/6 230	CACHET PHARMACEUTICALS PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	EMITINO	ONDANSETRON	4MG	CACHET PHARMACEUTICALS PVT LTD THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016

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3132	NDA/MAL/HDP/6 231	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP DISPERSIBLE	DIHYDROARTEMI SININ/PIPERAQUI NE	20MG/160MG	GUILIN PHARMACEUTICAL CO LTDNO.43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X2.0X3.0 TABLET BLISTER,1.0X3.0X35 .0 TABLET BLISTER	01/07/2016
3133	NDA/MAL/HDP/6 232	FREDUN PHARMACEUTICAL S LTD	PLANET PHARMACEUTICAL S UGANDA LTD	H-CURE	LANSOPRAZOLE + CLARITHROMYCIN + TINIDAZOLE	30MG + 250MG + 500MG	FREDUN PHARMACEUTICALS LTDVEEOR PALGHAR ( E ) 401 404	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X7.0X6.0 TABLET BLISTER (BLISTER CONTAINS 2CAPSULES OF LANSOPRAZOLE + 2 TABLETS OF CLARITHROMYCIN + 2 TABLETS OF TINIDAZOLE)	01/07/2016

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3134	NDA/MAL/HDP/6 234	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP DISPERSIBLE	DIHYDROARTEME SININE/ PIPERAQUINE PHOSPHATE	40MG/320MG	GUILIN PHARMACEUTICAL CO.,LTDNO 43 QLIDIAN ROAD GUILIN 541002, GUANGXI	CHINA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X2.0X3.0 TABLET BLISTER,1.0X3.0X25 .0 TABLET BLISTER	01/07/2016
3135	NDA/MAL/HDP/6 235	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ANGINET 160MG	VALSARTAN	160MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTDP.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL- RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016



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3136	NDA/MAL/HDP/6 237	HETERO LABS LTD	AIVEEN (U) LIMITED	LOPINAVIR/RITON AVIR	LOPINAVIR/ RITONAVIR	100MG/25MG	HETERO LABS LTD22- 110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X120.0 TABLET BOTTLE,1.0X60.0 TABLET CONTAINER	01/07/2016
3137	NDA/MAL/HDP/6 238	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	NEBILONG -AM	NEBIVOLOL HYDROCHLORIDE + AMLODIPINE BESILATE	5MG + 5MG	MICRO LABS LTD 92 SIPCOT 92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016

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3138	NDA/MAL/HDP/6 239	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GSUNATE	ARTESUNATE	60MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA BLISS GVS PHARMA LTD PLOT 73 -76 SILVER INDUSTRIAL ESTATE BHIMPORE DAMAN 396 210 (UT)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 1*5 ML AMPOULE OF 0.9%W/V NACL + 1*1 ML OF 5%W/V SODIUM BICARBONATE	01/07/2016
3139	NDA/MAL/HDP/6 242	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP	DIHYDROARTEME SININ/PIPERAQUI NE PHOSPHATE	80MG/640MG	GUILIN PHARMACEUTICAL CO LTDNO.43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER,1.0X6.0X25 .0 TABLET BLISTER	01/07/2016

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3140	NDA/MAL/HDP/6 243	ABBVIE (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	SURVANTA	BERACTANT	100MG/4ML	ABBVIE NORTH CHICAGO FACILITY1401 SHERDAN ROAD NORTH CHICAGO FACILITY ILLINOIS 60064 -4000	UNITED STATES	TOPICAL EXTERNAL INSTILLATION VIALS	1.0X4.0 ML VIAL,1.0X8.0 ML VIAL	01/07/2016
3141	NDA/MAL/HDP/6 244	CACHET PHAMACUITICALS PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	CABALIN	PREGABALIN	75MG	CACHET PHARMACEUTICALS PVT LTDVILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X12.0 CAPSULE BLISTER,1.0X3.0X10 .0 CAPSULE BLISTER	01/07/2016

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3142	NDA/MAL/HDP/6 245	BIOLOGICAL E. LTD	ABACUS PHARMA (AFRICA) LIMITED	COSCOPIN LINCTUS	NOSCAPINE + CHLORPHENIRAM INE MALEATE + SODIUM CITRATE + AMMONIUM CHLORIDE	7MG+2 MG+ 3.25 MG+28 MG/5 ML.	BIOLOGICAL E. LTD PLOT NO.31 & 32 PHARMA CITY SELAQUI INDUSTRIAL AREA SELAQUI DEHRADUN-248 197 UTTARAKHAND,INDI A	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2016
3143	NDA/MAL/HDP/6 246	CIRON DRUGS & PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	LUTHER	ARTEMETHER	80MG/ML	CIRON DRUGS AND PHARMACEUTICALS PVT. LTDN-118, N119, N113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, INDIA	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE	01/07/2016

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3144	NDA/MAL/HDP/6 247	MILAN LABORATORIES LTD (INDIA) PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	MILOXY 250-DT	AMOXICILLIN TRIHYDRATE	250MG	MILAN LABORATORIES (INDIA ) PVT LTD PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA	INDIA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X2.0X10 .0 TABLET BLISTER,1.0X1.0X10 .0 TABLET BLISTER	01/07/2016
3145	NDA/MAL/HDP/6 249	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL METRONIDAZOLE 200 TABLETS	METRONIDAZOLE	200MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016

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3146	NDA/MAL/HDP/6 250	REMINGTON PHARMACEUTICAL INDUSTRIES PVT LTD	HEALTHCARE LTD.	ROCIP EYE DROPS	CIPROFLOXACIN HYDROCHLORIDE	3MG/ML	REMINGTON PHARMACEUTICAL INDUSTRIES (PVT) LTD18 KM MULTAN ROAD LAHORE 53800 PAKISTAN	PAKISTAN	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2016
3147	NDA/MAL/HDP/6 256	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AZIMAX- 250	AZITHROMYCIN DIHYDRATE	250MG	HOVID BHDLOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0X10.0 TABLET BLISTER	01/07/2016

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3148	NDA/MAL/HDP/6 257	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	EDURANT	RILPIVIRINE	25MG	JANSSEN CILAG S.P.AVIA C.JANSSEN, BORGIO	ITALY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2016
3149	NDA/MAL/HDP/6 264	ACINO PHARMA AG -	LABOREX UGANDA LIMITED	PARACONICA 1000 MG IV	PARACETAMOL	10MG/ML	S.M FARMACEUTICI SRLZONA INDUSTRIALE, 85050 TITO- POTENZA (PZ) ITALY	ITALY	PARENTERAL ORDINARY I V VIALS	1.0X100.0 ML VIAL	01/07/2016

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3150	NDA/MAL/HDP/6 267	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	TRAMADOL DENK 50	TRAMADOL HYDROCHLORIDE	50MG	LOSAN PHARMA GMBH OTTO-HAHN- STR 13 79395 NEUENBURG	GERMANY	ORAL SOLID ORDINARY EFFERVESCENT TABLETS	1.0X10.0 TABLET BOTTLE	01/07/2016
3151	NDA/MAL/HDP/6 270	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	FEBUMAC 80	FEBUXOSTAT	80MG	MACLEODS PHARMACEUTICALS LTD - VILLAGE THEDA P.O LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH INDIA 174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER,1.0X2.0X14 .0 TABLET BLISTER	01/07/2017



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3152	NDA/MAL/HDP/6 275	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICAL S LIMITED	BENZYL BENZOATE APPLICATION BP	BENZYL BENZOATE	25%W/V	SEV PHARMACEUTICALS LTD, PLOT 100 MASAKA ROAD ,NALUKOLONGO KAMPALA,UGANDA.	UGANDA	TOPICAL EXTERNAL EMULSIONS	1.0X100.0 ML BOTTLE	27/11/2018
3153	NDA/MAL/HDP/6 279	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CIFF-200 DT	CEFIXIME TRIHYDRATE	200MG	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X10.0 TABLET STRIP	27/11/2018

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3154	NDA/MAL/HDP/6 281	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	HOMAGON	CHLORPHENAMIN E MALEATE + CAFFEINE ANHYDROUS + PSEUDOEPHEDRI NE HYDROCHLORIDE + PARACETAMOL	4MG + 30MG + 30MG + 400MG	LABORATORY AND ALLIED LTD PLOT 209/10349- MOMBASA ROAD NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER,1.0X10.0X1 0.0 CAPSULE BLISTER	07/11/2018
3155	NDA/MAL/HDP/6 282	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	MEBUX-40	FEBUXOSTAT	40MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	07/11/2018

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3156	NDA/MAL/HDP/6 283	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MEBUX-80	FEBUXOSTAT	80 MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	07/11/2018
3157	NDA/MAL/HDP/6 288	THEON PHARMACEUTICALS LTD	AIVEEN (U) LIMITED	THEOFIX-100 DS	CEFIXIME TRIHYDRATE	100MG/5ML	THEON PHARMACEUTICALS LIMITED. VILLAGE SAINI MAJRA, TEHSIL NALAGARH, DISTT. SOLAN, HIMACHAL PRADESH 174 101 INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1X1X60 ML BOTTLE	17/12/2018

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3158	NDA/MAL/HDP/6 292	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VENAXAN 250 MG	LEVOFLOXACIN HEMIHYDRATE	250MG	SOUTH EGYPT DRUG INDUSTRIES CO-1ST INDUSTRIAL ZONE, 6 OCTOBER CITY, EGYPT.	EGYPT	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X5.0 TABLET BLISTER	27/11/2018
3159	NDA/MAL/HDP/6 293	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	NEUROGAB 150	PREGABALIN	150MG	"MACLEODS PHARMACEUTICALS LTD,-BLOCK N2, VILLAGE THEDA, POST OFFICE LODHIMAJRA, TEHSIL BADDI, DISTRICT SOLAN, HIMACHAL PRADESH - 174101 INDIA."	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	27/11/2018

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3160	NDA/MAL/HDP/6 294	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	NEXAVAR	SORAFENIB TOSYLATE	200MG	BAYER PHARMA AG 51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X28.0 TABLET BLISTER	07/11/2018
3161	NDA/MAL/HDP/6 300	GUILIN PHARMACEUTICAL (SHANGHAI) CO., LTD	TRIDEM PHARMA UGANDA LIMITED	AMOXICILLIN	AMOXICILLIN	250MG	SINOPHARM WEIQIDA PHARMACEUTICAL CO., LTD-OSD WORKSHOP OF ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, SECOND MEDICAL ZONE DATONG, SHANXI, CHINA	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X2.0 X10.0 CAPSULE BLISTER, 1.0X10.0X10.0 CAPSULE BLISTER	31/01/2018

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3162	NDA/MAL/HDP/6 302	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	PLENOX	OFLOXACIN	200MG	AKUMS DRUGS & PHARMACEUTICALS LTD19-20,21, SECTOR 6-4, SIDCUL, IIE, RANIPUR HARIDWAR-249403	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	27/03/2019
3163	NDA/MAL/HDP/6 304	UNOSOURCE PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	UNOSURE 72	LEVONORGESTRE L	1.5MG	AKUMS DRUGS & PHARMACEUTICALS LTD .PLOT NO. 47, 48, SECTOR 6A, IIE, SIDCUL HARIDWAR, UTTRAKHAND – 249403, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0 TABLET BLISTER	27/03/2019

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3164	NDA/MAL/HDP/6 314	YELURI FORMULATIONS PVT LTD	SUPER MEDIC	ELMOX-CV 625	AMOXICILLIN TRIHYDRATE+CLA VULANATE POTASSIUM	500MG+125MG	YELURI FORMULATIONS PVT. LTD-SY. NO. 296 / 7 / 6 IDA BOLLARAM,MEDAK DIST.502325, TELANGANA,INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X5.0 TABLET BLISTER,1.0X2.0X10 .0 TABLET BLISTER	30/05/2018
3165	NDA/MAL/HDP/6 327	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENESTEN-V	CLOTRIMAZOLE	100MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X6.0 PESSARY BLISTER	27/11/2018

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3166	NDA/MAL/HDP/6 332	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMOXIREN DT 250	AMOXICILLIN TRIHYDRATE	250MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	27/11/2018
3167	NDA/MAL/HDP/6 334	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	ENDOPROST 250MCG/1ML	CARBOPROST TROMETHAMINE	250MCG/ML	BHARAT SERUM AND VACCINES LIMITED PLOT NO. K- 27 ADDITIONAL MIDC AMBERNATH (EAST) INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X1.0 ML VIAL	27/03/2019



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3168	NDA/MAL/HDP/6 338	BIOTON S.A.	BHL HEALTHCARE LIMITED	GENSULIN M30 (30/70)	INSULIN HUMAN OF RECOMBINANT DNA ORIGIN (30% SOLUBLE INSULIN + 70% ISOPHANE INSULIN)	100 IU/ML	BIOTON S.AMACIERZYSZ, POZNANSKA 12 STR., 05-850 OZAROW MAZOWIECKI	POLAND	PARENTERAL ORDINARY S C VIALS	1.0X1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE	27/03/2019
3169	NDA/MAL/HDP/6 339	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OXY-POL	OXYTETRACYCLIN E HCL + POLYMYXIN B SULPHATE	5MG+10000IU/G	EGYPTIAN INT.PHARMACEUTIC AL INDUSTRIES CO. E.I.P.C.O --10TH OF RAMADAN CITY – INDUSTRIAL AREA B1- P.O BOX: 149 TENTH - EGYPT	EGYPT	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE	30/05/2018

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3170	NDA/MAL/HDP/6 340	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	AXYLIN CAPSULES	AMPICILLIN TRIHYDRATE + CLOXACILLIN SODIUM	250MG +250 MG	LABORATORY & ALLIED LTD PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	31/01/2018
3171	NDA/MAL/HDP/6 341	MACLEODS PHARMACEUTICAL S LTDS LTD	VITACARE LIMITED	ROSUMAC 20	ROSUVASTATIN CALCIUM	20MG	MACLEODS PHARMACEUTICALS LTD., NO. 25-27 PLOT NO. 25-26-27, SURVEY NO.366, PREMIER INDUSTRIAL ESTATE , DAMAN - 396210, KACHIGAM, DAMAN	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	31/01/2018

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3172	NDA/MAL/HDP/6 342	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIFENAC EYE DROPS	DICLOFENAC SODIUM SALT	1MG/ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B EGYPT	EGYPT	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	30/05/2018
3173	NDA/MAL/HDP/6 343	BIOTON S.A.	BHL HEALTHCARE LIMITED	GENSULIN N	ISOPHANE HUMAN HUMAN OF RECOMBINANT DNA ORIGIN	100 IU/ML	BIOTON S.AMACIERZYSZ, POZNANSKA 12 STR., 05-850 OZAROW MAZOWIECKI	POLAND	PARENTERAL ORDINARY S C VIALS	1.0X1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE	27/03/2019

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3174	NDA/MAL/HDP/6 344	S KAGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	LACTEASE	LACTULOSE SOLUTION	66.7% W/W	S KANT HEALTHCARE LTD PLOT NO. 1802- 1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT.	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE	26/09/2018
3175	NDA/MAL/HDP/6 345	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MAGNABIOTIC 600MG VIAL	AMOXYCILLIN SODIUM/ CLAVULANATE POTASSIUM	500MG/100MG	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA, EGYPT	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	25/07/2018

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3176	NDA/MAL/HDP/6 346	BIOTON S.A.	BHL HEALTHCARE LIMITED	GENSULIN R	SOLUBLE HUMAN INSULIN OF RECOMBINANT DNA ORIGIN	100 IU/ML	BIOTON S.AMACIERZYSZ, POZNANSKA 12 STR., 05-850 OZAROW MAZOWIECKI	POLAND	PARENTERAL ORDINARY S C VIALS	1.0X1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE	27/03/2019
3177	NDA/MAL/HDP/6 348	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	COMPOUND SODIUM LACTATE INTRAVENOUS INFUSION BP	SODIUM LACTATE SOLUTION +SODIUM CHLORIDE + CALCIUM CHLORIDE + POTASSIUM CHLORIDE	0.533 GM +0.600 GM + 0.027G+ 0.040 GM/100ML	ABARIS HEALTHCARE PVT. LTD-PLOT NO: 1407- 1411 VILLAGE: RAJPUR TALUKA: KADI, DIST.: MEHSANA 382 740, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	28/03/2018

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3178	NDA/MAL/HDP/6 349	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GSUNATE -120	ARTESUNATE	120MG	BLISS INDASI LIFESCINCES PRIVATE LIMITED - PLOT 73-76 SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN 396 210, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1*10ML 0.9%W/W SODIUM CHLORIDE SOLUTION AMPOULE + 1*2ML 5.0%W/W SODIUM BICARBONATE SOLUTION AMPOULE	26/09/2018
3179	NDA/MAL/HDP/6 350	MEGA LIFESCINCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	INVEL	METRONIDAZOLE + MICONAZOLE NITRATE	500MG + 100MG	BLISS GVS PHARMA LIMITED10,11 & 12,DEWAN UDYOG NAGAR,ALIYALI,PALG HAR,MAHARASHTRA 401404,INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X7.0 SUPPOSITORY STRIP	27/03/2019

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3180	NDA/MAL/HDP/6 352	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	OMIPIN-20	OMEPRAZOLE	20MG	BRAWN LABORATORIES LTD .13, NIT, INDUSTRIAL AREA, FARIDABAD- 121001, HARYANA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	28/03/2019
3181	NDA/MAL/HDP/6 353	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	DOLUTEGRAVIR/L AMIVUDINE/TEN OFOVIR DISOPROXIL FUMARATE TABLETS 50MG/300MG/30 0MG	DOLUTEGRAVIR+L AMIVUDINE+TEN OFOVIR DISOPROXIL FUMARATE TABLETS	50MG+300MG+30 0MG	LAURUS LABS LIMITED, (UNIT-2) - PLOT NO:19, 20 & 21,WESTERN SECTOR, APSEZ, ATCHUTAPURAM MANDAL, VISAKHAPATNAM- DISTRICT-531011, ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE,1.0X1.0X90 .0 TABLET BOTTLE	07/11/2018

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3182	NDA/MAL/HDP/6 354	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TIMOSOL <sup>®</sup>	TIMOLOL MALEATE	O.5%W/V	AHLCONPARENTERA LS (INDIA) LIMITEDSP 918, PHASE-III, BHIWADI-301019, RAJASTHAN (INDIA) TEL: +91-1493- 305300 (30 LINES) FAX: +91-1493- 221045, 305345	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2017
3183	NDA/MAL/HDP/6 360	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	ETOCOXX 90MG	ETORICOXIB	90MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X7 TABLET BLISTER	31/01/2018



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3184	NDA/MAL/HDP/6 361	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	NYSKA-P	NYSTATIN	1,00,000 I.U/ML	S.KANT HEALTHCARE LTD PLOT 1802, 1805, GIDC PHASE III VAPI 39179, GUJARAT	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2018
3185	NDA/MAL/HDP/6 365	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	EASY PILL	LEVONORGESTRE L	1.5MG	CORONA REMEDIES PVT LTDCORONA HOUSE, C MONDEAL BUSINESS PARK, NR. GURUDWARA GOVINDDHAM LANE, SG HIGHWAY, THALTEJ, AHMEDABAD 380059, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0 TABLET BLISTER	27/03/2019

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3186	NDA/MAL/HDP/6 368	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	ETOCOXX 120MG	ETORICOXIB	120MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X7 TABLET BLISTER	31/01/2018
3187	NDA/MAL/HDP/6 369	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVXIM SUSPENSION	CEFIXIME TRIHYDRATE	100MG/5ML	ASSOCIATED BIOTECH-VILLAGE : KISHANPURA, GURU MAJRA, BADDI, DISTT. SOLAN, INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE	31/01/2018

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3188	NDA/MAL/HDP/6 374	MICRO LABS	MALIX PHARMA (U) LIMITED	PREDLEB-5 DT	PREDNISOLONE	5MG	LEBEN LABORATORIES PVT. LTD PLOT NO. L-4, PHASE-III, MIDC, AKOLA- 444 104 (MS).	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X20.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	28/03/2018
3189	NDA/MAL/HDP/6 375	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	ETHAMBUTOL DISPERSIBLE TABLETS 100 MG	ETHAMBUTOL HYDROCHLORIDE	100MG	OXALIS LABS LIMITED VILLAGE THEDA, P.O LODHIMAJRA, TEHSIL, BADDI, DIST. SOLAN, INDIA MACLEODS PHARMACEUTICALS LTD ,.PHASE I & II, PLOT NO. 25-27 SURVEY NO. 366, PREMIERE INDUSTRIAL ESTATE, KACHIGAN, DAMAN- 396210	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET STRIP	27/11/2018

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3190	NDA/MAL/HDP/6 377	REGAL PHARMA U LIMITED	REGAL PHARMA U LIMITED	EPHICOL CAPSULES	CHLORPHENIRAM INE MALEATE+ PARACETAMOL+ CAFFEINE ANHYDROUS+ PHENYLEPHRINE HCL	2MG+500 MG+30 MG+5MG	REGAL PHARMACEUTICALS LTD..PLOT 7879/18 OFF BABA DOGO ROAD, RUARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X12.0 CAPSULE BLISTER	01/07/2017
3191	NDA/MAL/HDP/6 380	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MAGNABIOTIC 1200MG VIAL	AMOXICILLIN + CLAVULANIC ACID	1000MG+120MG	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.2 G VIAL	25/07/2018

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3192	NDA/MAL/HDP/6 381	MANKIND PHARM LTD	TATA UGANDA LIMITED	SERTAKIND	SERTACONAZOLE NITRATE	2.0%W/W	CURETECH SKINCAREPLOT NO. 33 & 34, PHASE IV, BHATOLI KALAN, BADDI DISTT. SOLAN (HP) 173205	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X10.0 G TUBE,1.0X20.0 G TUBE	27/03/2019
3193	NDA/MAL/HDP/6 383	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	EXXIB	CELECOXIB	200MG	GRACURE PHARMACEUTICALS LIMITED E- 1105, RIICO INDUSTRIAL AREA, PHASE-III BHIWADI, PIN- 301019 DIST. ALWAR, RAJASTHAN, INDI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	31/01/2018

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3194	NDA/MAL/HDP/6 385	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	AMOXIKID-250	AMOXICILLIN	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD PLOT NO. M444B, STRETCHER ROAD, NTINDA, KAMPALA	UGANDA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X10.0 TABLET STRIP	25/07/2018
3195	NDA/MAL/HDP/6 386	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	JUSDEE 60K GRANULES	COLECALCIFEROL	60000 IU	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X8.0X1.0 G SACHET	30/05/2018

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3196	NDA/MAL/HDP/6 389	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	METRONIDAZOLE BP	METRONIDAZOLE	0.5%W/V	ABARIS HEALTHCARE PVT. LTD-PLOT NO: 1407- 1411 VILLAGE: RAJPUR TALUKA: KADI, DIST.: MEHSANA 382 740, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	28/03/2018
3197	NDA/MAL/HDP/6 390	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	ROSUMAC 10	ROSUVASTATIN CALCIUM	10MG	MACLEODS PHARMACEUTICALS LTD ,.PHASE I & II, PLOT NO. 25-27 SURVEY NO. 366, PREMIERE INDUSTRIAL ESTATE, KACHIGAN, DAMAN- 396210	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	06/02/2019

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3198	NDA/MAL/HDP/6 392	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MET XL 50	METOPROLOL SUCCINATE	50 MG	AJANTA PHARMA LTD .B-4//5/6, MIDC INDUSTRIALAREA, PAITHAN-431 128, AURANGBAD	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	30/05/2018
3199	NDA/MAL/HDP/6 395	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	FLOXSOL ®	NORFLOXACIN	0.3%W/V	AHLCON PARENTERALS (INDIA) LIMITEDSP- 917-918, PHASE 111, BHIWADI -301019, ALWAR, RAJASTHAN INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML VIAL	28/05/2019



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3200	NDA/MAL/HDP/6 400	MERIDIAN ENTERPRISES PRIVATE LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	FENSUPP-100	DICLOFENAC SODIUM	100MG	MERIDIAN ENTERPRISES PVT. LTD-PLOT NO. 418, G.I.D.C., KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	RECTAL SYSTEMIC ADULT SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY STRIP	01/07/2017
3201	NDA/MAL/HDP/6 401	MERIDIAN ENTERPRISES PRIVATE LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	SUPPOL 250 SUPPOSITORIES	ACETAMINOPHEN	250MG	MERIDIAN ENTERPRISES PVT. LTD PLOT NO. 418, G.I.D.C., KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP	01/07/2017

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3202	NDA/MAL/HDP/6 404	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	STEDNAC GEL	ACECLOFENAC + LINSEED OIL + METHYL SALICYLATE	1.5%W/W + 3.0W/W +10.0%W/W	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE,1.0X15.0 G TUBE,1.0X50.0 G TUBE,1.0X100.0 G TUBE	01/07/2017
3203	NDA/MAL/HDP/6 405	ZIM LABORATORIES LTD	REDDYS PHARMA LIMITED	CLOPRAZ	CLOPIDOGREL BISULFATE	75MG	ZIM LABORATORIES LTDB-21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X3X10 TABLET BLISTER	01/07/2017

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3204	NDA/MAL/HDP/6 407	ZIM LABORATORIES LTD	REDDYS PHARMA LIMITED	ZIMCOX 200	CELECOXIB	200 MG	ZIM LABORATORIES LTDB-21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA,	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	29/11/2017
3205	NDA/MAL/HDP/6 408	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DECOZAL	XYLOMETAZOLINE HCL	0.1%W/V	AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	JORDAN	NASAL TOPICAL METERED DOSE AEROSOLS	1.0X10.0 ML BOTTLE	28/05/2019

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3206	NDA/MAL/HDP/6 414	CIPLA LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	IMATIB 100	IMATINIB MESYLATE	100MG	CIPLA LTD, GOA UNIT V & UNIT XL-139, S- 103&M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	28/05/2019
3207	NDA/MAL/HDP/6 415	CIPLA LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	IMATIB 400	IMATINIB MESYLATE	400MG	CIPLA LTD, GOA UNIT V & UNIT XL-139, S- 103&M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	28/05/2019

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3208	NDA/MAL/HDP/6 416	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	PAN-D	PANTOPRAZOLE + DOMPERIDONE	40MG + 30MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	29/05/2019
3209	NDA/MAL/HDP/6 419	SEGURA PHARMA PRIVATE LTD	ABACUS PHARMA (AFRICA) LIMITED	CLINICEF CV	CEFIXIME + POTASSIUM CLAVULANATE	200MG + 125MG	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD - UNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE-247668. DIST.-HARIDWAR, UTTARAKHAND	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	26/09/2018

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3210	NDA/MAL/HDP/6 422	INTERNATIONAL ORGANIZATION FOR MIGRATION	AIVEEN (U) LIMITED	EMADON	ONDANSETRON	4MG	CORONA REMEDIES PVT LTD-VILLAGE JATOLI,POST OFFICE - OACHGHAT, TEHSIL SOLAN, DIST. OLAN HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017
3211	NDA/MAL/HDP/6 423	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	CLARITEK	CLARITHROMYCIN	250MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	25/11/2021

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3212	NDA/MAL/HDP/6 424	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICAL S LTD	ASCORIL LS	LEVOSALBUTAMO L SULPHATE + AMBROXOL HYDROCHLORIDE + GUAIFENESIN	1 MG + 30 MG + 100 MG	GLENMARK PHARMACEUTICALS LTD .VILLAGE KISHANPURA, BADDI- NALAGARH ROAD, TEHSIL BADDI, DISTRICT SOLAN HP 173205	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE	27/03/2019
3213	NDA/MAL/HDP/6 425	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	CLARITEK	CLARITHROMYCIN	500MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	25/11/2021

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3214	NDA/MAL/HDP/6 426	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	SODIUM CHLORIDE INTRAVENOUS INFUSION BP	SODIUM CHLORIDE	0.9%W/V	ABARIS HEALTHCARE PVT. LTD-PLOT NO: 1407- 1411 VILLAGE: RAJPUR TALUKA: KADI, DIST.: MEHSANA 382 740, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2017
3215	NDA/MAL/HDP/6 430	IPCA LABORATOIES LTD	MEDVIN PHARMA LIMITED	LUMERAX DT 20/120	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	IPCA LABORATORIES LIMITED .PLOT 225/1, VILLAGE ATHAL, DANDRA AND NAGAR HAVELI UNION TERRITORY, SILVASSA-396 230	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X30.0X1.0X6.0 TABLET BLISTER,1.0X30.0X1 .0X12.0 TABLET BLISTER	27/03/2019



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3216	NDA/MAL/HDP/6 431	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BRUMOX 125	AMOXICILLIN TRIHYDRATE	125MG/5ML	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
3217	NDA/MAL/HDP/6 432	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	UMBI-GEL	CHLORHEXIDINE GLUCONATE	4 % W/W	KAMPALA PHARMACEUTICALS INDUSTRIES (1996)LTDSTRETCH R ROAD PLOT M444B NTINDA KAMPALA	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X50.0X1.0X5.0 G TUBE	27/03/2019

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3218	NDA/MAL/HDP/6 433	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	FICYC CREAM	ACICLOVIR	5%W/W	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE	01/07/2017
3219	NDA/MAL/HDP/6 435	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	FIMABUTE 200	CEFIXIME TRIHYDRATE	200MG	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2017

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3220	NDA/MAL/HDP/6 437	MERIDIAN ENTERPRISES PRIVATE LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	PILORECT	HYDROCORTISON E ACETATE +LIDOCAINE +ZINC OXIDE +ALLANTOIN	0.25%W/W+3%W/ W+5%W/W+0.5% W/W	MERIDIAN ENTERPRISES PVT. LTD PLOT NO. 418, G.I.D.C., KABILPORE, NAVSARI GUJARAT, INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X6.0 SUPPOSITORY STRIP	29/11/2017
3221	NDA/MAL/HDP/6 438	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMADOL PLUS	PARACETAMOL + CAFFEINE	500 MG + 65 MG	KAMPALA PHARMACEUTICALS INDUSTRIES (1996)LTD STRETCH R ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	27/03/2019

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3222	NDA/MAL/HDP/6 439	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	LIZOMAC 600	LINEZOLID	600MG	MACLEODS PHARMACEUTICALS LIMITED BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH - 174101 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X6.0X10.0 TABLET STRIP,1.0X10.0X10. 0 TABLET STRIP	01/07/2017
3223	NDA/MAL/HDP/6 440	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	CEFIWEL 400	CEFIXIME TRIHYDRATE	400MG	MALIK LIFESCIENCES PRIVATE LIMITED PLOT NO. 16, NH 58, VARDHMAN INDUSTRIAL ESTATE, VILLAGE BAHADARPUR SAINI HARIDWAR, UTTARAKHAND- 247667	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	28/03/2018

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3224	NDA/MAL/HDP/6 441	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	OFLOXACIN INTRAVENOUS INFUSION	OFLOXACIN	0.2%W/V	ABARIS HEALTHCARE PVT. LTD-PLOT NO: 1407- 1411 VILLAGE: RAJPUR TALUKA: KADI, DIST.: MEHSANA 382 740, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1X100 ML BOTTLE	30/05/2018
3225	NDA/MAL/HDP/6 442	ZIM LABORATORIES LTD	REDDYS PHARMA LIMITED	AZITO SUSPENSION	AZITHROMYCIN DIHYDRATE	200 MG/5ML	ZIM LABORATORIES LTDB-21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA,	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X30.0 ML BOTTLE,1.0X15.0 ML BOTTLE	31/01/2018

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3226	NDA/MAL/HDP/6 443	MICRO LABS	MALIX PHARMA (U) LIMITED	SINURHON SUSPENSION	CHLORPHENIRAM INE + PHENYLEPHRINE + PARACETAMOL	1MG + 5MG + 125MG	LEBEN LABORATORIES PVT LTD .L-14 PHASE III MIDC AKOLA 444 104	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	27/03/2019
3227	NDA/MAL/HDP/6 447	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	AZIBRU 500	AZITHROMYCIN DIHYDRATE	500MG	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0 TABLET BLISTER	01/07/2017

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3228	NDA/MAL/HDP/6 448	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIZOLONE- DEPOT 40 MG/ 1 ML VIAL	METHYLPREDNIS OLONE ACETATE	40 MG/ ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B1,EGYPT	EGYPT	PARENTERAL ORDINARY VIALS	1.0X1.0X1.0 ML VIAL	25/07/2018
3229	NDA/MAL/HDP/6 449	EVA PHARMA FOR PHARMACEUTICAL S & MEDICAL APPLIANCES	UNITED HEALTHCARE DISTRIBUTORS LTD	DESLORAT SYRUP	DESLORATIDINE	0.5MG/ML	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2017

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3230	NDA/MAL/HDP/6 454	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MAGRILAN 20MG	FLUOXETINE HYDROCHLORIDE	20MG	MEDOCHEMIE (FACTORY AZ).-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	29/01/2019
3231	NDA/MAL/HDP/6 455	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	FICYC TABLETS	ACYCLOVIR	200MG	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017



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3232	NDA/MAL/HDP/6 456	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	GLUCOSE INTRAVENOUS INFUSION BP (5% W/V)	GLUCOSE ANHYDROUS	5%W/V	ABARIS HEALTHCARE PVT. LTD-PLOT NO: 1407- 1411 VILLAGE: RAJPUR TALUKA: KADI, DIST.: MEHSANA 382 740, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2017
3233	NDA/MAL/HDP/6 459	MACLEODS PHARMACEUTICAL S LTDS LTD	VITACARE LIMITED	MACSUNATE AQ FORTE	ARTESUNATE + AMODIAQUINE	100MG + 270MG	MACLEODS PHARMACEUTICALS LTD ,.PHASE I & II, PLOT NO. 25-27 SURVEY NO. 366, PREMIERE INDUSTRIAL ESTATE, KACHIGAN, DAMAN- 396210	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER,1.0X25.0X3 .0 TABLET BLISTER,1.0X25.0X6 .0 TABLET BLISTER,1.0X6.0 TABLET BLISTER	27/03/2019

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3234	NDA/MAL/HDP/6 460	MANKIND PHARM LTD	TATA UGANDA LIMITED	NUROKIND-OD	MECOBALAMIN	1500MCG/ML	MANKIND PHARMA LTD.VILLAGE KISHANPURA, POAMTA SAHI DISTRICT SIRMOUR HIMACHAL PRADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X4.0X1.0 ML AMPOULE	27/03/2019
3235	NDA/MAL/HDP/6 462	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	AMOXYN-500	AMOXICILLIN TRIHYDRATE	500MG	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	26/09/2018

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3236	NDA/MAL/HDP/6 465	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	NEUROGAB 75	PREGABALIN	75MG	MACLEODS PHARMACEUTICALS LIMITED BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH - 174101 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2017
3237	NDA/MAL/HDP/6 468	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CIROLAZINE	HYDRALAZINE HYDROCHLORIDE	20MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE, 1.0X5.0X 1.0 ML AMPOULE	30/05/2018

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3238	NDA/MAL/HDP/6 472	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MOXICLAV 375	AMOXICILLIN TRIHYDRATE + CLAVULINIC ACID	250MG + 125MG	MEDOCHEMIE LTD – FACTORY B-PLOT 48, IAPETOU STREET, AGIOS ATHANASSIOS INDUSTRIAL; AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X10.0 CAPSULE STRIP	29/01/2019
3239	NDA/MAL/HDP/6 476	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIZOLONE- DEPOT	METHYLPREDNIS OLONE	80MG/2ML	EGYPTIAN INT.PHARMACEUTIC AL INDUSTRIES CO. E.I.P.C.O --10TH OF RAMADAN CITY – INDUSTRIAL AREA B1- P.O BOX: 149 TENTH - EGYPT	EGYPT	PARENTERAL RETARD VIALS	1.0X1.0X2.0 ML VIAL	25/07/2018

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3240	NDA/MAL/HDP/6 477	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MEDOFULVIN	GRISEOFULVIN	500 MG	MEDOCHEMIE (FACTORY AZ).-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	27/03/2019
3241	NDA/MAL/HDP/6 482	MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	EUTHROX 75MCG	LEVOTHYROXINE SODIUM	75 MCG	MERCK KGAA- PHARMA PRODUCTION DARMSTADT FRANKFURTER STRABE 250, D- 64293, DARMSTADT	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X2.0X25.0 TABLET BLISTER	27/03/2019

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3242	NDA/MAL/HDP/6 491	INTAS PHARMACEUTICAL S LIMITED	NORVIK ENTERPRISES LIMITED	PREGATAS ME 75	PREGABALIN +MECOBALAMIN	75MG+750MCG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI- 248197,DEHRADUN UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	28/03/2018
3243	NDA/MAL/HDP/6 495	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	MACROLYN® 500 MG FILM COATED TABLETS	AZITHROMYCIN DIHYDRATE	500MG	DEVA HOLDING A. S.ÇERKEZKÖY ORGANIZE SANAYI BOLGESI. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKİRDAĞ/ TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	29/11/2017

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3244	NDA/MAL/HDP/6 498	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	AMOXICILLIN DISPERSIBLE TABLETS 250 MG	AMOXICILLIN TRIHYDRATE	250MG	MICRO LABS LIMITED PLOT NO. 16, VEERASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BANGALORE – 560 100. KARNATAKA, INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET STRIP	25/07/2018
3245	NDA/MAL/HDP/6 499	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	TACROZ FORTE	TACROLIMUS USP	0.1%W/W	GLENMARK PHARMACEUTICALS LTD .PLOT E-37, 39, D ROAD, MIDC, SATPUR, NASHIK 422007, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X10.0 G TUBE	28/05/2019

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3246	NDA/MAL/HDP/6 500	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICAL S LTD	DERIVA C GEL	ADAPLENE BP + CLINDAMYCIN PHOSPHATE USP EQUIVALENT TO CLINDAMYCIN	1MG + 10MG	GLENMARK PHARMACEUTICALS LTD .PLOT E-37, 39, D ROAD, MIDC, SATPUR, NASHIK 422007, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X15.0 G TUBE	28/05/2019
3247	NDA/MAL/HDP/6 501	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICAL S LIMITED	AARTROGYL 200 TABLET	METRONIDAZOLE	200MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/11/2017



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3248	NDA/MAL/HDP/6 504	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	CAPXCEL	CAPECITABINE	500MG	KHANDELWAL LABORATORIES PVT. LTD (B-1, WAGLE INDUSTRIAL ESTATE, THANE - 400 604 INDIA)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET Blister	29/05/2029
3249	NDA/MAL/HDP/6 506	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	ACTITOP	ETOPOSIDE	50MG	KHANDELWAL LABORATORIES PVT. LTDB-1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1X8 CAPSULE BOTTLE	29/05/2019

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3250	NDA/MAL/HDP/6 507	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	ZITRAM P	ACETAMINOPHEN + TRAMADOL HYDROCHLORIDE	325MG + 37.5MG	IPCA LABORATORIES LTD PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3251	NDA/MAL/HDP/6 508	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	XALIPAT-100	OXALIPLATIN	100 MG/ 50ML (2MG/ML)	KHANDELWAL LABORATORIES PVT. LTDB-1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	PARENTERAL ORDINARY VIALS	1X1X50 ML VIAL	29/05/2019

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3252	NDA/MAL/HDP/6 510	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	TACROZ	TACROLIMUS USP	0.03%W/W	GLENMARK PHARMACEUTICALS LTD .PLOT E-37, 39, D ROAD, MIDC, SATPUR, NASHIK 422007, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X10.0 G TUBE	28/05/2019
3253	NDA/MAL/HDP/6 512	AXA PARENTERALS LTD	VITACARE LIMITED	AXACIP	CIPROFLOXACIN	200MG/100ML	AXA PARENTERAL LIMITEDPLOT NO.936,937&939, VILL. KISHANPUR, JAMALPUR,ROORKEE 247667, DISTT. HARIDWAR (UTTARAKHAND) INDIA.	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	31/01/2018

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3254	NDA/MAL/HDP/6 513	MACARTHYS LABORATORIES	LABOREX UGANDA LIMITED	GLYCOPYRRONIUM BROMIDE 200 MICROGRAMS PER ML SOLUTION FOR INJECTION	GLYCOPYRRONIUM BROMIDE	200MCG/ML	MACARTHYS LABORATORIES LIMITED T/A MARTINDALE PHARMABAMPTON ROAD, ROMFORD, ESSEX RM3 8UG,	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0 ML AMPOULE	28/05/2019
3255	NDA/MAL/HDP/6 514	EXPHAR SA.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	FEBRILEX	PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + CHLORPHENAMINE MALEATE	500MG + 5M + 2MG	MILAN LABORATORIES (INDIA) PVT LTD,63,67,87,35,36, 64, 65 JAWAHAR CO- OP INDUSTRIAL ESTATE KAMOTHE, PANVEL NAVI MUMBAI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET STRIP	28/05/2019

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3256	NDA/MAL/HDP/6 515	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	WOMASTIN	CARBOPLATIN	150MG/15ML	KHANDELWAL LABORATORIES PVT. LTDB-1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	PARENTERAL ORDINARY VIALS	1X15 ML VIAL	29/05/2019
3257	NDA/MAL/HDP/6 516	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	WOMASTIN	CARBOPLATIN	150MG/15ML	KHANDELWAL LABORATORIES PVT. LTDB-1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1X45 ML VIAL	29/05/2019

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3258	NDA/MAL/HDP/6 520	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	VOMIKIND-MD 8	ONDASENTRON	8MG	MANKIND PHARMA LTD-UNIT II VILLAGE KISHANPURA P.O JAMNIWALA TEHSIL PAONTA SAHIB DISTRICT SIRMOUR 173 025 HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017
3259	NDA/MAL/HDP/6 521	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	KIPEL 4	MONTELUKAST	4MG	MSN LABORATORIES LTD. PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, ZIP CODE - 502 325, ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/03/2019

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3260	NDA/MAL/HDP/6 522	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EPNONE 25	EPLERENONE	25MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/03/2019
3261	NDA/MAL/HDP/6 523	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	FLEXDOL	IBUPROFEN+MET HOCARBAMOL	200MG+500MG	GRACURE PHARMACEUTICAL LTDE-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017

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3262	NDA/MAL/HDP/6 524	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S LIMITED	RAMGIC	TRAMADOL HYDROCHLORIDE	50MG/ML	MSN LABORATORIES LTD. PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, ZIP CODE - 502 325, ANDHRA PRADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X2.0 ML AMPOULE	27/03/2019
3263	NDA/MAL/HDP/6 525	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S LIMITED	DAPOXEM 30	DAPOXETINE	30MG	MSN LABORATORIES LTD. PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, ZIP CODE - 502 325, ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/03/2019



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3264	NDA/MAL/HDP/6 526	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S LIMITED	DAPOXEM 60	DAPOXETINE	60MG	MSN LABORATORIES LTD. PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, ZIP CODE - 502 325, ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/03/2019
3265	NDA/MAL/HDP/6 527	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PULMOFIRST 62.5	BOSENTAN MONOHYDRATE	62.5MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISION PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	27/03/2019

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3266	NDA/MAL/HDP/6 528	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PULMOFIRST 125	BOSENTAN MONOHYDRATE	125MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	27/03/2019
3267	NDA/MAL/HDP/6 532	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	BUNASE 200	BUDESONIDE	200MCG / ACTUATION	OXALIS LABS- VILLAGE THEDA,P.O.LODHIM AJRA ,TEHSIL BADDI,DIST .SOLAN (HIMACHAL PRADESH) - 174101 INDIA	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X1.0 CANNISTER CARTON	28/03/2018

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3268	NDA/MAL/HDP/6 536	PHARMATHEN INVESTMENTS GROUP LTD	GOODMAN INTERNATIONAL LTD	OZAPEX 5MG	OLANZAPINE	5MG	PHARMATHEN S.A6, DERVENAKION STR. 15351 PALLINI ATHENS	GREECE	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X4.0X7.0 TABLET BLISTER	28/03/2019
3269	NDA/MAL/HDP/6 537	EXPHAR LTD.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CARBOSOL	CARMELLOSE SODIUM	0.5%W/V	AHLCONPARENTERA LS (INDIA) LIMITEDSP- 918, PHASE-III, BHIWADI-301019, RAJASTHAN (INDIA) TEL: +91-1493- 305300 (30 LINES) FAX: +91-1493- 221045, 305345	INDIA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE	31/01/2018

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3270	NDA/MAL/HDP/6 538	PHARMATHEN INVESTMENTS GROUP LTD	GOODMAN INTERNATIONAL LTD	OZAPEX 10MG	OLANZAPINE	10MG	PHARMATHEN S.A6, DERVENAKION STR. 15351 PALLINI ATHENS	GREECE	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X4.0X7.0 TABLET BLISTER	28/03/2019
3271	NDA/MAL/HDP/6 545	RAPTAKOS, BRETT & CO. LTD.	EUROPA HEALTHCARE (U) LTD	ZYTEE RB	CHOLINE SALICYLATE + BENZALKONIUM CHLORIDE	9%W/W + 0.02% W/V	RAPTAKOS BRETT & CO.LTD1ST POKHRAN ROAD,THANE 400 606	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X10.0 ML TUBE	27/03/2019

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3272	NDA/MAL/HDP/6 546	RAPTAKOS, BRETT & CO. LTD.	EUROPA HEALTHCARE (U) LTD	NEOPEPTINE	ALPHA AMYLASE + PAPAIN	100MG + 50MG /5ML	RAPTAKOS BRETT & CO.LTD1ST POKHRAN ROAD,THANE 400 606	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X60.0 ML BOTTLE	27/03/2019
3273	NDA/MAL/HDP/6 549	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	PIRAV-75	PREGABALIN	75MG	RAVIAN LIFE SCIENCE PVT LTD PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1X10X10 CAPSULE BLISTER, 1X3X10 CAPSULE BLISTER	28/03/2019

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3274	NDA/MAL/HDP/6 550	REDDYS PHARMA LIMITED	REDDYS PHARMA LIMITED	REDCEPHIN	CEFTRIAZONE	1 G	INJECT CARE PARENTERALS PVT LTD PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	27/03/2019
3275	NDA/MAL/HDP/6 551	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICAL S LIMITED	NUROFEN FOR CHILDREN SUGAR FREE	IBUPROFEN	100MG/5ML	RECKITT BENCKISER HEALTHCARE - DAMSON LANE, HULL, HUB HU8 7DS	UNITED KINGDOM	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	27/03/2019

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3276	NDA/MAL/HDP/6 552	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICAL S LIMITED	NUROFEN	IBUPROFEN + LYSINE	342MG	RECKITT BENCKISER HEALTHCARE - DAMSON LANE,HULL, HUB HU8 7DS	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X12.0 TABLET BLISTER	27/03/2019
3277	NDA/MAL/HDP/6 553	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENSOL SOLUTION	CHLORHEXIDINE GLUCONATE + ISOPROPYL ALCOHOL	0.5% W/W + 70% W/W	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X5.0 L CONTAINER	27/03/2019

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3278	NDA/MAL/HDP/6 554	SEGURA PHARMA PRIVATE LTD	ABACUS PHARMA (AFRICA) LIMITED	RESPIQUIN-750	LEVOFLOXACIN	750MG	SAI MIRRA INNOPHARM PVT LIMITED 288&299, SIDCO ESTATE AMBTTUR, CHENNAI 600098	INDIA	ORAL SOLID ORDINARY TABLETS	2.0X1.0X1.0X10.0 TABLET BLISTER	27/03/2019
3279	NDA/MAL/HDP/6 556	SAVA HEALTHCARE LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	BECLOGEN CREAM	CLOTRIMAZOLE USP, BECLOMETASONE DIPROPIONATE BP, GENTAMICIN SULPHATE BP	1%W/W, 0.025%W/W, 0.1%W/W	SAVA HEALTHCARE LIMITED.PLOT NO 507B -512, G.I.D.C. ESTATE, WADHWANCITY-363 035 SURENDRANAGAR, GUJARAT, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	27/03/2019



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3280	NDA/MAL/HDP/6 562	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	ATROPINE EYE DROP BP 1 %W/V	ATROPINE SULPHATE	1%W/V	SWISS PARENTERALS PVT LTD ..809, KERALA INDUSTRIAL ESTAE, GIDC NEAR BAVLA, AHMEDABAD 382220, GUJARAT	INDIA	OPHTHALMIC LIQUIDS	1X1X10 ML VIAL	28/03/2019
3281	NDA/MAL/HDP/6 563	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ANATAX <sup>®</sup> 16MG	BETAHISTINE DIHYDROCHLORID E	16MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANYJORDAN - NUZHAT SAHAB	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X6.0X10.0 TABLET BLISTER	27/03/2019

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3282	NDA/MAL/HDP/6 565	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	IBUPROFEN	IBUPROFEN	200MG	TRIVENI FORMULATIONS LTD PLOT NO. 52,53,54,63,62,64 ALEAP INDUSTRIAL ESTATE SARAMPALLI VIJAYWADA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	28/03/2019
3283	NDA/MAL/HDP/6 568	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	PINNADIP 50 TABLET	DICLOFENAC	50MG	PINNACLE LIFE SCIENCE PVT LTD KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017

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3284	NDA/MAL/HDP/6 569	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	MARDAGRA 50	SILDENAFIL CITRATE	50MG	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA PSA CHEMICALS & PHARMACEUTICALS PRIVATE LIMITED - 3, SEZ-II, PITHAMPUR, DISTT. DHAR, MADHYA PRADESH - 454 774, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	27/03/2019
3285	NDA/MAL/HDP/6 572	NTICALS LTD.	VITACARE LIMITED	METOMAC 50	METOPROLOL SUCCINATE	50MG	MACLEODS PHARMACEUTICALS LIMITED BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH - 174101 INDIA	INDIA	ORAL SOLID RETARD TABLETS	1.0X1.0X10.0 TABLET BLISTER	27/11/2018

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3286	NDA/MAL/HDP/6 573	NTICALS LTD.	VITACARE LIMITED	EFAVIRENZ TABLETS USP 400MG	EFAVIRENZ	400MG	MACLEODS PHARMACEUTICALS LIMITED BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH - 174101 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE	25/07/2018
3287	NDA/MAL/HDP/6 577	UNOSOURCE PHARMA LTD	MEDVIN PHARMA LIMITED	CEFIWEL-200	CEFIXIME	200MG	MALIK LIFESCIENCES PRIVATE LIMITED PLOT NO. 16, NH 58, VARDHMAN INDUTRIAL ESTATE, VILLAGE BAHADARPUR SAINI HARIDWAR, UTTARAKHAND- 247667	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	21/11/2019

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3288	NDA/MAL/HDP/6 578	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ACINET DRY SYRUP 228.5MG/5ML	AMOXYCILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	200MG + 28.5MG PER 5ML	INDCHEMIE HEALTH SPECIALITIES PVT. LTDVILLAGE-THANA, BADDI, DIST. SOLAN, HIMACHAL PRADESH- 173 205.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	27/08/2019
3289	NDA/MAL/HDP/6 579	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	PLENCOXIB 200	CELECOXIB	200 MG	AKUMS DRUGS AND PHARMACEUTICALS1 9,20,21, SEC.6-A, IIE, SIDCUL, RANIPUR,HARIDWAR- 249403, UTTARAKHAND, INDIAINDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X6.0X10.0 CAPSULE BLISTER,10.0X10.0 CAPSULE BLISTER	27/08/2019

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3290	NDA/MAL/HDP/6 584	ZIFAM PINNACLE LTD	DELMAW ENTERPRISES LIMITED	ZIFLODIP 5	AMLODIPINE BESYLATE	5 MG	FREDUN PHARMACEUTICALS LIMITED14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PA LGHAR (E), DIST: PALGHAR-401 404	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	27/08/2019
3291	NDA/MAL/HDP/6 585	ZIFAM PINNACLE PTY. LTD.	DELMAW ENTERPRISES LIMITED	ZIFLODIP 10	AMLODIPINE BESYLATE	10 MG	FREDUN PHARMACEUTICALS LIMITED14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PA LGHAR (E), DIST: PALGHAR-401 404	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	27/08/2019

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3292	NDA/MAL/HDP/6 589	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICAL S LIMITED	VANBACT	VANCOMYCIN HYDROCHLORIDE	500MG	NABIQASIM INDUSTRIES (PVT) LTD .17/24 KORANGI INDUSTRIAL AREA KORANGI KARACHI	PAKISTAN	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	28/05/2019
3293	NDA/MAL/HDP/6 590	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICAL S LIMITED	LOPROT	OMEPRAZOLE SODIUM	40MG	NABIQASIM INDUSTRIES (PVT) LTD .17/24 KORANGI INDUSTRIAL AREA KORANGI KARACHI	PAKISTAN	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	28/05/2019

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3294	NDA/MAL/HDP/6 593	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICAL S LIMITED	TRANSIC	TRANEXAMIC ACID	500MG	SURGE LABS (PVT) LTD10TH KM FAISALABAD ROAD, BIKHI DISTRICT SHEIKHUPURA	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0 ML AMPOULE	28/05/2019
3295	NDA/MAL/HDP/6 598	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S LIMITED	BREATHEZY-L (10/5)	MONTELUKAST SODIUM + LEVOCETIRIZINE DIHYDROCHLORID E	10MG + 5MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/01/2019



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3296	NDA/MAL/HDP/6 600	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	PROSTALEN	ALFUZOSIN HYDROCHLORIDE	10MG	GRACURE PHARMACEUTICAL LTDE-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/03/2019
3297	NDA/MAL/HDP/6 602	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	CARDIURINE	CAPTOPRIL + HYDROCHLOROT HIAZIDE	50MG + 25MG	GRACURE PHARMACEUTICAL LTDE-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/03/2019

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3298	NDA/MAL/HDP/6 608	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CIPROCIN 0.3%	CIPROFLOXACIN HYDROCHLORIDE	0.3%W/W	ORCHIDIA10TH RAMADHAN CITY INDUSTRIAL AREA- B1 , P. O. BOX 149 TENTH, EGYPT	EGYPT	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE	28/05/2019
3299	NDA/MAL/HDP/6 610	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	VOMIKIND	ONDANSETRON HYDROCHLORIDE	2MG/ML	MANKIND PHARMA LTD-UNIT II VILLAGE KISHANPURA P.O JAMNIWALA TEHSIL PAONTA SAHIB DISTRICT SIRMOUR 173 025 HIMACHAL PRADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X4.0X2.0 ML AMPOULE,1.0X4.0X 4.0 ML AMPOULE	01/07/2014

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3300	NDA/MAL/HDP/6 611	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	MARDAGRA 100	SILDENAFIL CITRATE	100MG	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA PSA CHEMICALS & PHARMACEUTICALS PRIVATE LIMITED - 3, SEZ-II, PITHAMPUR, DISTT. DHAR, MADHYA PRADESH - 454 774, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	29/05/2019
3301	NDA/MAL/HDP/6 612	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	APRAZOLE PLUS- 20	OMEPRAZOLE + SODIUM BICARBONATE	20MG/6G + 1680MG/6G	AJANTA PHARMA LIMITED PAITHANMANUFACT URING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY POWDERS	1.0X20.0X6.0 G SACHET	01/07/2008

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3302	NDA/MAL/HDP/6 613	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	OLMAT-40	OLMESARTAN MEDOXOMIL	40MG	MICRO LABS LTD 92 SIPCOT 92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3303	NDA/MAL/HDP/6 614	MEDOCHÉMIE LTD	LABOREX UGANDA LIMITED	AXETINE	CEFUROXIME SODIUM	1.5MG	MEDOCHÉMIE LIMITED (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL - CYPRUS.	CYPRUS	PARENTERAL ORDINARY VIALS	1.0X10.0 VIAL CARTON	01/07/2008

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3304	NDA/MAL/HDP/6 616	SHIN POONG PHARMACEUTICAL S CO.LTD	AAFIYA (A) LIMITED	PYRAMAX	PYRONARIDINE TETRAPHOSPHAT E + ARTESUNATE	180MG + 60MG	SHIN POONG PHARM. CO., LTD70, SANDAN-RO, 19 BEON-GIL, DANWON- GU, ANSAN-SI, GYEONGGI-DO, REPUBLIC OF KOREA	SOUTH KOREA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X9.0 TABLET BLISTER	01/07/2016
3305	NDA/MAL/HDP/6 617	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	APFLU	CHLOROPHENERA MINE + PARACETAMOL + VITAMIN C	0.5MG + 120MG + 50MG	AJANTA PHARMA LIMITED31-0 MIDC INDUSTRIAL AREA CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA STATE	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2009

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3306	NDA/MAL/HDP/6 619	ESAPHARM SRL	BYAMA KA PHARMACEUTICAL COMPANY LTD	ORANVATE	CLOBETASOL PROPIONATE	0.05G/100G	ESAPHARMA SRL VIA DE GASPERI, 13- 20066 MELZO (MILAN) ITALY	ITALY	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/2016
3307	NDA/MAL/HDP/6 620	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILET 5MG	NEBIVOLOL HYDROCHLORIDE	5MG	BERLIN-CHEMIE AG BERLIN-CHEMIE AG GLIENICKER WEG 125 D-12489 BERLIN	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X14.0 TABLET BLISTER, 1.0X2.0X14 .0 TABLET BLISTER	01/07/2016

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3308	NDA/MAL/HDP/6 621	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	BAROLE 20	RABEPRAZOLE	20MG	INVENTIA HEALTHCARE LIMITEDF-1 - F-1/1 - F75/1, ADDITIONAL AMBERNATH MIDC, AMBERNATH EAST 421506, DIST. THANE, MAHARASHTRA - INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2011
3309	NDA/MAL/HDP/6 622	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	CEFIWEL-100 DT	CEFIXIME TRIHYDRATE	100MG	MALIK LIFESCIENCES PRIVATE LIMITEDPLOT NO. 16, NH 58, VARDHMAN INDUTRIAL ESTATE, VILLAGE BAHADARPUR SAINI HARIDWAR, UTTARAKHAND- 247667	INDIA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016

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3310	NDA/MAL/HDP/6 624	SQUARE PHARMACEUTICAL S LTD.PABNA UNIT	GAMA PHARMACEUTICAL S (U) LIMITED	CIPROKEN	CIPROFLOXACIN HYDROCHLORIDE	0.3%W/V	SQUARE PHARMACEUTICALS LTD DHAKA UNIT KALIAKOIR GAZIPUR	BANGLADESH	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2016
3311	NDA/MAL/HDP/6 625	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	NEBILET PLUS 5/12.5	NEBIVOLOL HYDROCHLORIDE + HYDROCHLOROT HIAZIDE	5MG + 12.5MG	BERLIN-CHEMIE AG/MENARINI,GLIEN ICKER WEG 125, D- 12489 BERLIN GERMANY BERLIN- CHEMIE AG, SITE BRITZ (BULK PRODUCTION, ) BERLIN-CHEMIE AG, SITE BRITZ (BULK PRODUCTION, BATCH CONTROL) TEMPELHOFFER WEG 83 D-12347 BERLIN GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER,1.0X1.0X4. 0 TABLET BLISTER (FREE MEDICAL SAMPLE)	01/07/2016



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3312	NDA/MAL/HDP/6 627	RECKITT BENCKISER HEALTHCARE INTERNATIONAL	GITTOES PHARMACEUTICAL S LIMITED	STREPSILS HONEY & LEMON	MULTI- INGREDIENT	MULTI- INGREDIENT	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED65 MOO 12,LARD KRABANG- BANGPLEE ROAD, BANGPLEE SAMUTPRAKARAN 10 540, THALAND	THAILAND	ORAL SOLID ORDINARY LOZENGES	1.0X24.0 LOZENGE PACK,1.0X70.0 LOZENGE PACK,50.0X2.0 LOZENGE BLISTER,2.0X12.0 LOZENGE BLISTER	01/07/1997
3313	NDA/MAL/HDP/6 628	RECKITT BENCKISER HEALTHCARE INTERNATIONAL	GITTOES PHARMACEUTICAL S LIMITED	STREPSILS ORIGINAL	MULTI- INGREDIENT	MULTI- INGREDIENT	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITEDRECKITT BENCKISER HEALTHCARE INTERNATIONAL-65 MOO 12,LARD KRABANG-BANGPLEE ROAD, BANGPLEE SAMUTPRAKARAN 10 540, THALAND	THAILAND	ORAL SOLID ORDINARY LOZENGES	1.0X24.0 LOZENGE PACK,1.0X70.0 LOZENGE PACK,100.0X2.0 LOZENGE BLISTER,2.0X12.0 LOZENGE BLISTER	01/07/1997

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3314	NDA/MAL/HDP/6 629	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILET PLUS 5/25	NEBIVOLOL+HYDR OCHLOROTHIAZID E	5MG+25MG	BERLIN-CHEMIE AG/MENARINIGLIENI CKER WEG 125, D- 12489 BERLIN GERMANY(BATCH RELEASE) BERLIN- CHEMIE AG, SITE BRITZ (BULK PRODUCTION)TEMP ELHOFER WEG 83 D-12347 BERLIN GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER,1.0X1.0X4. 0 TABLET BLISTER	01/07/2016
3315	NDA/MAL/HDP/6 630	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TOPRAZ 20	PANTOPRAZOLE	20MG	AUROBINDO PHARMA LIMITED (SEZ, UNIT " VII), SURVEY NO.411, 425, 434, 435 & 458, APIIC, PLOT NO. SI GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHERLA MANDAL, MAHABOOB NAGAR DISTRICT, HYDERABAD, ANDHRA PRADESH 500090, INDIA AUROBINDO UNIT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016

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3316	NDA/MAL/HDP/6 631	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOBURN	SILVER SULFADIAZINE	1%W/W	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X500.0 G JAR	01/07/2016
3317	NDA/MAL/HDP/6 633	SHELYS PHARMACEUTICAL S LTD	BETA HEALTHCARE UGANDA LIMITED	COLDRIL	PARACETAMOL + CHLORPHENIRAM INE MALEATE + PSEUDOEPHEDRI NE HCL	500MG + 30MG + 2MG	BETA HEALTHCARE INTERNATIONAL LTD -PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X12.0X1 .0X2.0X10.0 CAPSULE BLISTER	01/07/2017

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3318	NDA/MAL/HDP/6 636	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S LIMITED	COSAMIDE 100	LACOSAMIDE	100MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISION PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016
3319	NDA/MAL/HDP/6 638	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S LIMITED	COSAMIDE 50	LACOSAMIDE	50MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISION PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016

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3320	NDA/MAL/HDP/6 640	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SAFETELMI H ( 40/ 12.5)	TELMISARTAN + HYDROCHLOROT HIAZIDE	40MG + 12.5MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3321	NDA/MAL/HDP/6 641	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	CEFTRISONE- S 1.5G	CEFTRIAZONE SODIUM + SULBACTAM SODIUM	1.0G + 0.5G	AKUMS DRUGS & PHARMACEUTICALS LTD. -PLANT III,PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL,RANIPUR, 249 403	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.5 G VIAL + 10ML WFI AMPOULE	01/07/2016

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3322	NDA/MAL/HDP/6 645	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SAFETELMI H ( 80/ 12.5)	TELMISARTAN + HYDROCHLOROT HIAZIDE	80MG + 12.5MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3323	NDA/MAL/HDP/6 650	INDUS LIFE SCIENCES PVT LIMITED	NORVIK ENTERPRISES LIMITED	INTRIAX-S-1	CEFTRIAXONE SODIUM+SULBAC TAM SODIUM	1G+0.5G	INJECT CARE PARENTERALS PVT LTD PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	01/07/2016

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3324	NDA/MAL/HDP/6 653	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	METSAFE 500 ER	METFORMIN HYDROCHLORIDE	500MG	MSN LABORATORIES PVT. LIMITED PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID RETARD TABLETS	1X3X10 TABLET BLISTER	01/07/2017
3325	NDA/MAL/HDP/6 654	PANACEA BIOTEC PHARMA LTD	VITACARE LIMITED	LIVOLUK FIBRE	LACTULOSE + ISPAGHULA HUSK	10G + 3.5G/ 15G	PANACEA BIOTEC PHARMA LIMITED MALPURI BADDI, DISTRICT SOLAN, HIMACHAL PRADESH-173205 - INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X90.0 G CONTAINER	01/07/2016

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3326	NDA/MAL/HDP/6 658	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	NEBIEM 10	NEBIVOLOL	10MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3327	NDA/MAL/HDP/6 662	SAKAR HEALTHCARE PVT LTD	ROYAL PHARMA 2011 LIMITED	DIAPAM	DIAZEPAM	5MG/ML	SAKAR HEALTHCARE PVT LIMITEDPLOT 10/13 SARKHEJ- BAVLA ROAD, AHMEDABAD, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X2.0 ML AMPOULE	01/07/2013



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3328	NDA/MAL/HDP/6 663	PANACEA BIOTEC PHARMA LTD	VITACARE LIMITED	SITCOM	EUPHORBIA PROSTATA DRY EXTRACT	10MG/G	PANACEA BIOTEC PHARMA LIMITEDMALPURI BADDI, DISTRICT SOLAN, HIMACHAL PRADESH-173205 - INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	01/07/2013
3329	NDA/MAL/HDP/6 664	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMOX 125 KID	AMOXICILLIN TRIHYDRATE	125MG	SPARSH BIO-TECH PVT. LIMITEDPLOT NO. 1;SURVEY NO. 242/243/244,LAKHA BAVAD,JAMNAGAR- 361 006, INDIA.	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016

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3330	NDA/MAL/HDP/6 665	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	SALBUMOL SYRUP	SALBUTAMOL	2MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997
3331	NDA/MAL/HDP/6 666	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	NEBIEM 5	NEBIVOLOL HYDROCHLORIDE	5MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017

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3332	NDA/MAL/HDP/6 667	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMOX 250 DT	AMOXICILLIN TRIHYDRATE	250MG	SPARSH BIO-TECH PVT. LIMITED PLOT NO. 1; SURVEY NO. 242/243/244, LAKHA BAVAD, JAMNAGAR- 361 006, INDIA.	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2016
3333	NDA/MAL/HDP/6 669	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	SUPER WELGRA - 100	SILDENAFIL CITRATE + DAPOXETINE HYDROCHLORIDE	100MG + 60MG	AKUMS DRUGS AND PHARMACEUTICALS LTD PLANT-1 PLOT NO.19, 20&21 SECTOR-6A, 11E, SIDCUL, RAHIPUR DISTT; HARIDWAR, 249403, (UTTRAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0 TABLET BLISTER	01/07/2016

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3334	NDA/MAL/HDP/6 670	AFRICURE PHARMACEUTICAL S (INDIA) PRIVATE LIMITED	ROYAL PHARMA 2011 LIMITED	METROSIM-200	METRONIDAZOLE	200MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED PLOT 9- 12, DEWAN & SONS INDL. AREA, VEOOR, PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X1000.0 TABLET CONTAINER	01/07/1997
3335	NDA/MAL/HDP/6 675	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	UNOSEMIDE -10	FUROSEMIDE	10MG/ML	AKUMS DRUGS & PHARMACEUTICALS LTD. -PLANT III, PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL, RANIPUR, 249 403	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2016

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3336	NDA/MAL/HDP/6 679	BLUE CROSS LABORATORIES LIMITED	STAR PHARMACEUTICAL S LTD	WOMIBAN TABLETS	ALBENDAZOLE	400MG	BLUE CROSS LABORATORIES LTDL- 17, VERNA INDUSTRIAL ESTATE,VERNA GOA- 403722	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0 TABLET STRIP	01/07/1997
3337	NDA/MAL/HDP/6 681	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	WELQUINE	LEVOFLOXACIN	0.5%W/V	AKUMS DRUGS & PHARMACEUTICALS LTD. PLANT III, PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL, RANIPUR, HARIDWAR, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2016

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3338	NDA/MAL/HDP/6 685	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	EVACEF	CEFOTAXIME	1 G	NEON LABORATORIES LTD PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2014
3339	NDA/MAL/HDP/6 686	DAWA LIMITED	SUPER MEDIC LTD	DAWASOLONE	PREDNISOLONE	5MG	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2010

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3340	NDA/MAL/HDP/6 689	DAWA LIMITED	SUPER MEDIC LTD	EFLARON	METRONIDAZOLE	200MG	MEDICO REMEDIES PVT LTD.,8 & 9 DEWAN AND SONS, UDYOG NAGAR, PALGHAR, DIST. THANE-401404, MAHARSHITRA DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1997
3341	NDA/MAL/HDP/6 693	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	CERTICAN1	EVEROLIMUS	1MG	NOVARTIS PHARMA STEIN AG.SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X6.0X10.0 TABLET BLISTER	01/07/2016

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3342	NDA/MAL/HDP/6 694	NOVARTIS PHARMA SERVICES INC.	SURGIPHARM (U) LIMITED	CERTICAN 0.5	EVEROLIMUS	0.5MG	NOVARTIS PHARMA STEIN AG.SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X6.0X10.0 TABLET BLISTER	01/07/2016
3343	NDA/MAL/HDP/6 695	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ORAV-OZ	OFLOXACIN + ORNIDAZOLE	200MG + 500MG	RAVIAN LIFE SCIENCE PVT LTD PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1X1X10 TABLET BLISTER	29/05/2019



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3344	NDA/MAL/HDP/6 699	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ATVIN-20	ATORVASTATIN	20MG	RAVIAN LIFE SCIENCE PVT LTD PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	28/05/2019
3345	NDA/MAL/HDP/6 713	CACHET PHARMACEUTICAL S PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	CAMET	METOCLOPRAMI DE HYDROCHLORIDE	10MG	CACHET PHARMACEUTICALS PVT LTD THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009

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3346	NDA/MAL/HDP/6 715	CACHET PHARMACEUTICAL S PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	CAZITHRO	AZITHROMYCIN	200MG/5ML	CACHET PHARMACEUTICALS PVT LTD THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X15.0 ML BOTTLE	01/07/2009
3347	NDA/MAL/HDP/6 717	CACHET PHARMACEUTICAL S PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	CAZITHRO	AZITHROMYCIN	500MG	CACHET PHARMACEUTICALS PVT LTD THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER	01/07/2011

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3348	NDA/MAL/HDP/6 722	MEGA LIFSCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	CILZEC 40	TELMISARTAN	40MG	MSN LABORATORIES PVT. LIMITEDPLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	05/05/2017
3349	NDA/MAL/HDP/6 724	MEGA LIFSCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	CILZEC 80	TELMISARTAN	80MG	MSN LABORATORIES PVT. LIMITEDPLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016

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3350	NDA/MAL/HDP/6 728	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CIPROCOS-500 TABLETS	CIPROFLOXACIN	500MG	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,10.0X10.0 TABLET BLISTER	01/07/2000
3351	NDA/MAL/HDP/6 729	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSCOF 'C' LINCTUS	MULTI- INGREDIENT	MULTI- INGREDIENT	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2010

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3352	NDA/MAL/HDP/6 732	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSCOF EXPECTORANT ORIGINAL	MULTI- INGREDIENT	MULTI- INGREDIENT	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2010
3353	NDA/MAL/HDP/6 734	CACHET PHARMACEUTICAL S PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	EASCOF	BROMHEXINE HCL + SALBUTAMOL SULPHATE + GUAIPHENESIN + MENTHOL	(4MG + 2MG + 100MG + 1MG)/10ML	CACHET PHARMACEUTICALS PVT LTD THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2009

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3354	NDA/MAL/HDP/6 736	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	SANDOSTATIN	OCTREOTIDE ACETATE	0.05MG	NOVARTIS PHARMA STEIN AG.SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	PARENTERAL ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE	01/07/2016
3355	NDA/MAL/HDP/6 750	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	NYTIN	NYSTATIN	500,000IU	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER	01/07/2005

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3356	NDA/MAL/HDP/6 752	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	VITACEE	ASCORBIC ACID	100MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2000
3357	NDA/MAL/HDP/6 754	INDIAN IMMUNOLOGICALS LIMITED	TATA UGANDA LIMITED	ABHAYRAB	RABIES ANTIGEN DERIVED FROM RABIES VIRUS(L.PASTEUR 2061/VERO STRAIN)	>2.5 I.U PER VIAL	HUMAN BIOLOGICALS INSTITUTE ( A DIVISION OF INDIAN IMMUNOLOGICALS LTD) .KOZHIPPANAI PUDUMUND P.O DR. BASAVIAH NAGAR UDHAGAMANDALA M PIN: 643007 TAMIL NADU	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X2.5 I.U VIAL 1*0.5ML DILUENT(0.9%W/V SODIUM CHLORIDE INJ. B.P) - 1 DOSE VIAL	01/07/2016

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3358	NDA/MAL/HDP/6758	ADCOCK INGRAM LIMITED	SURGIPHARM (U) LIMITED	ADCO-NAPAMOL	PARACETAMOL	500MG	ADCOCK INGRAM LIMITED 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE  560099, KARNATAKA STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2016
3359	NDA/MAL/HDP/6759	ADCOCK INGRAM LIMITED	SURGIPHARM (U) LIMITED	BETAPYIN	PARACETAMOL+CODEINE PHOSPHATE+DOXYLAMINE+CAFFEINE	450 MG+10 MG+5 MG+50 MG	ADCOCK INGRAM LIMITED 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE  560099, KARNATAKA STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	2.0X9.0 TABLET BLISTER,6.0X9.0 TABLET BLISTER,1.0X1.0X9.0 TABLET BLISTER	01/07/2017



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3360	NDA/MAL/HDP/6 763	ADCOCK INGRAM LIMITED	SURGIPHARM (U) LIMITED	COMPRAL HEADACHE TABLETS	PARACETAMOL+A SPIRIN+CAFFEINE ANHYDROUS	100MG+400MG+1 30MG	ADCOCK INGRAM LIMITED 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE  560099, KARNATAKA STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X48.0X2.0 TABLET STRIP	01/07/2005
3361	NDA/MAL/HDP/6 764	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	IZRA 40	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40MG	UNICHEM LABORATORIES LTDUNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0 TABLET STRIP	01/07/2006

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3362	NDA/MAL/HDP/6 767	ADCOCK INGRAM LIMITED	SURGIPHARM (U) LIMITED	MEDI-KEEL A	BENZOCAINE+CET YLPYRIDINIUM CHLORIDE	12MG+1.5MG	UNIQUE PHARMACEUTICALS LABORATORIESSURV EY NO. 101/2 AND 102/1, DAMAN INDUSTRIAL ESTATE, AIRPORT ROAD, KADAIYA, DAMAN – 396 210 INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X2.0X8.0 LOZENGE BLISTER	01/07/2016
3363	NDA/MAL/HDP/6 769	ADCOCK INGRAM LIMITED	SURGIPHARM (U) LIMITED	MEDI-KEEL A HONEY & LEMON	BENZOCAINE+CET YLPYRIDINIUM CHLORIDE	12MG+1.5MG	UNIQUE PHARMACEUTICALS LABORATORIESSURV EY NO. 101/2 AND 102/1, DAMAN INDUSTRIAL ESTATE, AIRPORT ROAD, KADAIYA, DAMAN – 396 210 INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X2.0X8.0 LOZENGE BLISTER	01/07/2016

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3364	NDA/MAL/HDP/6 771	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DIFLUVID	FLUCONAZOLE	150MG	HOVID BERHAD,LOT 56442, 7 1/2 MILES JALAN IPOH/CHEMOR 31200, CHEMOR PERAK	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0 CAPSULE BLISTER	01/07/2016
3365	NDA/MAL/HDP/6 772	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	PIOSAFE 30	PIOGLITAZONE HCL	30MG	ARISTO PHARMACEUTICALS PVT LTD PLOT NO 208 NEW INDUSTRIAL GREEN NO2 MANDIDEED 462046	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2007

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3366	NDA/MAL/HDP/6776	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	M-FORLIN 500	METFORMIN	500MG	LINCOLN PHARMACEUTICAL LIMITED TRIMAL ESTATE KHATRAJ KOLOL, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010
3367	NDA/MAL/HDP/6778	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL IBUPROFEN	IBUPROFEN	100MG/5ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2016

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3368	NDA/MAL/HDP/6 781	IND SWIFT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	NETAZOX-500	NITAZOXANIDE	500MG	IND-SWIFT LIMITED INDUSTRIAL GROWTH CENTRE, PHASE I, SAMBA (JAMMU), J&K 184121, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X1.0X6.0 TABLET BLISTER	01/07/2007
3369	NDA/MAL/HDP/6 785	IND SWIFT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	NETAZOX DT	NITAZOXANIDE	200MG	IND-SWIFT LIMITED INDUSTRIAL GROWTH CENTRE, PHASE I, SAMBA (JAMMU), J&K 184121, INDIA	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0X1.0X6.0 TABLET BLISTER	01/07/2008

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3370	NDA/MAL/HDP/6 787	IND SWIFT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	NETAZOX	NITAZOXANIDE	100MG/5ML	IND-SWIFT LIMITED INDUSTRIAL GROWTH CENTRE, PHASE I, SAMBA (JAMMU), J&K 184121, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X30.0 ML BOTTLE	01/07/2008
3371	NDA/MAL/HDP/6 788	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ROYAL VIT G	MULTI- INGREDIENTS	MULTI- INGREDIENTS	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)-1ST INDUSTRIAL ZONE, S" OF OCTOBER CITY, EGYPT. PO. BOX 43, OCTOBER CITY. POSTAL CODE NO.12566	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2005

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3372	NDA/MAL/HDP/6 789	AFRICURE PHARMACEUTICAL S (INDIA) LTD	DELMAW ENTERPRISES LIMITED	AFRINAC	DICLOFENAC SODIUM	75MG/3ML	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II-31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X3.0 ML AMPOULE	01/07/2017
3373	NDA/MAL/HDP/6 790	MEGA LIFSCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	LIMZER	OMEPRAZOLE + DOMPERIDONE	20MG + 30MG	INVENTIA HEALTHCARE PVT. LTDFI – FI /1 ADDITIONAL AMBERNATH, M.I.D.C. AMBERNATH (EAST) – 421 506, DIST. THANE, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE STRIP	01/07/2016

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3374	NDA/MAL/HDP/6 792	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	PREZISTA	DARUNAVIR	400MG	JANSSEN ORTHO LLC. STATE ROAD 933 KM 0.1 MARNEY WARD GURABO PUERTO RICO 00778	UNITED STATES	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2017
3375	NDA/MAL/HDP/6 794	HETERO LABS LTD	AIVEEN (U) LIMITED	ZOLID	LINEZOLID	600MG	HETERO LABS LIMITED UNIT VAPIIC PHARMA SEZ, S. NO. 439, 440, 441 & 458 MOLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOBNAGAR (DISTRICT). PIN 509301	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2017



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3376	NDA/MAL/HDP/6 797	MARTINDALE PHARMACEUTICAL S LTD	LABOREX UGANDA LIMITED	PETHIDINE INJECTION	PETHIDINE	100MG/2ML	MARTINDALE PHARMACEUTICAL LIMITED BAMPTON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/1997
3377	NDA/MAL/HDP/6 808	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	GLYGEN-500	METFORMIN HYDROCHLORIDE	500MG	LINCOLN PHARMACEUTICALS LTD-TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016

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3378	NDA/MAL/HDP/6 810	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CERVARIX	HUMAN PAPILLOMA VIRUS VACCINE (RDNA)	TYPE 16 L1 PROTEIN + TYPE 18 L1 PROTEIN + 3-O- DESACYL- 4'MONOPHOSPHO RYL LIPID A(MPL)	GLAXOSMITHKLINE BOIOLOGICALSS.A RUE DE I'INSTITUT 89 B- 1330 RIXENSART	BELGIUM	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X10.0X0.5 ML VIAL,1.0X0.5 ML PRE- FILLED SYRINGE (1 DOSE) + A 25 GAUGE NEEDLE	01/07/2007
3379	NDA/MAL/HDP/6 812	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	NOFLOX	NORFLOXACIN	0.3%W/V	ABACUS PARENTERAL DRUGS LIMITEDPLOT 114, BLOCK 191	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE,1.0X5.0 ML BOTTLE	01/07/2016

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3380	NDA/MAL/HDP/6 815	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABCROM EYE DROPS	SODIUM CROMOGLYCATE	2%W/V	ABACUS PARENTERAL DRUGS LTD.PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE,1.0X5.0 ML BOTTLE	01/07/2016
3381	NDA/MAL/HDP/6 817	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	LETROZOLE DENK 2.5	LETROZOLE	2.5MG	HAUPT PHARMA MÜNSTER GMBH SCHLEEBRÜGG ENKAMP 15 48159 MÜNSTER GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016

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3382	NDA/MAL/HDP/6 818	SANOPI PASTEUR	LABOREX UGANDA LIMITED	IMOVAX POLIO	POLIO VIRUS; (MAHONEY) TYPE 1- INACTIVE + (MEF-1) TYPE 2- INACTIVE + (SAUKETT) TYPE 3- INACTIVE	40 D + 8D + 32 D ANTIGEN UNITS/ 0.5ML	SANOPI PASTEURMÉRIEUX 69280 MARCY L'ETOILE	FRANCE	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL	01/07/2016
3383	NDA/MAL/HDP/6 820	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABBORI EAR DROPS	BORIC ACID	1.83%W/V	ABACUS PARENTERAL DRUGS LIMITEDBLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	OTIC DROPS	1.0X10.0 ML BOTTLE	01/07/2017

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3384	NDA/MAL/HDP/6 821	LABOREX UGANDA LIMITED	LABOREX UGANDA LIMITED	MAGNESIUM SULPHATE INJECTION	MAGNESIUM SULPHATE	50%W/V	MARTINDALE PHARMACEUTICAL LIMITED BAMP TON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X10.0 ML AMPOULE	01/07/2016
3385	NDA/MAL/HDP/6 823	LABOREX UGANDA LIMITED	LABOREX UGANDA LIMITED	EPHEDRINE HYDROCHLORIDE	EPHEDRINE HYDROCHLORIDE	30MG/ML	MARTINDALE PHARMACEUTICALS .ROMFORD ESSEX RM3 8UG UK	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE	01/07/2016

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3386	NDA/MAL/HDP/6 833	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	ON.SENTRON- DENK 8MG ODT	ONDANSETRON	8MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X6.0 TABLET BLISTER	01/07/2016
3387	NDA/MAL/HDP/6 837	ZEE PHARMACEUTICAL S LTD	ZEE PHARMACEUTICAL S LIMITED	ZEEL KIT	CLARITHROMYCIN + METRONIDAZOLE + PANTOPRAZOLE SODIUM SESQUIHYDRATE	250MG + 400MG +40MG	THE MADRAS PHARMACEUTICALS1 37-B,OLD MAHABALI PURAM ROAD,KARAPAKKAM ,CHENNAL INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET STRIP	01/07/2016

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3388	NDA/MAL/HDP/6 843	CADILA PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S LTD.	FYTOBACT	CEFOPERAZONE + SULBACTAM	0.5 G + 0.5 G	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2009
3389	NDA/MAL/HDP/6 845	CADILA PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S LTD.	FYTOBACT 2G	SULBACTAM SODIUM + CEFOPERAZONE SODIUM	1G + 1G	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X2.0 G VIAL	01/07/2017

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3390	NDA/MAL/HDP/6 857	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BRUCIPRO TABLETS	CIPROFLOXACIN	500MG	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	10.0X10.0 TABLET BLISTER	29/11/2017
3391	NDA/MAL/HDP/6 859	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BRUVEL-500 TABLETS	LEVOFLOXACIN HEMIHYDRATE	500MG	BRAWN LABORATORIES LTD..13,NEW INDUSTRIAL TOWNSHIP, FARIDABAD-121 001,HARYANA - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	26/09/2018



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3392	NDA/MAL/HDP/6 862	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	DITS GEL	DICLOFENAC DIETHYLAMINE	1%W/W	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X15.0 G TUBE,1.0X30.0 G TUBE	01/07/2017
3393	NDA/MAL/HDP/6 865	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	DITS INJECTION	DICLOFENAC SODIUM	25MG/ML	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X3.0 ML AMPOULE	29/11/2017

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3394	NDA/MAL/HDP/6 870	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	HYDROSONE 100MG	HYDROCORTISON E SODIUM SUCCINATE	100MG	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON (1*100MG GLASS VIAL + 1*2ML AMP WFI),1.0X50.0 VIAL CARTON	29/11/2017
3395	NDA/MAL/HDP/6 871	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	VIVAX 100	SILDENAFIL	100MG	BRAWN LABORATORIES LTD..13,NEW INDUSTRIAL TOWNSHIP, FARIDABAD-121 001,HARYANA - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	26/09/2018

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3396	NDA/MAL/HDP/6 872	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	NETRACORTIL EYE/EAR SUSPENSION	OXYTETRACYCLIN E HYDROCHLORIDE +HYDROCORTISO NE ACETATE+POLYM YXIN B SULPHATE	10MG+5MG+1000 OI.U	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML BOTTLE	01/07/2017
3397	NDA/MAL/HDP/6 873	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	ROXITHIN TABLETS	ROXITHROMYCIN	150MG	BRAWN LABORATORIES LTD..13,NEW INDUSTRIAL TOWNSHIP, FARIDABAD-121 001,HARYANA - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	26/09/2018

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3398	NDA/MAL/HDP/6 874	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	CITRAX TABLETS	CETIRIZINE HYDROCHLORIDE	10MG	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017
3399	NDA/MAL/HDP/6 875	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BRUMOX-250 CAPSULES	AMOXICILLIN TRIHYDRATE	250MG	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER	29/11/2017

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3400	NDA/MAL/HDP/6 879	RAVIAN LIFE SCIENCE PVT. LTD	ROYAL PHARMA 2011 LIMITED	ORAV-200	OFLOXACIN	200MG	RAVIAN LIFE SCIENCE PVT LTD PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/05/2019
3401	NDA/MAL/HDP/6 882	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	VORM-400	ALBENDAZOLE	400MG	RAVIAN LIFE SCIENCE PVT LTD PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0X1.0 TABLET BLISTER	28/05/2019

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3402	NDA/MAL/HDP/6 887	RAVIAN LIFE SCIENCE PVT. LTD	ROYAL PHARMA 2011 LIMITED	WELBEEN-L	LEVOCETIRIZINE DIHYDROCHLORID E	5MG	RAVIAN LIFE SCIENCE PVT LTD PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1X10X10 TABLET BLISTER	29/05/2019
3403	NDA/MAL/HDP/6 897	BROOKES PHARMACEUTICAL LABORATORIES L	HARLEYS UGANDA LIMITED	PYODINE GARGLE & MOUTH WASH	POVIDONE IODINE	1G/100ML	BROOKES PHARMACEUTICALS LABORATORIES (PAKISTAN) LTD PLOT 58 SECTOR 15 KORANGI INDUSTRIAL AREA, KARACHI-PAKISTAN	PAKISTAN	ORAL TOPICAL LIQUIDS	1.0X60.0 ML BOTTLE	01/07/2017

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3404	NDA/MAL/HDP/6 898	F. HOFFMANN LA- ROCHE	LABOREX UGANDA LIMITED	RECORMON	EPOETIN BETA	5000I.U/0.3ML	ROCHE DIAGNOSTICS GMBH MANNHEIMSANDHO FER STRASSE 116, 68305 MANNHEIM - GERMANY	GERMANY	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X6.0X1.0X0.3 ML PRE- FILLED SYRINGE	28/05/2019
3405	NDA/MAL/HDP/6 901	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	ZINKORA KIT	[GLUCOSE ANHYDROUS + SODIUM CHLORIDE + TRISODIUM CITRATE DIHYDRATE + POTASSIUM CHLORIDE ] + [ZINC SULPHATE MONOHYDRATE]	[13.5G + 2.9G + 2.6G + 1.5G] + [20MG]	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY COMBINATION PACK POWDERS/GRANU LES	1.0X2.0X20.5 G SACHET + 1*10 TABLET BLISTER	28/05/2019

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3406	NDA/MAL/HDP/6 905	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICAL S LIMITED	NUROFEN	IBUPROFEN	400MG	ASTRA ZENECA TURKEYNOTTINGHA M SITE, THANE ROAD, NOTTINGHAM, NOTTINGHAMSHIRE, NG90 2DB, UNITED KINGDOM	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X1.0X12.0 TABLET BLISTER	28/05/2019
3407	NDA/MAL/HDP/6 907	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICAL S LIMITED	NUROFEN EXPRESS	IBUPROFEN	400MG	ASTRA ZENECA TURKEYNOTTINGHA M SITE, THANE ROAD, NOTTINGHAM, NOTTINGHAMSHIRE, NG90 2DB, UNITED KINGDOM	UNITED KINGDOM	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	28/05/2019



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3408	NDA/MAL/HDP/6 911	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	SCABION	CROTAMITON + SULPHUR	10 G + 2 G	ATCO LABS LTD,B-18, S.I.T.E, KARACHI	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2004
3409	NDA/MAL/HDP/6 919	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	MACSUNATE AQ JUNIOR	ARTESUNATE + AMODIAQUINE	50MG + 135MG	MACLEODS PHARMACEUTICALS LTD.PLOT NO. 25-27 SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN (UT) - 396210, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0 TABLET BLISTER,1.0X25.0X3 .0 TABLET BLISTER	27/03/2019

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

3410	NDA/MAL/HDP/6 921	B & O PHARM ZAC	TRIDEM PHARMA UGANDA LIMITED	DUFENAC	DICLOFENAC SODIUM	75MG	GUILIN PHARMACEUTICAL CO LTD-NO. 43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	ORAL SOLID ORDINARY ENTERIC-COATED CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/2017
3411	NDA/MAL/HDP/6 922	EXPHAR S.A. ZONING INDUSTRIEL DE NIVELLES SUD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	FLUCAZOL	FLUCONAZOLE	50 MG / 5 ML	GRACURE PHARMACEUTICALS LIMITED E- 1105, RIICO INDUSTRIAL AREA, PHASE-III BHIWADI, PIN- 301019 DIST. ALWAR, RAJASTHAN, INDI	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE	27/11/2018

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

3412	NDA/MAL/HDP/6 923	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	MACSUNATE AQ KID	ARTESUNATE + AMODIAQUINE	25MG + 67.5MG	MACLEODS PHARMACEUTICALS LTD ,,PHASE I & II, PLOT NO. 25-27 SURVEY NO. 366, PREMIERE INDUSTRIAL ESTATE, KACHIGAN, DAMAN- 396210	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER,1.0X25.0X3 .0 TABLET BLISTER	27/03/2019
3413	NDA/MAL/HDP/6 924	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	NAC MR	DICLOFENAC POTASSIUM+PAR ACETAMOL+CHLO RZOAZONE	50MG+325MG+25 0MG	CORONA REMEDIES PVT LIMITEDVILLAGE JATOLI, POST OFFICE OACHGHAT, TEHSIL SOLAN, DIST. SOLAN HIMACHAL PRADESH – 173223. INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	31/01/2018

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

3414	NDA/MAL/HDP/6 926	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	ERYTHROKANT-ES	ERYTHROMYCIN ETHYL SUCCINATE	125MG/5ML	S KANT HEALTHCARE LTD PLOT NO. 1805, G.I.D.C PHASE III, VAPI 396195, GUJARAT	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	29/05/2019
3415	NDA/MAL/HDP/6 927	SEGURA PHARMA PRIVATE LTD	ABACUS PHARMA (AFRICA) LIMITED	GOPAYN MR	ACECLOFENAC BP+TIZANIDINE HYDROCHLORIDE USP+PARACETAM OL BP	100MG+2MG+500 MG	SAI MIRRA INNOPHARM PVT LIMITED 288&299, SIDCO ESTATE AMBTUR, CHENNAI 600098	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	28/05/2019

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

3416	NDA/MAL/HDP/6 928	SAVA HEALTHCARE LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	MOMENAP NS 0.05	MOMETASONE FUROATE	0.05%W/V	SAVA HEALTHCARE LIMITED.PLOT NO 507B -512, G.I.D.C. ESTATE, WADHWANCITY-363 035 SURENDRANAGAR, GUJARAT, INDIA	INDIA	NASAL SYSTEMIC UNIT DOSE AEROSOLS	1.0X1.0X12.0 ML CANNISTER	28/05/2019
3417	NDA/MAL/HDP/6 929	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	RANCV1000	RANOLAZINE	1000MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/03/2019

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3418	NDA/MAL/HDP/6 930	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S LIMITED	TAPAL 50	TAPENTADOL	50MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	27/03/2019
3419	NDA/MAL/HDP/6 931	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AMORIV	AMBROXOL HYDROCHLORIDE	15MG/5ML	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	27/08/2019

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

3420	NDA/MAL/HDP/6 932	PSYCHOTROPICS INDIA LTD	ABACUS PHARMA (AFRICA) LIMITED	VALATE-200	SODIUM VALPROATE	200 MG	PSYCHOTROPICS INDIA LTD PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	25/07/2018
3421	NDA/MAL/HDP/6 933	PSYCHOTROPICS INDIA LTD	ABACUS PHARMA (AFRICA) LIMITED	VALATE 500	SODIUM VALPROATE BP	500MG	PSYCHOTROPICS INDIA LTD PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	25/07/2018

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

3422	NDA/MAL/HDP/6 936	SAVA HEALTHCARE LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	RANKOF	PARACETAMOL+C AFFEINE, PHENYLEPHRINE + CHLORPHENAMIN E MALEATE	500MG+30MG+10 MG+2MG	SAVA HEALTHCARE LIMITED.PLOT NO 507B -512, G.I.D.C. ESTATE, WADHWANCITY-363 035 SURENDRANAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	28/05/2019
3423	NDA/MAL/HDP/6 937	SAKAR HEALTHCARE LIMITED	ROYAL PHARMA 2011 LIMITED	CEFROTIL750	CEFUROXIME SODIUM	750MG	SAKAR HEALTHCARE LIMITED (BLOCK NO. 10-13, SARKHEJ- BAVLA HIGHWAY, VILL: CHANGODAR, DIST: AHMEDABAD- 382213, GUJARAT " INDIA.)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X750MG VIAL + 1.0X10.0 ML WFI	29/05/2019



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3424	NDA/MAL/HDP/6 939	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	TAPAL 100	TAPENTADOL	100MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	27/03/2019
3425	NDA/MAL/HDP/6 941	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TOLVAT 30	TOLVAPTAN	30MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	07/11/2018

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3426	NDA/MAL/HDP/6 942	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TOLVAT 15	TOLVAPTAN	15MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	07/11/2018
3427	NDA/MAL/HDP/6 946	PHARMACTIV FZCO	JEET PHARMACEUTICAL S LIMITED	FEVERAL	PARACETAMOL	10MG/ML	SURGE LABORATORIES (PVT) LTD.,,10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN.	PAKISTAN	PARENTERAL ORDINARY I V VIALS	1.0X1.0X100.0 ML VIAL	28/05/2019

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

3428	NDA/MAL/HDP/6 948	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	D3 MUST 60 K	CHOLECALCIFERO L	60000IU	MANKIND PHARMA LTD-UNIT II VILLAGE KISHANPURA P.O JAMNIWALA TEHSIL PAONTA SAHIB DISTRICT SIRMOUR 173 025 HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	01/07/2017
3429	NDA/MAL/HDP/6 949	PHARMACTIV FZCO	JEET PHARMACEUTICAL S LIMITED	MEGA FER	IRON SUCROSE	100MG/5ML	SURGE LABORATORIES (PVT) LTD.,,10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN.	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X5.0 ML AMPOULE	28/05/2019

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

3430	NDA/MAL/HDP/6 953	SYNOKEM PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MISOFREE	MISOPROSTOL	200MCG	SYNOKEM PHARMACEUTICALS LIMITEDSYNOKEM PHARMACEUTICALS LIMITED, PLOT NO. 35-36, SECTOR-6A, IIE, (SIDCUL), RANIPUR (BHEL), HARIDWAR, 249403, (UTTARAKHAND) - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	28/05/2019
3431	NDA/MAL/HDP/6 955	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SEVOTROY 250	SEVOFLURANE	250	TROIKAA PHARMACEUTICALS LIMITED..SANAND - KADI ROAD, THOL, CITY: THOL - 382 728, DIST. MEHSANA, GUJARAT STATE - INDIA	INDIA	OTHER SYSTEMIC LIQUID INHALATIONS	1.0X250.0 ML BOTTLE	28/05/2019

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

3432	NDA/MAL/HDP/6 956	TROIKAA PHARMACEUTICAL S LTD	ABACUS PHARMA (AFRICA) LIMITED	NUROTROY SR	MECOBALAMIN + FOLIC ACID + PYRIDOXINE HYDROCHLORIDE	1500MCG + 5MG + 20MG	TROIKAA PHARMACEUTICALS LIMITED,,C-1, SARA INDUSTRIAL ESTATE, SELAQUI, DEHRADUN-248197, UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X4.0 TABLET BLISTER	28/05/2019
3433	NDA/MAL/HDP/6 961	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICAL S LTD	MERROBE 1000	MEROPENEM	1G	ZEISS PHARMACEUTICALS PVT LTD - PLOT 72, EPIP, PHASE 1, JHARMAJRI BADDI, 173205, DIST: SOLAN HIMACHAL PRADESH, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL	29/05/2019

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3434	NDA/MAL/HDP/6 962	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROXONE- S	CEFTRIAZONE SODIUM + SULBACTAM SODIUM	1G+0.5G	ZEISS PHARMACEUTICALS PVT LTD - PLOT 72, EPIP, PHASE 1, JHARMAJRI BADDI, 173205, DIST: SOLAN HIMACHAL PRADESH, INDIA INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL	28/05/2019
3435	NDA/MAL/HDP/6 963	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	LANAC	LANSOPRAZOLE	30MG	ZIM LABS LTD.B 21/22, MIDC AREA, KALMESHWAR 441501, DIST- NAGPUR	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	28/05/2019

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3436	NDA/MAL/HDP/6 964	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	TOXXET 200	CEFPODOXIME PROXETIL	200MG	ZIM LABORATORIES LTDB-21/22 MIDC, KALMESHWAR 441501	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	29/05/2019
3437	NDA/MAL/HDP/6 967	EVA PHARMA FOR PHARMACEUTICAL S & MEDICAL APPLIANCES -	UNITED HEALTHCARE DISTRIBUTORS LTD	MICAZOLE	MICONAZOLE	2%W/W	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL TOPICAL GELS AND SOLS	1.0X20.0 G TUBE	27/11/2019

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3438	NDA/MAL/HDP/6 970	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	VOMIKIND ORAL SOLUTION	ONDANSETRON	4MG/5ML	MANKIND PHARMA LTD-UNIT II VILLAGE KISHANPURA P.O JAMNIWALA TEHSIL PAONTA SAHIB DISTRICT SIRMOUR 173 025 HIMACHAL PRADESH	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X50.0 ML BOTTLE	01/07/2017
3439	NDA/MAL/HDP/6 971	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	MONTIRIV-10	MONTELUKAST SODIUM	10 MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1X3X10 TABLET BLISTER	28/08/2019



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3440	NDA/MAL/HDP/6 973	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIFED DM SYRUP 120ML	TRIPROLIDINE HYDROCHLORIDE + PSEUDOEPHEDRI NE HYDROCHLORIDE + DEXTROMETHOR PHAN	1.25MG + 30MG + 10MG/5ML	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	21/11/2019
3441	NDA/MAL/HDP/6 974	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	VOMIKIND-MD 4	ONDANSETRON	4MG	MANKIND PHARMA LIMITED, UNIT-II. VILLAGE KISHANPURA, P.O JAMNIWALA, PAONTA SAHIB IN H.P.	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017



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3444	NDA/MAL/HDP/6 978	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	DEXARIV	DEXAMETHASON E SODIUM PHOSPHATE	4 MG/ML	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0X2.0ML VIAL, 1.0X100.0X2.0ML VIAL	28/08/2019
3445	NDA/MAL/HDP/6 979	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	TERBIRIV	TERBINAFINE HYDROCHLORIDE	1.0%W/W	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	28/08/2019

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3446	NDA/MAL/HDP/6 980	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	KETORIV	KETOCONAZOLE	2.0%W/W	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	NASAL TOPICAL CREAMS	1.0X1.0X15.0 G TUBE	28/08/2019
3447	NDA/MAL/HDP/6 981	ZIFAM PINNACLE PTY. LTD.	DELMAW ENTERPRISES LIMITED	KIT LANZ	LANSOPRAZOLE + CLARITHROMYCIN + TINIDAZOLE	30MG + 250MG + 500MG	FREDUN PHARMACEUTICALS LIMITED <sup>14,15,16</sup> , ZORABIAN INDUSTRIAL COMPLEX, VEOOR, PA LGHAR (E), DIST: PALGHAR-401 404	INDIA	ORAL SOLID ORDINARY OTHER SPECIAL FORMS	1.0X7.0X6.0 TABLET BLISTER PACK HAS BOTH CAPSULES AND TABLETS	27/08/2019

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3448	NDA/MAL/HDP/6 982	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	DEXARIV	DEXAMETHASON E SODIUM PHOSPHATE	0.5 MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	27/08/2019
3449	NDA/MAL/HDP/6 983	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	FASICON	FLUCONAZOLE	200 MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	27/08/2019

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3450	NDA/MAL/HDP/6 984	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	VIREXIM-400	CEFIXIME TRIHYDRATE	400 MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X5.0 CAPSULE BLISTER,1.0X10.0X1 0.0 CAPSULE BLISTER	27/08/2019
3451	NDA/MAL/HDP/6 985	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	COLDRID SYRUP	CETIRIZINE DIHYDROCHLORID E + PHENYLEPHRINE HCL + PARACETAMOL	2.5MG + 5MG + 125MG	MEDLEY PHARMACEUTICALS, LTD PLOT 18/19 ZORIC CORSE WAY ROAD KACHIGAM DAMAN	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2017

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3452	NDA/MAL/HDP/6 986	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	REPRAZ 20 TABLETS	RABEPRAZOLE SODIUM	20MG	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3453	NDA/MAL/HDP/6 989	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIFED EXPECTORANT SYRUP 120ML	TRIPROLIDINE HYDROCHLORIDE + PSEUDOEPHEDRI NE HYDROCHLORIDE + GUAIFENESIN	1.25MG+30MG+10 0MG/5ML	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	21/11/2019

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3454	NDA/MAL/HDP/6 990	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ESORIV-40	ESOMEPRAZOLE MAGNESIUM	40MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	28/05/2019
3455	NDA/MAL/HDP/6 991	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ESORIV-20	ESOMEPRAZOLE MAGNESIUM	20MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	28/05/2019



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3456	NDA/MAL/HDP/6 992	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AZIRIV-200	AZITHROMYCIN	200MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X15.0 ML BOTTLE	28/05/2019
3457	NDA/MAL/HDP/6 993	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AZIRIV-500	AZITHROMYCIN (AS DIHYDRATE)	500MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	28/05/2019

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3458	NDA/MAL/HDP/6999	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	NYSTATIN ORAL SUSPENSION	NYSTATIN	100000 UNITS/5ML	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N-119, N-113 MIDC TARAPUR BOISAR DIST. THANE 401506 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1X30 ML BOTTLE	31/01/2018
3459	NDA/MAL/HDP/7003	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	NAC-SP	DICLOFENAC POTASSIUM + SERRATIOPEPTID ASE	50MG + 10MG	CORONA REMEDIES PVT LTD..VILLAGE JATOLI, POST OFFICE - OACHGHAT, TEHSIL SOLAN, DIST. SOLAN HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	07/11/2018

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3460	NDA/MAL/HDP/7004	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	DUOCETZ	PARACETAMOL+TRAMADOL HYDROCHLORIDE	325MG+37.5MG	MEGA LIFE SCIENCES PUBLIC COMPANY LIMITED..515/1 MOO 4, SOI 8, BANGPOO INDUSTRIAL ESTATE, PATTANA 3 ROAD, PHRAEKSA, MUEANG	THAILAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	31/01/2018
3461	NDA/MAL/HDP/7005	CIPLA LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ABACAVIR, DOLUTEGRAVIR AND LAMIVUDINE	ABACAVIR + DOLUTEGRAVIR + LAMIVUDINE	600MG + 50MG + 300MG	CIPLA LTDUNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S-112, L-147/1 TO L-147/3, L-138, L-147/A, VERNA INDUSTRIAL ESTATE, VERNA SALCETTE-GOIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	27/08/2019

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3462	NDA/MAL/HDP/7 006	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	PREDNIMAX	PREDNISOLONE	5MG	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	27/08/2019
3463	NDA/MAL/HDP/7 007	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EPNONE 50	EPLERENONE	50MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/11/2018

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3464	NDA/MAL/HDP/7009	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	DARUNAVIR TABLETS	DARUNAVIR ETHANOLATE	600 MG	CIPLA LTD ,PLOT NO. A-33, A-2 (UNIT 1), A42 (UNIT II), MIDC PATALGANGA, DISTRICT-RAIGAD MAHARASHTRA, 410220 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET CONTAINER	27/08/2019
3465	NDA/MAL/HDP/7010	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	CALCAC 300	CALCIUM LACTATE	300MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	02/09/2019

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3466	NDA/MAL/HDP/7011	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	URSOLIV 250	URSODEOXYCHOLIC ACID	250MG	MEGA LIFE SCIENCES PUBLIC COMPANY LIMITED..515/1 MOO 4, SOI 8, BANGPOO INDUSTRIAL ESTATE, PATTANA 3 ROAD, PHRAEKSA, MUEANG	THAILAND	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X10.0 CAPSULE BLISTER	27/03/2019
3467	NDA/MAL/HDP/7012	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	MYHEP DVIR	DACLATASVIR + SOFOSBUVIR	60MG + 400MG	MYLAN LABORATORIES LIMITEDF- 4 & F-12, MIDC, MALEGAON, SINNAR, NASHIK - 422 113 MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X28.0 TABLET BOTTLE	31/01/2018

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3468	NDA/MAL/HDP/7013	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	AZITHRAA 500	AZITHROMYCIN	500MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	29/11/2017
3469	NDA/MAL/HDP/7014	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	ACEAAR 100 TABLET	ACECLOFENAC	100MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	29/11/2017

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3470	NDA/MAL/HDP/7 015	KOPRAN LIMITED	TATA UGANDA LIMITED	LOKIT	OMEPRAZOLE	20MG	KOPRAN LTDVILLAGE SAVROLI TAL KHARAPUR DIST RAIGAD 410 202	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	31/01/2018
3471	NDA/MAL/HDP/7 018	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	AXYLIN	AMPICILLIN TRIHYDRATE + CLOXACILLIN SODIUM	125MG + 125MG	LABORATORY & ALLIED LTD PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, NEXT TO LIBRA HOUSE, MOMBASA ROAD- NAIROBI - KENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	27/08/2019



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3472	NDA/MAL/HDP/7019	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	LECOTRIM	SULFAMETHOXAZOLE + TRIMETHOPRIM	200MG + 40MG / 5ML	LABORATORY & ALLIED LTD PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, NEXT TO LIBRA HOUSE, MOMBASA ROAD- NAIROBI - KENYA	KENYA	ORAL LIQUID ORDINARY LIQUIDS	1.0X50.0 ML BOTTLE	27/08/2019
3473	NDA/MAL/HDP/7020	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	KEMOXYL 250 DT	AMOXICILLIN TRIHYDRATE	250MG	LABORATORY AND ALLIED LTD ..PLOT 209/10349, OFF MOMBASA ROAD	KENYA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER	27/08/2019

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3474	NDA/MAL/HDP/7021	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	PINNOFEC PLUS	ACECLOFENAC+PARACETAMOL	100MG+500MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/11/2017
3475	NDA/MAL/HDP/7022	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	PINNAFLAM PLUS	DICLOFENAC SODIUM+PARACETAMOL	50MG+500MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017

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3476	NDA/MAL/HDP/7 023	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	VERZOL ORAL SUSPENSION	ALBENDAZOLE	200 MG / 5 ML	GRACURE PHARMACEUTICAL LTDE-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X10.0 ML BOTTLE,1.0X20.0X1 0.0 ML BOTTLE	28/03/2018
3477	NDA/MAL/HDP/7 024	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	MICOZAL	KETOCONAZOLE	2%W/W	GRACURE PHARMACEUTICAL LTDE-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	29/11/2017

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3478	NDA/MAL/HDP/7027	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	CELCOXX	CELECOXIB	200MG	GETZ PHARMA (PVT) LIMITED 29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	25/11/2021
3479	NDA/MAL/HDP/7028	JAMJOOM PHARMACEUTICALS COMPANY	MU PHARMA CO - SMC LIMITED	DEXAFLOX	OFLOXACIN + DEXAMETHASONE	3MG + 1MG PER ML	JAMJOOM PHARMACEUTICALS CO. PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	OPHTHALMIC LIQUIDS	1.0X5.0 ML BOTTLE	02/09/2019

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3480	NDA/MAL/HDP/7 029	ZIM LABORATORIES LTD	REDDYS PHARMA LIMITED	LIPIZAR 20	ATORVASTATIN CALCIUM (TRIHYDRATE)	20MG	ZIM LABORATORIES LTDB-21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X3X10 TABLET BLISTER	28/03/2018
3481	NDA/MAL/HDP/7 037	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	O2	OFLOXACIN + ORNIDAZOLE	50MG + 125MG	MEDLEY PHARMACEUTICALS LTDLANE 03, PHASE 1, SIDCO INDUSTRIAL COMPLEX, BARI BRAHMANA JAMMU 181133	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X30.0 ML BOTTLE	27/08/2019

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3482	NDA/MAL/HDP/7 039	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	O2	OFLOXACIN + ORNIDAZOLE	200MG + 500MG	MEDLEY PHARMACEUTICALS LTDLANE 03, PHASE 1, SIDCO INDUSTRIAL COMPLEX, BARI BRAHMANA JAMMU 181133	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	27/08/2019
3483	NDA/MAL/HDP/7 053	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	KETOVID CREAM	KETOCONAZOLE	2%W/W	HOVID BHD 121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2017

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3484	NDA/MAL/HDP/7 057	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	VIREST CREAM 5%	ACICLOVIR	5%W/W	HOVID BHD 121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE	01/07/2017
3485	NDA/MAL/HDP/7 058	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	NEURAN 300 MG CAPSULE	GABAPENTIN	300MG	HOVID BERHAD,LOT 56442, 7 1/2 MILES JALAN IPOH/CHEMOR 31200, CHEMOR PERAK	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1X10X10 CAPSULE BLISTER	28/08/2019

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3486	NDA/MAL/HDP/7 063	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	GRISEOFULVIN 500MG FILM- COATED TABLET	GRISEOFULVIN	500MG	HOVID BHDLOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	31/01/2018
3487	NDA/MAL/HDP/7 064	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLIMICRON 80MG TABLET	GLICLAZIDE	80MG	HOVID BHDLOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2018



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3488	NDA/MAL/HDP/7065	JAMJOOM PHARMACEUTICALS COMPANY	MU PHARMA CO - SMC LIMITED	BRIMO	BRIMONIDINE TARTRATE	2%W/V	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	OPHTHALMIC LIQUIDS	1.0X5.0 ML BOTTLE	02/09/2019
3489	NDA/MAL/HDP/7066	MEDOCHÉMIE LTD	LABOREX UGANDA LIMITED	MABRON SR	TRAMADOL HYDROCHLORIDE	100MG	MEDOCHÉMIE (FACTORY AZ).-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	ORAL SOLID RETARD CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER,1.0X3.0X10.0 BLISTER BLISTER	27/08/2019

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3490	NDA/MAL/HDP/7067	MERIDIAN ENTERPRISES PRIVATE LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	SUPPOL 125	PARACETAMOL	125MG	MERIDIAN ENTERPRISES PVT. LTD-PLOT NO. 418, G.I.D.C., KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY STRIP	27/08/2019
3491	NDA/MAL/HDP/7070	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DIABETMIN 1000 MG FILM-COATED TABLET	METFORMIN HYDROCHLORIDE	1000MG	HOVID BERHAD (CHEMOR SITE)-LOT 56442, 71/2, JALAN IPOH/CHEMOR 31200, PERAK. MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	31/01/2018

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3492	NDA/MAL/HDP/7075	HETERO DRUGS LTD	AIVEEN (U) LIMITED	Q-TAB-200	QUETIAPINE FUMARATE	200MG	HETERO LABS LIMITED (UNIT V)SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X1.0X8.0 TABLET BLISTER	28/08/2019
3493	NDA/MAL/HDP/7080	HETERO DRUGS LTD	AIVEEN (U) LIMITED	Q-TAB-100	QUETIAPINE FUMARATE	100MG	HETERO LABS LIMITED (UNIT V)SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/08/2019

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3494	NDA/MAL/HDP/7 083	HETERO DRUGS LTD	AIVEEN (U) LIMITED	ETROBAX 90	ETORICOXIB	90MG	HETERO LABS PRIVATE LIMITED UNIT IISURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) JEEDIMETLA, HYDERABAD-500 055, TELANGANA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1X3X10 TABLET BLISTER	28/08/2019
3495	NDA/MAL/HDP/7 084	PHARMACTIV FZCO	JEET PHARMACEUTICAL S LIMITED	GABA 300	GABAPENTIN	300MG	NABIQASIM INDUSTRIES (PVT) LTD.17/24, KORANGI INDUSTRIAL AREA, KORANGI, KARACHI - PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	28/08/2019

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3496	NDA/MAL/HDP/7085	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	DYSEN SUSPENSION	SECNIDAZOLE	750MG	NABIQASIM INDUSTRIES (PVT) LTD.17/24, KORANGI INDUSTRIAL AREA, KORANGI, KARACHI - PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X30.0 ML BOTTLE	27/08/2019
3497	NDA/MAL/HDP/7088	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICALS LIMITED	PINNOX 200	OFLOXACIN	200MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	30/05/2018

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3498	NDA/MAL/HDP/7089	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	ES-LOPROT	ESOMEPRAZOLE SODIUM	40MG	NABIQASIM INDUSTRIES (PVT) LTD.17/24, KORANGI INDUSTRIAL AREA, KORANGI, KARACHI - PAKISTAN	PAKISTAN	PARENTERAL ORDINARY DRY VIALS	1.0X40.0 MG VIAL (+ 1*10ML AMPOULE OF 0.9% NAACL)	27/08/2019
3499	NDA/MAL/HDP/7091	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	AARLEFLOX 500 TABLETS	LEVOFLOXACIN HEMIHYDRATE	500MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/11/2017

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3500	NDA/MAL/HDP/7092	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	PATMAC	PANTOPRAZOLE SODIUM	40MG	NABIQASIM INDUSTRIES (PVT) LTD.17/24, KORANGI INDUSTRIAL AREA, KORANGI, KARACHI - PAKISTAN	PAKISTAN	PARENTERAL ORDINARY DRY VIALS	1.0X40.0 MG VIAL (+ 1*10ML AMPOULE OF 0.9% NAACL)	27/08/2019
3501	NDA/MAL/HDP/7094	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	GLANDIN-E2	DINOPROSTONE	2MG	NABIQASIM INDUSTRIES (PVT) LTD.17/24, KORANGI INDUSTRIAL AREA, KORANGI, KARACHI - PAKISTAN	PAKISTAN	TOPICAL EXTERNAL GELS AND SOLS	1.0X3.0 G PRE-FILLED SYRINGE	27/08/2019

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3502	NDA/MAL/HDP/7095	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS UGANDA LTD	FREMOL EXTRA	PARACETAMOL + CAFFEINE	500MG + 65MG	FREDUN PHARMACEUTICALS LIMITED14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PALGHAR (E), DIST: PALGHAR-401 404	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X25.0X4.0 CAPLET STRIP	21/11/2019
3503	NDA/MAL/HDP/7096	GAMA PHARMACEUTICALS (U) LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DEXAPHEN SYRUP	DEXAMETHASONE + CHLORPHENIRAMINE MALEATE	10MG + 40MG/100ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT, P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2017



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3504	NDA/MAL/HDP/7098	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	ACEFORCE SP	ACECLOFENAC+PARACETAMOL+SERRATIOPEPTIDASE	100MG+325MG+15MG	AKUMS DRUGS AND PHARMACEUTICALS LTDPLANT-1 PLOT NO.19, 20&21 SECTOR-6A, 11E, SIDCUL, RAHIPUR DISTT; HARIDWAR, 249403, (UTTRAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER	31/01/2018
3505	NDA/MAL/HDP/7099	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	MYGESTY	MEDROXYPROGESTERONE ACETATE	150MG/ML	MYLAN LABORATORIES LIMITED-PLOT NO. 20 & 21, PHARMEZ, SARKHEJ - BAVLA, NATIONAL HIGHWAY NO. 8 - A, NEAR VILLAGE - MATODA, TAL - SANAND, DIST., AHMEDABAD - 382213	INDIA	PARENTERAL ORDINARY VIALS	1.0X12.0X1.0 ML VIAL,1.0X25.0X1.0 ML VIAL	27/11/2019

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3506	NDA/MAL/HDP/7 101	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	ASTHAREN	SALBUTAMOL SULPHATE	4MG	RENE INDUSTRIES LIMITEDPLOT 680 KAMULI- KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
3507	NDA/MAL/HDP/7 102	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REPRAZINE	CHLORPROMAZIN E HYDROCHLORIDE	100MG	RENE INDUSTRIES LIMITEDPLOT 680 KAMULI- KIREKA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016

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3508	NDA/MAL/HDP/7 103	MACARTHYS LABORATORIES LTD	LABOREX UGANDA LIMITED	CAFFEINE CITRATE 10MG/ ML SOLUTION FOR INJECTION	CAFFEINE CITRATE	10MG/ML	MACARTHYS LABORATORIES LIMITED T/A MARTINDALE PHARMABAMPTON ROAD, ROMFORD, ESSEX RM3 8UG,	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	21/11/2019
3509	NDA/MAL/HDP/7 104	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPISOPT	DOROZOLAMIDE + TIMOLOL	20MG/1ML + 5MG/1ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B EGYPT	EGYPT	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	30/05/2018

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3510	NDA/MAL/HDP/7 105	CACHET PHARMACEUTICAL S PVT LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TRAMACETAL TABLETS	ACETAMINOPHEN +TRAMADOL HYDROCHLORIDE	325MG+37.5MG	CACHET PHARMACEUTICALS PVT LTDVILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	29/01/2019
3511	NDA/MAL/HDP/7 106	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REVIVE	GLUCOSE ANHYDROUS + TRISODIUM CITRATE DIHYDRATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE	13.5G + 2.9G + 2.6G + 1.5G	RENE INDUSTRIES LIMITEDPLOT 680 KAMULI- KIREKA	UGANDA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X1.0 SACHET CARTON	01/07/2016

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3512	NDA/MAL/HDP/7 107	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	FEBUMAC 40	FEBUXOSTAT	40 MG	MACLEODS PHARMACEUTICALS LIMITED BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH - 174101 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	27/03/2019
3513	NDA/MAL/HDP/7 109	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	BRUTAFLAM-60	ETORICOXIB	60MG	MANKIND PHARMA LTD, UNIT II ,VILLAGE- KISHANPURA, PAONTA SAHIB, DIST. SIRMOUR, HP	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019

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3514	NDA/MAL/HDP/7 110	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIFED EXTRA SYRUP 120ML	TRIPROLIDINE HYDROCHLORIDE + PSEUDOEPHEDRI NE HYDROCHLORIDE + DEXTROMETHOR PHAN + GUAIFENESIN	1.25MG + 10MG + 7.5MG + 50MG/5ML	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	21/11/2019
3515	NDA/MAL/HDP/7 112	HETERO DRUGS LTD	AIVEEN (U) LIMITED	ETROBAX 60	ETORICOXIB	60MG	HETERO LABS PRIVATE LIMITED UNIT III SURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) JEEDIMETLA, HYDERABAD-500 055, TELANGANA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1X3X10 TABLET BLISTER	28/08/2019

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3516	NDA/MAL/HDP/7 115	INTAS, PHARMACEUTICAL S LTD	STAR BIOTECH UGANDA LTD	SARTEL 40H	TELMISARTAN +HYDROCHLOROT HIAZIDE	(40+12.5)MG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI- 248197,DEHRADUN UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	07/11/2018
3517	NDA/MAL/HDP/7 116	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIFED SYRUP 120ML	TRIPROLIDINE HYDROCHLORIDE + PSEUDOEPHEDRI NE HYDROCHLORIDE	1.25MG + 30MG/5ML	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	21/11/2019

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3518	NDA/MAL/HDP/7 117	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIFED TABLETS	TRIPROLIDINE HYDROCHLORIDE + PSEUDOEPHEDRI NE HYDROCHLORIDE	2.5MG+60MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	21/11/2019
3519	NDA/MAL/HDP/7 118	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	BRUTAFLAM-90	ETORICOXIB	90MG	MANKIND PHARMA LTD, UNIT II ,VILLAGE- KISHANPURA, PAONTA SAHIB, DIST. SIRMOUR, HP	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019



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3520	NDA/MAL/HDP/7 119	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	OLMAT-40 H	OLMESARTAN MEDOXOMIL + HYDROCHLOROT HIAZIDE	40MG + 12.5MG	MICRO LABS LIMITED .,92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
3521	NDA/MAL/HDP/7 120	BESINS HEALTHCARE BENELUX SA	SURGIPHARM (U) LIMITED	ANDROGEL	TESTOSTERONE	16.2MG/G	BESINS MANUFACTURING BELGIUM (BMB)GROOT BIJGAARDENSTRAAT, 128. 1620	BELGIUM	TOPICAL EXTERNAL EMULSION GELS	1.0X88.0 G CANNISTER	21/11/2019

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3522	NDA/MAL/HDP/7 122	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	ATERISE-50	ATENOLOL	50MG	SUNRISE INTERNATIONAL LABS LTD PLOT NO. 100, LANE-5, SECTOR II, PHASE-II, IDA, CHERLAPALLY INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/08/2019
3523	NDA/MAL/HDP/7 123	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	MARTINEZ 10	MONTELUKAST SODIUM	10MG	AKUMS DRUGS AND PHARMACEUTICALS LTD PLANT-1 PLOT NO.19, 20&21 SECTOR-6A, 11E, SIDCUL, RAHIPUR DISTT; HARIDWAR, 249403, (UTTRAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER, 1.0X3.0X10 .0 TABLET BLISTER	28/03/2018

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3524	NDA/MAL/HDP/7 124	PHARCO PHARMACEUTICAL S	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VITAMIN E 400 MG.	VITAMIN E	400 MG	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT, P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X12.0 CAPSULE BLISTER	01/07/2017
3525	NDA/MAL/HDP/7 125	SYNOKEM PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	I-FREE 72	LEVONORGESTRE L	1.5MG	SYNOKEM PHARMACEUTICALS LTD-PLOT NO.- 35- 36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X1.0 TABLET BLISTER	29/01/2019

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3526	NDA/MAL/HDP/7 127	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	CASPOGIN 50	CASPOFUNGIN ACETATE	50MG	CIPLA LTDUNIT IX, M 61, M-62 & M-63, VERNA INDUSTRIAL ESTATE, VERNA, SALCETTE GOA 403 722	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	07/11/2018
3527	NDA/MAL/HDP/7 128	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	COTRIKANT-960	TRIMETHOPRIM+ SULFAMETHOXAZ OLE	800MG+160MG	S KANT HEALTHCARE LTD PLOT NO. 1802- 1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	26/09/2018

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3528	NDA/MAL/HDP/7 131	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPOTCLAV OS	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	125MG + 31.25MG/5ML	SPARSH BIO-TECH PVT. LTD.-PLOT NO. 1, SURVEY NO. 242/243/244, VILLAGE LAKHABAVAD POST KHODIYAR COLONY DISTRICT, JAMNAGAR – 361006 GUJARAT INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	26/09/2018
3529	NDA/MAL/HDP/7 132	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	CASPOGIN 70	CASPOFUNGIN ACETATE	70MG	CIPLA LTDUNIT IX, M 61, M-62 & M-63, VERNA INDUSTRIAL ESTATE, VERNA, SALCETTE GOA 403 722	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	07/11/2018

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3530	NDA/MAL/HDP/7 133	LIPTIS EGYPT FOR PHARMACEUTICALS AND MEDICAL PRODUCTS	HARLEYS UGANDA LIMITED	WELLNESS	DAY TABLET: PARACETAMOL + PSEUDOEPHEDRINE HYDROCHLORIDE + DEXTROMETHORPHAN HYDROBROMIDE   NIGHT TABLET: PARACETAMOL + PSEUDOEPHEDRINE HYDROCHLORIDE + DIPHENHYDRAMINE	DAY TABLET: 325MG + 30MG + 4.5MG   NIGHT TABLET : 500MG + 30MG + 25MG	LIPTIS EGYPT FOR PHARMACEUTICALS AND MEDICAL PRODUCTS PLOT NO. 2/B, 6TH INDUSTRIAL ZONE, 6TH OF OCTOBER CITY	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER (5 DAY TABLETS + 5 NIGHT TABLETS)	29/01/2019
3531	NDA/MAL/HDP/7 135	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICALS LTD)	PLANET PHARMACEUTICALS UGANDA LTD	CILACAR *10	CILNIDIPINE	10MG	UNIQUE PHARMACEUTICAL LABS LIMITED. .215-216, 216-219, 304-308, GIDC PANOLI 394116-GUJARAT	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	29/08/2019

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3532	NDA/MAL/HDP/7 136	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	AMIKACIN 100 MG / 2ML	AMIKACIN SULPHATE	100MG/2ML	EGYPTIAN INT.PHARMACEUTIC AL INDUSTRIES CO. E.I.P.C.O --10TH OF RAMADAN CITY – INDUSTRIAL AREA B1- P.O BOX: 149 TENTH - EGYPT	EGYPT	PARENTERAL ORDINARY VIALS	1.0X1.0X2.0 ML VIAL	25/07/2018
3533	NDA/MAL/HDP/7 145	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LEVOTOP 0.5%	LEVOFLOXACIN	0.5%W/V	CIRON DRUGS AND PHARMACEUTICALS PVT LTD .N-118, 118/1, 119, 119/1, 119/2, 113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, MAHARASHTRA STATE	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	28/03/2019

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3534	NDA/MAL/HDP/7 147	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BIMAT	BIMATOPROST	0.03% W/V	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X3.0 ML VIAL	30/05/2018
3535	NDA/MAL/HDP/7 148	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	OMEPSUN	OMEPRAZOLE	20 MG	SUNRISE INTERNATIONAL LABS LTD.PLOT NO. 100, LANE 5, SECTOR II, PHASE II IDA CHERLAPALLY, HYDERABAD-500 051	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X10.0X1 0.0 TABLET STRIP	25/07/2018



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3536	NDA/MAL/HDP/7 149	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	OLOPAT OD	OLOPATADINE HYDROCHLORIDE	0.2% W/V	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	OPHTHALMIC DROPS	1.0X1.0X3.0 ML VIAL	30/05/2018
3537	NDA/MAL/HDP/7 150	SAKAR HEALTHCARE LIMITED	ROYAL PHARMA 2011 LIMITED	SEFIXI - SB 1500	CEFTRIAXONE SODIUM +SULBACTAM SODIUM	1000 MG +500MG	SAKAR HEALTHCARE LIMITEDBLOCK NO. 10-13, SARKHEJ- BAVLA HIGHWAY, VILL: CHANGODAR, DIST: AHMEDABAD- 382213, GUJARAT – INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL + 1X10ML FFS PLASTIC BOTTLE FOR WFI	29/08/2019

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3538	NDA/MAL/HDP/7 151	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	APDROPS DX	MOXIFLOXACIN HYDROCHLORIDE + DEXAMETHASON E SODIUM PHOSPHATE	5MG+1MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML VIAL	30/05/2018
3539	NDA/MAL/HDP/7 152	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	MINOXIN PLUS	MINOXIDIL	50MG/ML	BROOKES PHARMA (PRIVATE) LIMITED58 59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	TOPICAL EXTERNAL LIQUIDS	1.0X1.0X6.0 ML BOTTLE WITH A DERMA ROLLER ADMINISTRATION DEVICE	29/01/2019

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3540	NDA/MAL/HDP/7 154	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CIPROFLOXACIN HYDROCHLORIDE	CIPROFLOXACIN HYDROCHLORIDE	2MG/ML	ABARIS HEALTHCARE PVT LTD - SURVEY NO. 1407-11, VILLAGE RAJPUR, TALUKA KADI DIST. MEHSANA, GUJARAT- 382740	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	29/11/2017
3541	NDA/MAL/HDP/7 162	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	TEXAVIR	TENOFOVIR DISOPROXIL FUMARATE	300MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED PLOT 1-7, LUZIRA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2017

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3542	NDA/MAL/HDP/7 163	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	STODIL	LOPERAMIDE HYDROCHLORIDE	2MG	TRIVENI FORMULATIONS LTD PLOT NO. 52,53,54,63,62,64 ALEAP INDUSTRIAL ESTATE SARAMPALLI VIJAYWADA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	27/08/2019
3543	NDA/MAL/HDP/7 167	SPARSH BIO-TECH PVT.LTD.	ABACUS PHARMA (AFRICA) LIMITED	SPOTCLAV DS	AMOXICILLIN TRIHYDRATE + CLAVULANATE	200MG + 28.5MG PER 5ML	SPARSH BIO-TECH PRIVATE LIMITED, PLOT NO.1, SURVEY NO. 242/243/244, VILLAGE LAKHABVAD, JAMNAGAR 361006	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	27/08/2019

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3544	NDA/MAL/HDP/7 172	WOCKHARD LTD	ROYAL PHARMA 2011 LIMITED	MERIMIX	MEROPENEM TRIHYDRATE + SULBACTAM SODIUM	1G + 0.5G	ZEISS PHARMACEUTICALS PVT LTD - PLOT 72, EPIP, PHASE 1, JHARMAJRI BADDI, 173205, DIST: SOLAN HIMACHAL PRADESH, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1X1 VIAL CARTON	29/08/2019
3545	NDA/MAL/HDP/7 175	PSYCHOTROPICS INDIA LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	TELPRESS-AM 40/5	TELMISARTAN + AMLODIPINE BESYLATE	40MG + 5MG	PSYCHOTROPICS INDIA LTD PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	25/07/2018

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3546	NDA/MAL/HDP/7 179	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	AVONZA	TENOFOVIR DISOPROXIL FUMARATE+LAMI VUDINE+EFAVIRE NZ	300MG+300MG+4 00MG	MYLAN LABORATORIES LIMITEDD ,PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE-II, SECTOR-III, PITHAMPUR-454775 DIST. DHAR, MADHYA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER,1.0X90. 0 TABLET CONTAINER	07/11/2018
3547	NDA/MAL/HDP/7 180	SQUARE PHARMACEUTICAL S LTD	GAMA PHARMACEUTICAL S (U) LIMITED	IVENTI	MOXIFLOXACIN HYDROCHLORIDE	0.5%W/V	SQUARE PHARMACEUTICALS LIMITED - DHAKA UNITKALIAKOIR GAZIPUR	BANGLADESH	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	29/08/2019

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3548	NDA/MAL/HDP/7 181	PHARMACTIV FZCO	JEET PHARMACEUTICAL S LIMITED	SURGIBION	VITAMIN B1 + VITAMIN B6 + VITAMIN B12	100MG, + 100MG + 1000MCG	SURGE LABORATORIES (PVT) LTD.,10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN.	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X5.0X5.0X3.0 ML AMPOULE	27/08/2019
3549	NDA/MAL/HDP/7 182	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	SUNFLAM	MELOXICAM	7.5G	SUNRISE INTERNATIONAL LABS LTD PLOT NO. 100, LANE-5, SECTOR II, PHASE-II, IDA, CHERLAPALLY INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/08/2019

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3550	NDA/MAL/HDP/7 183	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	LEVOSUN-500	LEVOFLOXACIN HEMIHYDRATE	500MG	SUNRISE INTERNATIONAL LABS LTD PLOT NO. 100, LANE-5, SECTOR II, PHASE-II, IDA, CHERLAPALLY INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X10.0 TABLET BLISTER	27/08/2019
3551	NDA/MAL/HDP/7 187	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	ZITHROSUN-500	AZITHROMYCIN DEHYDRATE	500MG	SUNRISE INTERNATIONAL LABS LTD PLOT NO. 100, LANE-5, SECTOR II, PHASE-II, IDA, CHERLAPALLY INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X3X10 TABLET BLISTER	29/08/2019



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3552	NDA/MAL/HDP/7 191	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROSOL	HYPROMELLOSE	0.7%W/V	AUROLAB .NO. 1, SIVAGANGAI MAIN ROAD, VEERAPANJANI, MADURAI 1 - 625 020	INDIA	OPHTHALMIC LIQUIDS	1.0X1.0X10.0 ML VIAL	29/01/2019
3553	NDA/MAL/HDP/7 192	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TINAZOL	TINIDAZOLE	500 MG	GRACURE PHARMACEUTICAL LTDE-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	28/05/2019

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3554	NDA/MAL/HDP/7 193	EXPHAR SA.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	FLUOXINE	CIPROFLOXACIN	500 MG	GRACURE PHARMACEUTICAL LTDE-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	28/05/2019
3555	NDA/MAL/HDP/7 194	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENSCRUB SOLUTION	LINEZOLID ,CHLORHEXIDINE GLUCONATE	200 MG/100 ML ,4%W/V	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X500.0 ML BOTTLE	29/01/2019

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3556	NDA/MAL/HDP/7 198	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICAL S LTD)	PLANET PHARMACEUTICAL S UGANDA LTD	SILBECOR	SILVER SULFADIAZINE	1%W/W	UNIQUE PHARMACEUTICAL LABS LIMITED. .215- 216, 216-219, 304- 308, GIDC PANOLI 394116-GUJARAT	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X50.0 G TUBE	29/08/2019
3557	NDA/MAL/HDP/7 206	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	LOS ANGIO	LOSARTAN POTASSIUM	50MG	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA PSA CHEMICALS & PHARMACEUTICALS PRIVATE LIMITED - 3, SEZ-II, PITHAMPUR, DISTT. DHAR, MADHYA PRADESH - 454 774, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER	29/08/2019

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3558	NDA/MAL/HDP/7 207	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	TOXXET 50	CEFPODOXIME PROXETIL	50MG	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X30.0 ML BOTTLE	29/08/2019
3559	NDA/MAL/HDP/7 211	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	PYODINE GEL	POVIDONE- IODINE	5GM/100GM	BROOKES PHARMA (PRIVATE) LIMITED58 59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	TOPICAL EXTERNAL GELS AND SOLS	1.0X1.0X20.0 G TUBE	27/03/2019

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3560	NDA/MAL/HDP/7 215	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	CELCOXX	CELECOXIB	100MG	GETZ PHARMA (PVT) LIMITED 29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	10/01/2022
3561	NDA/MAL/HDP/7 216	SHIN POONG PHARMACEUTICAL S CO.LTD	AAFIYA (A) LIMITED	PYRAMAX	PYRONARIDINE TETRAPHOSPHAT E + ARTESUNATE	60MG + 20MG	SHIN POONG PHARM. CO., LTD70, SANDAN-RO, 19 BEON-GIL, DANWON- GU, ANSAN-SI, GYEONGGI-DO, REPUBLIC OF KOREA	SOUTH KOREA	ORAL LIQUID ORDINARY OTHER POWDERS/GRANU LES	1.0X90.0 SACHET CARTON	27/08/2019

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3562	NDA/MAL/HDP/7 217	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICAL S LIMITED	AARPANTO 40	PANTOPRAZOLE	40MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	25/07/2018
3563	NDA/MAL/HDP/7 218	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICAL S LIMITED	AARTMIN 500	METFORMIN	500MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/11/2017

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3564	NDA/MAL/HDP/7 219	THEON PHARMACEUTICAL S LTD	AIVEEN (U) LIMITED	THEOXONE -1 G	CEFTRIAZONE	1G	THEON PHARMACEUTICALS LTD.VILLAGE SAINI MAJRA, TEHSIL NALAGARH DIST, SOLAN- 174101,	INDIA	PARENTERAL ORDINARY DRY VIALS	1X1 G VIAL	29/11/2017
3565	NDA/MAL/HDP/7 220	RAINBOW LIFE SCIENCES PVT.LTD.	EUROPA HEALTHCARE (U) LTD	NAPRIN	NAPROXEN	500MG	GLOBELA PHARMA PVT.LTD.357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/08/2019

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3566	NDA/MAL/HDP/7 222	I-CARE PHARMA LTD	AIVEEN (U) LIMITED	SAMSUNATE	ARTESUNATE	60MG	SAMRUDH PHARMACEUTICALS PVT LTDJ-174, J-168 & J-168/1, MIDC, TARAPUL, BOISAR, DIST THANE-401506	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL OF ARTESUNATE +(1*1ML AMPOULE OF SODIUM BICARBONATE BP 5%W/V)+(1*5ML SODIUM CHLORIDE BP 0.9%W/V)	21/11/2019
3567	NDA/MAL/HDP/7 223	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	DOLUTEGRAVIR	DOLUTEGRAVIR	50MG	LAURUS LABS LTD (UNIT 2)PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE	21/11/2019



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3568	NDA/MAL/HDP/7 225	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	LUMITER 80/480	ARTEMETHER + LUMEFANTRINE	80MG + 480MG	OXALIS LABVILLAGE THEDA, P.O. LODHIMAJRA, TEHSIL BADDI, DIST. SOLAN (HP) PIN CODE 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X6.0 TABLET BLISTER	21/11/2019
3569	NDA/MAL/HDP/7 226	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	ELICA-M	MOMETASONE FUROATE + MICONAZOLE NITRATE	0.1%W/W + 2%W/W	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	27/11/2019

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3570	NDA/MAL/HDP/7 229	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICAL S LIMITED	AARCIFLOX 500	CIPROFLOXACIN	500MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/11/2017
3571	NDA/MAL/HDP/7 234	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	LEVOFLOXACIN INTRAVENOUS INFUSION	LEVOFLOXACIN HEMIHYDRATE + GLUCOSE ANHYDROUS	500MG + 5W/V%	ABARIS HEALTHCARE PVT. LTDSURVEY NO. 1407/11, VILLAGE RAJPUR, TAL KADI DIST. MEHSANA, GUJARAT-382740	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	27/08/2019

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3572	NDA/MAL/HDP/7 235	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	OPTIDEX-T	DEXAMETHASON E + TOBRAMYCIN	0.1W/V + 0.3%W/V	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML BOTTLE	27/11/2019
3573	NDA/MAL/HDP/7 237	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	CONTUS PAEDIATRIC	CHLORPHENAMIN E MALEATE + PHENYLEPHRINE HYDROCHLORIDE	1MG + 2.5MG	STEDMAN PHARMACEUTICALS PVT. LTD.C-4, SIDCO PHARMACEUTICALS COMPLEX, ALATHUR, THIRUPORUR- 603 110, TAMIL NADU INDIA	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X15.0 ML BOTTLE	21/11/2019

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3574	NDA/MAL/HDP/7 238	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILONG-10	NEBIVOLOL HYDROCHLORIDE	10MG	MICRO LABS LTD 92 SIPCOT 92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/03/2018
3575	NDA/MAL/HDP/7 239	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICALS LIMITED	GAVISCON PEPPERMINT LIQUID	SODIUM AGINATE + SODIUM BICARBONATE + CALCIUM CARBONATE	500MG + 267MG + 160MG	RECKITT BENCKISER HEALTHCARE - DAMSON LANE,HULL, HUB HU8 7DS	UNITED KINGDOM	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X12.0X10.0 ML SACHET,1.0X200.0 ML BOTTLE	28/05/2019

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3576	NDA/MAL/HDP/7 240	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED	GITTOES PHARMACEUTICAL S LIMITED	GAVISCON DOUBLE ACTION	SODIUM AGINATE + SODIUM BICARBONATE + CALCIUM CARBONATE	250MG + 106.5MG + 187.5MG	RECKITT BENCKISER HEALTHCARE - DAMSON LANE,HULL, HUB HU8 7DS	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X4.0X8.0 TABLET BLISTER	28/05/2019
3577	NDA/MAL/HDP/7 241	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	GENTASOL	GENTAMICIN SULFATE	0.3%W/V	AHLCON PARENTERAL (I) LTD.- SP-918,BHLWADI (RAJ) INDIA M.LIC.: RAJ 2002	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	29/11/2017

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3578	NDA/MAL/HDP/7 242	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	AMINORICH	MULTIVITAMINS, MINERALS	NA	STEDMAN PHARMACEUTICALS PVT. LTD.C-4, SIDCO PHARMACEUTICALS COMPLEX, ALATHUR, THIRUPORUR- 603 110, TAMIL NADU INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X15.0 CAPSULE BLISTER,1.0X1.0X2. 0 CAPSULE BLISTER	21/11/2019
3579	NDA/MAL/HDP/7 245	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	CEFAKIND-500	CEFUROXIME AXETIL	500MG	COPMED PHARMACEUTICALS PVT LTDUNIT-II, PLOT NO. 50, GONDPUR INDUSTRIAL AREA, TEHSIL-PAONTA SAHIB, DISTT. SIRMOUR,HIMACHAI PRADESH-173025, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	29/01/2019

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3580	NDA/MAL/HDP/7 246	EVA PHARMA FOR PHARMACEUTICAL S & MEDICAL APPLIANCES	UNITED HEALTHCARE DISTRIBUTORS LTD	DESLORAT	DESLORATIDINE	5MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY FILM- COATED TABLETS	2.0X10.0 TABLET STRIP	01/07/2017
3581	NDA/MAL/HDP/7 247	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	VITAFIL-Z	MULTIVITAMINS, MINERALS	NA	STEDMAN PHARMACEUTICALS PVT. LTD.C-4, SIDCO PHARMACEUTICALS COMPLEX, ALATHUR, THIRUPORUR- 603 110, TAMIL NADU INDIA	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X15.0 ML BOTTLE,1.0X30.0 ML BOTTLE	21/11/2019

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3582	NDA/MAL/HDP/7 248	EVA PHARMA FOR PHARMACEUTICAL & MEDICAL APPLIANCES	UNITED HEALTHCARE DISTRIBUTORS LTD	ESOMELODAN 20	ESOMEPRAZOLE	20MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	25/07/2018
3583	NDA/MAL/HDP/7 249	EVA PHARMA FOR PHARMACEUTICAL & MEDICAL APPLIANCES	UNITED HEALTHCARE DISTRIBUTORS LTD	ESOMELODAN 40	ESOMEPRAZOLE MAGNESIUM	40MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	25/07/2018



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3584	NDA/MAL/HDP/7 250	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	DOLUTEGRAVIR SODIUM, LAMIVUDINE AND TENOFVIR DISOPROXIL FUMARATE	DOLUTEGRAVIR SODIUM +LAMIVUDINE +TENOFVIR DISOPROXIL FUMARATE	50MG + 300MG + 300MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED (CIPLAQCIL)PLOT 1- 7, 1ST RING ROAD, LUZIRA INDUSTRIAL PARK	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE	21/11/2019
3585	NDA/MAL/HDP/7 251	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	HYDROXYUREA	HYDROXYCARBA MIDE	500MG	HAUPT PHARMA AMAREG GMBHDONAUSTAUF ER STRASSE 378, 93055 REGENSBURG	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	21/11/2019

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3586	NDA/MAL/HDP/7 253	MANKIND PHARM LTD	TATA UGANDA LIMITED	MONTICOPE	MONTELUKAST SODIUM + LEVOCETIRIZINE DIHYDROCHLORID E	10MG + 5MG	MANKIND PHARMA LTD, UNIT II ,VILLAGE KISHANPURA, PAONTA SAHIB, DIST. SIRMOUR, HP	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
3587	NDA/MAL/HDP/7 257	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICAL S LIMITED	PAARPIN TABLET	PARACETAMOL	650 MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017

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3588	NDA/MAL/HDP/7 258	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	DESCOVY 200MG/10MG	EMTRICITABINE + TENOFIVIR ALAFENAMIDE	200MG/10MG	PATHEON INC.-- TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9	CANADA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	31/01/2018
3589	NDA/MAL/HDP/7 259	FERRER INTERNATIONAL, S.A.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	ENEAS 10/20	ENALAPRIL + NITRENDIPINE	10MG + 20MG	FERRER INTERNATIONAL S.A ..JOAN BUSCALLA, 1 - 9, 08173 SANT CUGAT DEL VALLES, BARCELONA	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019

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3590	NDA/MAL/HDP/7 260	MICRO LABS LTD	LABOREX UGANDA LIMITED	ESOFAG-40	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40MG	MICRO LABS LIMITED .,92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
3591	NDA/MAL/HDP/7 264	PHARCO PHARMACEUTICAL S	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MIOPAN PLUS SUSPENSION	MAGALDRATE+SI METHICONE	540MG + 40MG/5ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT, P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2017

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3592	NDA/MAL/HDP/7 267	MICRO LABS LTD	LABOREX UGANDA LIMITED	ESOFAG-20	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	20MG	MICRO LABS LIMITED .,92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
3593	NDA/MAL/HDP/7 269	EXPHAR SA.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	FEBRILEX SYRUP	PARACETAMOL+D EXTROMETORPHAN HYDROBROMIDE+ CHLORPHENAMINE MALEATE	125MG+5MG+1MG /5 ML	GRACURE PHARMACEUTICAL LTDE-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X150.0 ML BOTTLE	01/07/2017

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3594	NDA/MAL/HDP/7 271	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TURBOVAS CP	ROSUVASTATIN CALCIUM + CLOPIDOGREL	5MG + 75MG	MICRO LABS LIMITED .,92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	21/11/2019
3595	NDA/MAL/HDP/7 272	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	MONTIGET	MONTELUKAST SODIUM	10MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	25/11/2021

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3596	NDA/MAL/HDP/7 275	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TILYPTIN 20	TENELIGLIPTIN HYDROBROMIDE HYDRATE	20MG	MICRO LABS LIMITED .,92, SIPCOT, HOSUR 635126	INDIA	TOPICAL EXTERNAL TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
3597	NDA/MAL/HDP/7 284	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LTD	LIVERCOL 10	ROSUVASTATİN CALCIUM	10MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.3. 42050 SELÇUKLU / KONYA TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	25/07/2018

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3598	NDA/MAL/HDP/7 286	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TOBRIN OPHTHALMIC OINTMENT	TOBRAMYCIN	3MG/G	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B EGYPT	EGYPT	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE	01/07/2017
3599	NDA/MAL/HDP/7 287	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPISTIGMIN 0.05%	NEOSTIGMINE METHYLSULPHAT E	0.05%W/V	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B1,EGYPT	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE	01/07/2017



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3600	NDA/MAL/HDP/7 288	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	KETESSE FILM COATED TABLETS	DEXXETOPROFEN TROMETAMOL	25MG	A.MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.IVIA CAMPO DI PILE 67100 L'AQUILA	ITALY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	29/11/2017
3601	NDA/MAL/HDP/7 292	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	IBUPLUS SUSPENSION	IBUPROFEN+.PAR ACETAMOL	100MG + 125MG / 5ML	LEBEN LABORATORIES PVT LTD .L-14 PHASE III MIDC AKOLA 444 104	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	21/11/2019

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3602	NDA/MAL/HDP/7 293	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LTD	ALRINAST	DES Loratadine	5MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş. ORGANİZE SANAYİ BÖLGESİ KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	29/11/2017
3603	NDA/MAL/HDP/7 295	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	LAMIFEN	TERBINAFINE HYDROCHLORIDE	1%W/W	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	27/11/2019

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3604	NDA/MAL/HDP/7 296	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MEDAXONUM 2G	CEFTRIAZONE SODIUM	2G	MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X2.0 G VIAL	29/01/2019
3605	NDA/MAL/HDP/7 298	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILONG-2.5	NEBIVOLOL HYDROCHLORIDE	2.5 MG	MICRO LABS LTD 92 SIPCOT 92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/11/2017

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3606	NDA/MAL/HDP/7299	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	CLOTINEX 60	ENOXAPARIN SODIUM	60MG/PRE-FILLED SYRINGE	SQUARE PHARMACEUTICALS LIMITED- (DHAKA UNIT KALIAKOIR GAZIPUR " 1750, BANGLADESH)	BANGLADESH	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X1.0 PRE-FILLED	06/10/2018
3607	NDA/MAL/HDP/7301	HETERO LABS LTD	AIVEEN (U) LIMITED	PACLITERO 300	PACLITAXEL	60 MG/ML	HETERO LABS LIMITED UNIT-VI APIIC FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOB NAGAR (DISTRICT) ANDHRA PRADESH-509301, , INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X50.0 ML VIAL	26/09/2018

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3608	NDA/MAL/HDP/7 302	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	ACRETIN 0.025%	TRETINOIN	0.025%W/W	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	27/11/2019
3609	NDA/MAL/HDP/7 304	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	GABAZURE	GABAPENTIN	300 MG	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER,1.0X3.0X10 .0 CAPSULE BLISTER	26/09/2018

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3610	NDA/MAL/HDP/7 305	HETERO LABS LTD	AIVEEN (U) LIMITED	PACLITERO 30	PACLITAXEL	6 MG/ML	HETERO LABS LIMITED UNIT-VI APIIC FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOB NAGAR (DISTRICT) ANDHRA PRADESH-509301, , INDIA	INDIA	PARENTERAL ORDINARY VIALS	1X1X5 ML VIAL	26/09/2018
3611	NDA/MAL/HDP/7 306	HETERO LABS LTD	AIVEEN (U) LIMITED	PACLITERO 100	PACLITAXEL	100 MG/16.7 ML	HETERO LABS LIMITED UNIT-VI APIIC FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOB NAGAR (DISTRICT) ANDHRA PRADESH-509301, , INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X16.7 ML VIAL	26/09/2018

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3612	NDA/MAL/HDP/7 307	EXPHAR SA.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	VERZOL	ALBENDAZOLE	400 MG	GRACURE PHARMACEUTICAL LTDE-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0 TABLET BLISTER	28/05/2019
3613	NDA/MAL/HDP/7 310	JAMJOOM PHARMACEUTICALS COMPANY	MU PHARMA CO - SMC LIMITED	ACRETIN 0.05%	TRETINOIN	0.05%W/W	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	27/11/2019

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3614	NDA/MAL/HDP/7 311	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	FLUCA OPHTHALMIC SUSPENSION	FLUOROMETHOL ON + SODIUM CROMOGLICATE	1%W/V + 2%W/V	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML BOTTLE	27/11/2019
3615	NDA/MAL/HDP/7 312	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	BETADINE OINTMENT 5%W/W	POVIDONE IODINE	5%W/W	G.S PHAMBUTOR PVT LTD .B-172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE,1.0X125.0 G TUBE,1.0X250.0 G JAR	01/07/2017



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3616	NDA/MAL/HDP/7 317	CACHET PHARMACEUTICAL S PVT LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EMITINO TABLETS 8MG	ONDANSETRON	8MG	CACHET PHARMACEUTICAL PVT LTD. VILLAGE- THANA, NEAR BADDI, TEHSIL_NALAGARH, DIST. SOLAN, HIMACHAL PRADESH - 173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	21/11/2019
3617	NDA/MAL/HDP/7 318	MEDOCHÉMIE LTD	LABOREX UGANDA LIMITED	MOXICLAV 625	AMOXICILLIN TRIHYDRATE + CLAVULINIC ACID	500MG + 125MG	MEDOCHÉMIE LTD – FACTORY B-PLOT 48, IAPETOU STREET, AGIOS ATHANASSIOS INDUSTRIAL; AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE STRIP	29/01/2019

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3618	NDA/MAL/HDP/7 319	DROGSAN İLAÇLARI SAN. VE TIC. A.Ş.	BUFFALO HEALTH CARE LTD	SIPROSAN 500	CIPROFLOXACIN HYDROCHLORIDE	500MG	DROGSAN İLAÇLARI SAN. VE TIC. A.Ş.ESENBGA MERKEZ MAH CUBUK CAD NO.31 CUBUK ANKARA - TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X5.0 TABLET BLISTER	31/01/2018
3619	NDA/MAL/HDP/7 321	GLENMARK PHARMACEUTICAL S LTD	ABACUS PHARMA (AFRICA) LIMITED	ASCORIL-D	DEXTROMETHOR PHAN HYDROBROMIDE + TRIPROLIDINE HYDROCHLORIDE + PSEUDOEPHEDRI NE HYDROCHLORIDE + MENTHOL	10MG + 1.25MG + 30MG + 1.5MG / 5ML	GLENMARK PHARMACEUTICALS LTD .PLOT E-37, 39, D ROAD, MIDC, SATPUR, NASHIK 422007, MAHARASHTRA STATE	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	27/11/2019

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3620	NDA/MAL/HDP/7 325	DROGSAN İLAÇLARI SAN. VE TIC. A.Ş.	BUFFALO HEALTH CARE LTD	DALMAN AQ NASAL SPRAY	FLUTICASONE PROPIONATE	0.05%W/V	DROGSAN İLAÇLARI SAN. VE TIC. A.Ş. - ESENBOĞA MERKEZ MAH. ÇUBUK CADDESİ NO: 31 06760 ANKARA - TURKEY	TURKEY	NASAL SYSTEMIC UNIT DOSE AEROSOLS	1.0X1.0X120.0 METERED DOSE BOTTLE	25/07/2018
3621	NDA/MAL/HDP/7 329	DAWA LIMITED	SUPER MEDIC LTD	ACEPAR- MR	PARACETAMOL +ACECLOFENAC+ CHLORZOXAZONE	500 MG+100 MG +375 MG	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	28/03/2018

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3622	NDA/MAL/HDP/7 330	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	FAMY-POP	LEVONORGESTRE L	0.03MG	MYLAN LABORATORIES LIMITED PLOT NO. 20 & 21, PHARMEZ, SARKHEJ - BAVLA, NATIONAL HIGHWAY NO. 8 - A, NEAR VILLAGE - MATODA, TAL - SANAND, DIST., AHMEDABAD - 382213	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X35.0 TABLET BLISTER	27/11/2019
3623	NDA/MAL/HDP/7 335	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	BETADINE 5%	POVIDONE IODINE	5%W/V	G.S PHAMBUTOR PVT LTD .B-172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X100.0 ML BOTTLE,1.0X500.0 ML BOTTLE,1.0X50.0 ML BOTTLE	01/07/2017

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3624	NDA/MAL/HDP/7 336	MODI NUNDIPHARMA PVT LTD	SURGIPHARM (U) LIMITED	BETADINE GERMICIDE GARGLE 2% MINT	POVIDONE IODINE	2%W/V	G.S PHAMBUTOR PVT LTDG.S PHAMBUTOR PVT LTD B-172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA	INDIA	ORAL TOPICAL LIQUIDS	1.0X50.0 ML BOTTLE,1.0X100.0 ML BOTTLE	31/01/2018
3625	NDA/MAL/HDP/7 337	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	PREZISTA 150	DARUNAVIR	150MG	JANSSEN ORTHO LLC. STATE ROAD 933 KM 0.1 MARNEY WARD GURABO PUERTO RICO 00778	UNITED STATES	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X240.0 TABLET BOTTLE	01/07/2017

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3626	NDA/MAL/HDP/7 338	LEBEN LABORATORIES PVT.LTD	MALIX PHARMA (U) LIMITED	IBUPLUS	IBUPROFEN + PARACETAMOL	400MG + 325MG	LEBEN LABORATORIES PVT. LTD PLOT NO. L-4, PHASE-III, MIDC, AKOLA- 444 104 (MS).	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X15.0X2.0X20.0 TABLET BLISTER	27/08/2019
3627	NDA/MAL/HDP/7 339	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ADERAN 16	CANDESARTAN CILEXETIL	16 MG	AJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	30/05/2018

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3628	NDA/MAL/HDP/7 340	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	HIFEN -200	IBUPROFEN	200MG	PINNACLE LIFE SCIENCE PVT LTD- KHASRA NO. 1328 - 1330, VILLAGE MANPURA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH - 174101 KESAR PHARMA PVT LTD- PLOT SURVEY NO. 50/2. VILLAGE BILESHPUR CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	21/11/2019
3629	NDA/MAL/HDP/7 341	M/S.MAXHEAL PHARMACEUTICAL S(INDIA)	ABACUS PHARMA (AFRICA) LIMITED	ZITHROHEAL 500	AZITHROMYCIN	500MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328 - 1330, VILLAGE MANPURA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH - 174101 MAXHEAL PHARMACEUTICALS INDIA LIMITEDJ-7, MIDC, TERAPUR INDUSTRIAL AREA, BOISAR 401506 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER	28/11/2019

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3630	NDA/MAL/HDP/7 342	CADILA PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S LTD.	ZEALARGY	RUPATADINE FUMERATE	10 MG	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3631	NDA/MAL/HDP/7 343	WUHAN FUXING BIOLOGICAL PHARMACEUTICAL CO	KAIYUANTANG (U) LIMITED	GLEVIX	LEVOFLOXACIN + SODIUM CHLORIDE	0.5G + 0.9G	WUHAN FUXING BIOPHARMACEUTIC AL CO., LTDNO.9, FUXING ROAD, HANCUAN ECONOMIC & DEVELOPMENT DISTRICT, HUBEI PROVINCE	CHINA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	21/11/2019



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3632	NDA/MAL/HDP/7 345	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	DELTACEF	CEFEPIME	1G	MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	21/11/2019
3633	NDA/MAL/HDP/7 346	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REZN TABLETS	ZINC SULFATE MONOHYDRATE	20MG	RENE INDUSTRIES LIMITED PLOT 680 KAMULI- KIREKA	UGANDA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/11/2017

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3634	NDA/MAL/HDP/7 348	MSD (PTY) LTD	SURGIPHARM (U) LIMITED	ISENTRESS 25 MG	RALTEGRAVIR POTASSIUM	25MG	PATHEON PHARMACEUTICALS INC.-2110 E. GALBRAITH ROAD CINCINNATI, OH 45237-1625, USA MSD (PTY) LTD. -117- 16TH ROAD, HALFWAY HOUSE, 1685 SOUTH AFRICA	SOUTH AFRICA UNITED STATES OF AMERICA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X60.0 TABLET BOTTLE	28/03/2018
3635	NDA/MAL/HDP/7 348	MSD (PTY) LTD	SURGIPHARM (U) LIMITED	ISENTRESS 25 MG	RALTEGRAVIR POTASSIUM	25MG	MERCK SHARP & DOHME BV.- WAARDERWEG 39 HAARLEM, - 2031 BN, NETHERLANDS	SOUTH AFRICA UNITED STATES OF AMERICA NETHERLANDS	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X60.0 TABLET BOTTLE	28/03/2018

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3636	NDA/MAL/HDP/7 350	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	SULCEF	CEFOPERAZONE+ SULBACTUM	1G+1G	MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X1.0 ML VIAL	27/03/2019
3637	NDA/MAL/HDP/7 351	TWENTY FIRST CENTURY PHARMACEUTICAL S PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYFIX CV DS	CEFIXIME+CLAVU LANIC ACID	50MG+31.25MG	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD-ROORKEE DISTT HARIDWAR	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017

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3638	NDA/MAL/HDP/7 353	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE XR 500MG	METFORMIN HYDROCHLORIDE	500MG	MERCK SANTÉ S.A.S.2 RUE DU PRESOIR VERT 45400 SEMOY FRANCE MERCK KGAA-PHARMA PRODUCTION DARMSTADT FRANKFURTER STRABE 250, D- 64293, DARMSTADT	GERMANY FRANCE	ORAL SOLID RETARD TABLETS	1.0X6.0X15.0 TABLET BLISTER	28/03/2018
3639	NDA/MAL/HDP/7 355	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN SUSPENSION	ARTEMETHER+LU MEFANTRINE	180MG+1080MG	AJANTA PHARMA LIMITED.B-41516, MIDC INDUSTRIAL AREA, PAITHAN, AURANGABAD-431 148 DIST: AURANGABAD MAHARASHTRA,INDI A	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE	31/01/2018

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3640	NDA/MAL/HDP/7 357	CACHET PHARMACEUTICAL S PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	PAMAGIN-C SYRUP	CETIRIZINE HYDROCHLORIDE +DEXTROMETHO RPHAN HYDROBROMIDE+ ACETAMINOPHEN +PHENYLEPHRINE HYDROCHLORIDE +ZINC GLUCONATE+ME NTHOL	2.5MG+7.5MG+12 5MG+5MG+7.5MG +2.5MG/5ML	CACHET PHARMACEUTICALS PVT LTD THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	31/01/2018
3641	NDA/MAL/HDP/7 359	INDCHEMIE HEALTH SPECIALITIES PVT. LTD.	NUMED STORES SMC LIMITED	INDCLAV 625	AMOXICILLIN+CLA VULANATE POTASSIUM	500MG+125MG	INDCHEMIE HEALTH SPECIALITIES PVT LTDVILLAGE THANA TEHSIL BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X2.0X7. 0 TABLET BLISTER	01/07/2017

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3642	NDA/MAL/HDP/7 360	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICAL S LIMITED	GAVISCON DOUBLE ACTION LIQUID	SODIUM ALGINATE + SODIUM BICARBONATE + CALCIUM CARBONATE	500MG + 213MG + 325MG/10ML	RECKITT BENCKISER HEALTHCARE - DAMSON LANE,HULL, HUB HU8 7DS	UNITED KINGDOM	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X150.0 ML BOTTLE,1.0X300.0 ML BOTTLE,1.0X12.0X1 0.0 ML SACHET	21/11/2019
3643	NDA/MAL/HDP/7 361	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	DOLUTEGRAVIR	DOLUTEGRAVIR SODIUM	50MG	MYLAN LABORATORIES LTD PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR - 454775; DIST; DHAR; MADHYA PRADESH;	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X30.0 TABLET BOTTLE	21/11/2019

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3644	NDA/MAL/HDP/7 363	INDCHEMIE HEALTH SPECIALITIES PVT. LTD.	NUMED STORES SMC LIMITED	INDCLAV 228	AMOXICILLIN+CLA VULANATE POTASSIUM	200MG+28MG/5M L	INDCHEMIE HEALTH SPECIALITIES PVT. LTD.VILLAGE & P.O – THANA, TEHSIL – BADDI, DIST- SOLAN, HIMACHAL	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
3645	NDA/MAL/HDP/7 364	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	MOKSEFEN 400 MG	MOXIFLOXACIN HYDROCHLORIDE	400MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş3. ORGANİZE SANAYİ BÖLGESİ KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X7.0 TABLET BLISTER	01/07/2017

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3646	NDA/MAL/HDP/7 365	OCHOA LABORATORIES LIMITED -	SUPER MEDIC LTD	DOLOACT MR	PARACETAMOL+ DICLOFENAC POTASSIUM+CHL ORZOAZONE	500 MG+50 MG+250 MG	AUROCHEM PHARMACEUTICALS INDIA PRIVATE LIMITED58, PALGHAR TALUKA INDUSTRIAL CO - OPERATIVE ESTATE LIMITED PALGHAR, DISTRICT - PALGHAR, 401 404	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/01/2019
3647	NDA/MAL/HDP/7 366	TWENTY FIRST CENTURY PHARMACEUTICAL S PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYFIX	CEFIXIME	200MG	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD-ROORKEE DISTT HARIDWAR	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET STRIP	01/07/2017



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3648	NDA/MAL/HDP/7 367	TWENTY FIRST CENTURY PHARMACEUTICAL S PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYFIX 100 DS	CEFIXIME	100MG/5ML	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD-ROORKEE DISTT HARIDWAR	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
3649	NDA/MAL/HDP/7 369	TWENTY FIRST CENTURY PHARMACEUTICAL S PVT.LTD	SWASTIK PHARMACEUTICAL LTD	XOMOX CV DS	AMOXICILLIN TRIHYDRATE+POT ASSIUM CLAVULANATE	200MG+28.5MG/5 ML	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTDUNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017

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3650	NDA/MAL/HDP/7370	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	XOMOX CV 625	AMOXICILLIN TRIHYDRATE+POTASSIUM CLAVULANATE	500MG+125MG	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTDUNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET STRIP	01/07/2017
3651	NDA/MAL/HDP/7375	INTAS PHARMACEUTICALS LTD	AIVEEN (U) LIMITED	FOLISURGE 75	FOLLITROPIN ALFA	75IU/0.12 ML	INTAS PHARMACEUTICALS LTD (BIOPHARMA DIVISION)PLOT NO. 423/P/A, SARKHEJ-BAVLA HIGHWAY, MORAIYA, TALUKA SANAND, AHMEDABAD-382213, GUJARAT	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X0.12 ML PRE-FILLED SYRINGE	28/11/2019

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3652	NDA/MAL/HDP/7 381	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	BETADINE ANTISEPTIC CREAM 5%	POVIDONE- IODINE	5%W/W	G.S PHAMBUTOR PVT LTD .B-172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE,1.0X20.0 G TUBE	01/07/2017
3653	NDA/MAL/HDP/7 384	YURIA-PHARM LTD	PHARMA VILLE LIMITED	TIVORTIN	ARGININE HYDROCHLORIDE	42MG/ML	YURIA-PHARM LLC MANUFACTURING SITE NO. 1108, KOBZARSKA STREET, CHERKASY, 18030	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	28/03/2018

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3654	NDA/MAL/HDP/7 386	TWENTY FIRST CENTURY PHARMACEUTICAL S PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYLEXIN 125 DS	CEFALEXIN MONOHYDRATE	125MG/5ML	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD-ROORKEE DISTT HARIDWAR	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
3655	NDA/MAL/HDP/7 388	TWENTY FIRST CENTURY PHARMACEUTICAL S PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYFIX CV 200	CEFIXIME+CLAVU LANIC ACID	200MG+125MG	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD-ROORKEE DISTT HARIDWAR	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET STRIP	01/07/2017

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3656	NDA/MAL/HDP/7 389	EVA PHARMA FOR PHARMACEUTICAL S & MEDICAL APPLIANCES -	UNITED HEALTHCARE DISTRIBUTORS LTD	GAROPRIDE	ITOPRIDE HYDROCHLORIDE	50MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
3657	NDA/MAL/HDP/7 391	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	TAVIN-EM	TENOFOVIR DISOPROXIL FUMARATE + EMTRICITABINE	300MG + 200MG	EMCURE PHARMACEUTICALS LTD .PLOT NO. P-2 IT- BT PARK PHASE II MIDC HINJWADI PUNE 411057	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	27/11/2018

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3658	NDA/MAL/HDP/7 407	HETERO LABS LTD	AIVEEN (U) LIMITED	MONAST 5	MONTELUKAST SODIUM	5MG	HETERO LABS LIMITED (UNIT V)SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301 HETERO DRUGS LTD. VILLAGE KALYANPUR, CHAKKAN ROAD, BADDI, TEHSIL NALAGARH, DIST	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
3659	NDA/MAL/HDP/7 408	ZIM LABORATORIES LTD	ROYAL PHARMA 2011 LIMITED	ZIFLAM 100	ACECLOFENAC	100MG	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019

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3660	NDA/MAL/HDP/7409	S K AGE EXPORTS	DAVIMED PHARMA LIMITED	LARIACT DISPERSIBLE	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	S KANT HEALTHCARE LTD PLOT NO. 1805, G.I.D.C PHASE III, VAPI 396195, GUJARAT	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X6.0 TABLET BLISTER	28/11/2019
3661	NDA/MAL/HDP/7410	MEDOPHARM, INDIA	PLANET PHARMACEUTICALS UGANDA LTD	COTRIMOXAZOLE TABLETS BP 960 MG	TRIMETHOPRIM +SULPHAMETHOXAZOLE	960MG	WATERLAND LABORATORIES 34 B, INDUSTRIAL AREA, MALUR - 563160, KARNATAKA, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X50.0X10.0 TABLET BLISTER, 1.0X100.0X10.0 TABLET BLISTER, 1.0X1000.0 TABLET CONTAINER	26/09/2018

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3662	NDA/MAL/HDP/7 411	S K AGE EXPORTS	DAVIMED PHARMA LIMITED	LARIACT 180-1080	ARTEMETHER + LUMEFANTRINE	180MG + 1080MG /60ML	S KANT HEALTHCARE LTD PLOT NO. 1805, G.I.D.C PHASE III, VAPI 396195, GUJARAT	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE	28/11/2019
3663	NDA/MAL/HDP/7 413	S K AGE EXPORTS	DAVIMED PHARMA LIMITED	LARIACT	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	S KANT HEALTHCARE LTD PLOT NO. 1805, G.I.D.C PHASE III, VAPI 396195, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X24.0 TABLET BLISTER	21/11/2019



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3664	NDA/MAL/HDP/7 414	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	RIBOREA	HYDROXYUREA	500MG	KHANDELWAL LABORATORIES PVT. LTDB-1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	21/11/2019
3665	NDA/MAL/HDP/7 415	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	MAMOFEN-20	TAMOXIFEN CITRATE	20MG	KHANDELWAL LABORATORIES PVT. LTDB-1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1X10X10 TABLET STRIP	28/11/2019

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3666	NDA/MAL/HDP/7 417	INTAS PHARMACUITICALS LTD	STAR BIOTECH UGANDA LTD	SARTEL-40	TELMISARTAN	40MG	INTAS PHARMACEUTICALS LTD ...,CAMP ROAD, SELAQUI, DEHRADUN- 248197, UTTARKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
3667	NDA/MAL/HDP/7 418	INTAS PHARMACEUTICAL S LTD	AIVEEN (U) LIMITED	FOLISURGE 1200	FOLLITROPIN ALFA	1200 IU/1.92ML	INTAS PHARMACEUTICALS LTD (BIOPHARMA DIVISION)PLOT NO. 423/P/A, SARKHEJ- BAVLA HIGHWAY, MORAIYA, TALUKA SANAND, AHMEDABAD- 382213, GUJARAT	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.92 ML VIAL	28/11/2019

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3668	NDA/MAL/HDP/7419	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	PACLITAXEL	PACLITAXEL	6MG/ML	INTAS PHARMACEUTICALS LTD.PLOT NO. 457, 458, & 191/218P,VILLAGE: MATODA, TAL. SANAND, AHMEDABAD, GUJARAT, 382210 INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X16.7 ML VIAL	28/11/2019
3669	NDA/MAL/HDP/7421	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	GESIC ADL 200	IBUPROFEN	200MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017

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3670	NDA/MAL/HDP/7 424	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	ZINC SULFATE TABLETS USP 20MG	ZINC SULFATE MONOHYDRATE	20MG	MACLEODS PHARMACEUTICALS LTD - VILLAGE THEDA P.O LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH INDIA 174101	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017
3671	NDA/MAL/HDP/7 425	OCHOA LABORATORIES LIMITED -	AIVEEN (U) LIMITED	DOLOACT PLUS	ACECLOFENAC + PARACETAMOL	100MG + 500MG	AUROCHEM PHARMACEUTICALS (I)PLOT NO. 58, PTICE LTD PALGHAR 401404, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X1.0X10 .0 TABLET BLISTER	21/11/2019

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3672	NDA/MAL/HDP/7 426	MEDOCHÉMIE LTD	LABOREX UGANDA LIMITED	MEDOFED	GUAIFENESIN + DEXTROMETHOR PHAN HYDROBROMIDE + PSEUDOEPHEDRI NE HYDROCHLORIDE AND + TRIPROLIDINE HYDROCHLORIDE	100MG + 15MG + 20MG + 1.25MG/5ML	MEDOCHÉMIE ACTORY).....1-10 CONSTANTINOUPOL EOS STREET, 3011, LIMASSOL	CYPRUS	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE	21/11/2019
3673	NDA/MAL/HDP/7 429	SAKAR HEALTHCARE LIMITED	ROYAL PHARMA 2011 LIMITED	SEFIXI 1000	CEFTRIAXONE SODIUM	1G	SAKAR HEALTHCARE PVT LTD (BLOCK NO. 10-13, NR. M.N DESAI PETRO PUMP, SARKHEJ-BAVLA ROAD, CHANGODAR, DIST: AHMEDABAD- 382213, GUJARAT)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL, 1.0X50.0X1.0 G VIAL	28/11/2019

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3674	NDA/MAL/HDP/7 431	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	MOVICOL	MACROGOL 3350 (POLYETHYLENE GLYCOL)+SODIUM CHLORIDE+SODIU M BICARBONATE+ POTASSIUM CHLORIDE	13.125G+350.7MG +178.5MG+46.6M G	WIN-MEDICARE PVT. LTDMODIPURAM- 250 110, UTTAR PRADESH,INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X10.0X13.81 G SACHET	26/09/2018
3675	NDA/MAL/HDP/7 435	SQUARE FORMULATIONS LTD	GAMA PHARMACEUTICAL S (U) LIMITED	ZIMAX	AZITHROMYCIN DIHYDRATE	200MG/5ML	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X30.0 ML BOTTLE	28/11/2019

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3676	NDA/MAL/HDP/7 436	SQUARE PHARMACEUTICAL S LTD	GAMA PHARMACEUTICAL S (U) LIMITED	CEFOTIL PLUS 500	CEFUROXIME AXETIL + CLAVULANATE	500MG + 125MG	SQUARE CEPALOSPORINS LTD..KALIAKOIR GAZIPUR	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X6.0 TABLET BLISTER	28/11/2019
3677	NDA/MAL/HDP/7 439	DAWA PHARMACEUTICAL S LIMITED	SUPER MEDIC LTD	LORVIC	LORATADINE	5MG/5ML	DAWA LIMITED16633- 00620, RUARAKA, BABA DOGO ROAD, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	21/11/2019

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3678	NDA/MAL/HDP/7 440	MANKIND	TATA UGANDA LIMITED	TOTACEF-1000	CEFEPIME	1000MG	MANKIND PHARMA LTD.VILLAGE KISHANPURA, POAMTA SAHI DISTRICT SIRMOUR HIMACHAL PRADESH	INDIA	PARENTERAL RETARD DRY VIALS	1.0X1000.0 MG VIAL	28/11/2019
3679	NDA/MAL/HDP/7 441	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	HYORTH XL	SODIUM HYALURONATE	8MG/ML	VIRCHOW BIOTECH PVT LTDSURVEY NO. 172, PART GAGILLAPUR(P) QUTHBULLAPUR(MA NDAL), R.R, DISTRICT, TELANGANA STATE, 500043.INDIA	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X6.0 ML PRE- FILLED SYRINGE	29/11/2017



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3680	NDA/MAL/HDP/7 442	DAWA LIMITED-	SUPER MEDIC LTD	NERVILIN NT	PREGABALIN + NORTRIPTYLINE HYDROCHLORIDE	75MG + 10MG	DAWA LIMITED16633- 00620, RUARAKA, BABA DOGO ROAD, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
3681	NDA/MAL/HDP/7 447	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	LORADIN 10	LORATADINE	10MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	21/11/2019

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3682	NDA/MAL/HDP/7 448	OCHOA LABORATORIES LIMITED -	SUPER MEDIC LTD	SORID OINTMENT	CALCIPOTRIOL MONOHYDRATE + BETAMETHASONE DIPROPIONATE	50MCG +0.5MG	AUROCHEM LABORATORIES (I) PVT LTD8, PALGHAR TALUKA INDUSTRIAL CO - OPERATIVE ESTATE LIMITED PALGHAR, DISTRICT - PALGHAR, 401404	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE	29/11/2017
3683	NDA/MAL/HDP/7 450	OCHOA LABORATORIES	SUPER MEDIC LTD	DOLOACT GEL	KETOPROFEN + CAPSICUM OLEORESIN	2.50%W/W + 0.25%W/W	AUROCHEM LABORATORIES (I) PVT LTD-8 PALGHAR TALUKA INDUSTRIAL CO-OP ESTATE LTD PALGHAR 401 404 DIST THANE	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	29/11/2017

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3684	NDA/MAL/HDP/7 454	MEDISEL(K) LTD	AIVEEN (U) LIMITED	GIT	ITOPRIDE HYDROCHLORIDE	150MG	CORONA REMEDIES PVT. LTD VILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	OPHTHALMIC DROPS	1.0X1.0X10.0 CAPSULE BLISTER	28/11/2019
3685	NDA/MAL/HDP/7 456	INFUGEN PHARMA PVT. LTD.	TATA UGANDA LIMITED	INFUTRAX	CEFTRIAXONE SODIUM	1G	VENUS REMEDIES LIMITED ,,HILL TOP, INDUSTRIAL ESTATE, JHARMAJRI, EPIP, PHASE 1, EXT. BBATOLI KALAN, BADDI-SOLAN HIMACHAL PRADESH, INDIA PIN 173205 M/S ZEISS PHARMACEUTICALS PVT LTD,,PLOT 72, EPIP PHASE 1, JHARMAJRI BADDI, DIST: SOLAN HP- INDIA INNOVA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	21/11/2019

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3686	NDA/MAL/HDP/7460	INVENTIA HEALTHCARE PVT LTD	EUROPA HEALTHCARE (U) LTD	SEGABIN SR 75	PREGABALIN	75MG	INVENTIA HEALTHCARE PVT LTD F1-F1/1 ADDITIONAL MIDC AMBERNATH (E) DIST. THANE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
3687	NDA/MAL/HDP/7461	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	WOMAZOL	ANASTROZOLE	1MG	KHANDELWAL LABORATORIES PVT. LTDB-1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1X10 TABLET BLISTER	29/05/2019

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3688	NDA/MAL/HDP/7 463	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	ACURON	ATRACURIUM BESYLATE	10MG/ML	BROOKES PHARMA (PRIVATE) LIMITED58 59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X5.0X5.0 ML AMPOULE	27/08/2019
3689	NDA/MAL/HDP/7 464	INVENTIA HEALTHCARE PVT LTD	EUROPA HEALTHCARE (U) LTD	SEGABIN M 75	PREGABALIN + METHYCOBALAMI N	75MG + 1500MCG	INVENTIA HEALTHCARE PVT LTD F1-F1/1 ADDITIONAL MIDC AMBERNATH (E) DIST. THANE	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019

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3690	NDA/MAL/HDP/7 465	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	P-ALAXIN TS	DIHYDROARTEMI SININ + PIPERAQUINE PHOSPHATE	120MG + 960MG	M/S BLISS GVS PHARMA LIMITED PLOT 10, SURVEY NO. 38/1, DEWAN UDYOG NAGAR, ALIYALI VILLAGE PALGHAR, DIST. THANE - 401404	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X3.0 TABLET BLISTER	21/11/2019
3691	NDA/MAL/HDP/7 467	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	TEZOLE CREAM	KETOCONAZOLE	20 MG	BROOKES PHARMA (PRIVATE) LIMITED58 59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE	27/08/2019

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3692	NDA/MAL/HDP/7 468	AKRITI PHARMACEUTICAL S PVT LTD	PHARMA VILLE LIMITED	GYNO PLUS	METRONIDAZOLE + MICONAZOLE NITRATE	100MG + 100MG	AKRITI PHARMACEUTICALS PVT LTD PLOT NO. D- 10 & 11, MIDC, JEJURI, TAL. PURANDAR, DIST. PUNE (MAHARASHTRA) INDIA	INDIA	VAGINAL TABLETS	1.0X1.0X10.0 TABLET BLISTER	28/11/2019
3693	NDA/MAL/HDP/7 469	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	ECZEMUS 0.03% OINTMENT	TACROLIMUS MONOHYDRATE	0.03%W/W	BROOKES PHARMA (PRIVATE) LIMITED 58 59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X10.0 G TUBE	25/07/2018

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3694	NDA/MAL/HDP/7 470	AKRITI PHARMACEUTICAL S PVT LTD	PHARMA VILLE LIMITED	AKSONE	CEFTRIAZONE SODIUM	1G	AKRITI PHARMACEUTICALS PVT LTD PLOT NO. D- 10 & 11, MIDC, JEJURI, TAL. PURANDAR, DIST. PUNE (MAHARASHTRA) INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	21/11/2019
3695	NDA/MAL/HDP/7 473	INVENTIA HEALTHCARE PVT LTD	EUROPA HEALTHCARE (U) LTD	AFLODOR 16	ACECLOFENAC + THIOLCHICOSI DE	200MG + 16MG	INVENTIA HEALTHCARE PVT LTD F1-F1/1 ADDITIONAL MIDC AMBERNATH (E) DIST. THANE	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X6.0X5.0 CAPSULE BLISTER	21/11/2019



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3696	NDA/MAL/HDP/7 474	INVENTIA HEALTHCARE PVT LTD	EUROPA HEALTHCARE (U) LTD	AFLODOR 8	ACECLOFENAC + THIOLCHICOSI DE	200 MG + 8 MG	INVENTIA HEALTHCARE PVT LTD F1-F1/1 ADDITIONAL MIDC AMBERNATH (E) DIST. THANE	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X6.0X5.0 CAPSULE BLISTER	21/11/2019
3697	NDA/MAL/HDP/7 475	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	UMOCLOX 500	AMPICILLIN TRIHYDRATE+CLO XACILLIN SODIUM	250MG+250MG	UNI MEDICOLABS. 21 22 PHARMACITY SELAQUI DEHRADUN 248197	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2015

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3698	NDA/MAL/HDP/7 477	CHEPLAPHARM ARZNEIMITTEL GMBH	LABOREX UGANDA LIMITED	ROHYPNOL	FLUNITRAZEPAM	1 MG	CENEXI S.A.S52, RUE MARCEL ET JACQUES GAUCHER 94120 FONTENAY-SOUS- BOIS- FRANCE	FRANCE	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/03/2019
3699	NDA/MAL/HDP/7 480	DEVA HOLDING A.S	SHREEJI PHARMACEUTICAL S LIMITED	AMOKLAVIN BID	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	200MG + 28.5MG/5ML	DEVA HOLDING A.SCERKEZKOY ORGANIZE SANAYI BOLGESI, KARAAGAC MAH., ATATURK CAD., NO.: 32 KAPAKLI TEKIRDAG	TURKEY	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X70.0 ML BOTTLE	21/11/2019

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3700	NDA/MAL/HDP/7 481	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	INTAGRA 100	SILDENAFIL CIRATE	100MG	INTAS PHARMACEUTICALS LTD .PLOT NOS. 457, 458 & 191/218P SARKHEJ-BAVLA HIGHWAY MATODA SANAND AHMEDABAD GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0 TABLET BLISTER	01/07/2017
3701	NDA/MAL/HDP/7 483	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APISOPT PLUS	DORZOLAMIDE HYDROCHLORIDE + TIMOLOL MALEATE	2%W/V + 0.5%W/V	AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	JORDAN	OPHTHALMIC LIQUIDS	1.0X5.0 ML VIAL	21/11/2019

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3702	NDA/MAL/HDP/7 487	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	BETASALIC	BETAMETHASONE DIPROPIONATE + SALICYLIC ACID	0.05%W/W + 3%W/W	ATCO LABS LTD,B-18, S.I.T.E, KARACHI	PAKISTAN	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	21/11/2019
3703	NDA/MAL/HDP/7 488	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	FINTAS 5	FINASTERIDE	5MG	INTAS PHARMACEUTICALS LTD .PLOT NOS. 457, 458 & 191/218P SARKHEJ-BAVLA HIGHWAY MATODA SANAND AHMEDABAD GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2017

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3704	NDA/MAL/HDP/7489	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	DOLUTEGRAVIR, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE	DOLUTEGRAVIR + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE	50MG + 300MG + 300MG	OXALIS LABS LIMITED VILLAGE THEDA, P.O LODHIMAJRA, TEHSIL BADDI DIST: SOLAN (H.P.) PIN CODE: 174101 - INDIA MACLEODS PHARMACEUTICALS LTD BLOCK N2, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101 MACLEODS	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE, 1.0X90.0 TABLET BOTTLE, 1.0X100.0 TABLET BOTTLE, 1.0X180.0 TABLET BOTTLE	21/11/2019
3705	NDA/MAL/HDP/7490	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	INTAGRA 50	SILDENAFIL CITRATE	50MG	INTAS PHARMACEUTICALS LTD .PLOT NOS. 457, 458 & 191/218P SARKHEJ-BAVLA HIGHWAY MATODA SANAND AHMEDABAD GUJARAT	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0 TABLET BLISTER	01/07/2017

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3706	NDA/MAL/HDP/7491	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	CIPRO-DENK 750	CIPROFLOXACIN HYDROCHLORIDE	750MG	ALLPHAMED PHARBIL ARZNEIMITTEL GMBH. HILDEBRANDSTRABE 12 37081 GOTTINGEN	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017
3707	NDA/MAL/HDP/7492	LINCOLN PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	CYPRODINE	CYPROHEPTADINE HYDROCHLORIDE	2MG/5ML	LINCOLN PHARMACEUTICAL LIMITED..LINCOLN PHARMACEUTICALS LIMITED, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	27/08/2019

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3708	NDA/MAL/HDP/7 493	ZIM LABORATORIES LTD	REDDYS PHARMA LIMITED	CEFRAZ 200	CEFIXIME TRIHYDRATE	200 MG	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X1X10 TABLET BLISTER	27/11/2019
3709	NDA/MAL/HDP/7 503	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DUTABIT 0.5	DUTASTERIDE	0.5 MG	AUROBINDO PHARMA LTD-UNIT VII ,/SY. NO'S 411, 425, 434, 435 & 458, PLOT NO. S1 (PART), SPECIAL ECONOMIC ZONE (PHARMA), APIIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE JEDEHERLA MANDAL, MAHABOOB NAGAR DISTRICT-509302, ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	27/11/2019

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3710	NDA/MAL/HDP/7 504	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	IMATINATE 400	IMATINIB MESYLATE	400MG	KHANDELWAL LABORATORIES PVT. LTDB-1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1X1X10 CAPSULE BLISTER	26/09/2018
3711	NDA/MAL/HDP/7 507	ZIM LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	FINEVIT-D3 2000	CHOLECALCIFERO L (VITAMIN D3)	2000 IU	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0 TABLET STRIP	27/11/2019



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3712	NDA/MAL/HDP/7 510	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	IMAVIR EYE OINTMENT	ACYCLOVIR	3%	AMMAN PHARMACEUTICAL INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN, JORDAN  MMAN, JORDAN	JORDAN	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE	28/05/2019
3713	NDA/MAL/HDP/7 514	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	ILFLOX 500	LEVOFLOXACIN HEMIHYDRATE	500 MG	ILKO İLAÇ SANAYİ VE TİCARET A.Ş.ORGANIZE SANAYİ BOLGESİ, BUYUK KAYACIK MAH. KUDDİSİ CAD.23 SOKAKNO. 1 42050 SELÇUKLU, KONYA	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X7.0 TABLET BLISTER	21/11/2019

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3714	NDA/MAL/HDP/7 515	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	HEPBEST	PREGABALIN + NORTRIPTYLINE (AS HYDROCHLORIDE)	75MG + 10MG	MYLAN LABORATORIES LTD PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR - 454775; DIST; DHAR; MADHYA PRADESH;	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	21/11/2019
3715	NDA/MAL/HDP/7 516	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	ILFLOX 750	LEVOFLOXACIN HEMIHYDRATE	750 MG	ILKO İLAC SANAYİ VE TİCARET A.Ş.ORGANIZE SANAYİ BOLGESİ, BUYUK KAYACIK MAH. KUDDISI CAD.23 SOKAKNO. 1 42050 SELCUKLU, KONYA	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X7.0 TABLET BLISTER	21/11/2019

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3716	NDA/MAL/HDP/7 517	RESONANT PHARMACEUTICAL S PVT LTD	SHREEJI PHARMACEUTICAL S LIMITED	LEVOCET-M	LEVOCETIRIZINE DIHYDROCHLORID E + MONTELUKAST SODIUM	5MG + 10MG	RESONANT PHARMACEUTICALS PRIVATE LIMITED - PLOT NO – 430-1-A NEAR SAFFRO MELLOW COLOUR FACTORY, VILLAGE, NAVAGAM, DISTRICT KHEDA, GUJARAT - 387540, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
3717	NDA/MAL/HDP/7 518	RESONANT PHARMACEUTICAL S	SHREEJI PHARMACEUTICAL S LIMITED	LEVOCET-M SUSPENSION	LEVOCETIRIZINE DIHYDROCHLORID E + MONTELUKAST SODIUM	2.5MG / 5ML + 4MG / 5ML	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	21/11/2019

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3718	NDA/MAL/HDP/7 519	MACLEODS PHARMACEUTICAL S LTDS LTD	VITACARE LIMITED	LEVOFLOXACIN	LEVOFLOXACIN HEMIHYDRATE	250 MG	MACLEODS PHARMACEUTICALS LTD BLOCK N2, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X5.0 TABLET BLISTER	27/11/2019
3719	NDA/MAL/HDP/7 520	DAWA LIMITED	SUPER MEDIC LTD	LEVOXCIN	LEVOFLOXACIN HEMIHYDRATE	750 MG	DAWA LIMITED 16633-00620, RUARAKA, BABA DOGO ROAD, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	21/11/2019

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3720	NDA/MAL/HDP/7 523	DENK PHARMA GMB H &CO. KG	BENLE CONSULT LIMITED	LEVOFLOX-DENK 5 MG/ML	LEVOFLOXACIN HEMIHYDRATE	5MG/ML	SOLUPHARM PHARMAZEUTISCHE ERZEUGNISSE GMBH- INDUSTRIESTR. 3 34212 MELSUNGEN GERMANY	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML VIAL	01/07/2017
3721	NDA/MAL/HDP/7 524	AMMAN PHARMACEUTICAL S LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LOPROSTAN	LATANOPROST + TIMOLOL MALEATE	0.005% W/V + 0.5%W/V	AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	JORDAN	OPHTHALMIC LIQUIDS	1.0X2.5 ML VIAL	21/11/2019

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3722	NDA/MAL/HDP/7 525	DAWA LIMITED	SUPER MEDIC LTD	LORVIC	LORATADINE	10 MG	DAWA LIMITED16633-00620, RUARAKA, BABA DOGO ROAD, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
3723	NDA/MAL/HDP/7 526	I-CARE PHARMA LTD	AIVEEN (U) LIMITED	MANIGRA 100	SILDENAFIL CITRATE	100 MG	CORONA REMEDIES PVT. LTDVILLAGE JATOLI, POST OFFICE-OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	27/11/2019

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3724	NDA/MAL/HDP/7 529	FDC LTD	AIVEEN (U) LIMITED	MOSI EYE DROPS	MOXIFLOXACIN HYDROCHLORIDE	5 MG/ML	FDC LIMITED, WALUJ .PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD	INDIA	OPHTHALMIC LIQUIDS	1.0X1.0X5.0 ML VIAL	21/11/2019
3725	NDA/MAL/HDP/7 530	HETERO LABS LTD	AIVEEN (U) LIMITED	DOLUTEGRAVIR TABLETS 50MG	DOLUTEGRAVIR	50MG	HETERO LABS LTD UNIT III22-110 IDA JEEDIMETIA HYDERABAD ANDHRA PRADESH , HETERO LABS LIMITED (UNIT V)SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	07/11/2018

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3726	NDA/MAL/HDP/7 535	ACME FORMULATION PVT. LTD.	MARIE STOPES UGANDA LIMITED	MARIPRIST	MIFEPRISTONE + MISOPROSTOL	200MG + 200MCG	ACME FORMULATION PVT. LTDROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X1.0X4.0 TABLET BLISTER	27/08/2019
3727	NDA/MAL/HDP/7 536	PLANET PHARMACEUTICAL S UGANDA LTD	PLANET PHARMACEUTICAL S UGANDA LTD	SPINESIA-D	BUPIVACAINE HYDROCHLORIDE + DEXTROSE	5MG + 80MG /ML	UNIQUE PHARMACEUTICAL LABORATORIESPLOT NO.4, PHASE IV, GIDC, INDUSTRIAL AREA, PANOLI- 394 116, DIST: BHARUCH, INDIA SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X10.0X4.0 ML AMPOULE,1.0X10.0 X4.0 ML AMPOULE,1.0X1.0X 5.0X5.0X4.0 ML AMPOULE,1.0X5.0X 4.0 ML AMPOULE	01/07/2017



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3728	NDA/MAL/HDP/7 539	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICAL S LIMITED	COUGH LINCTUS	CHLORPHENIRAM INE	2MG/5ML	SEV PHARMACEUTICALS LIMITEDPLOT 100 NALUKOLONGO	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X1000.0 ML JERRYCAN,1.0X200. 0 ML BOTTLE	01/07/2011
3729	NDA/MAL/HDP/7 541	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICAL S LIMITED	CHLORHEXIDINE SCRUB	CHLORHEXIDINE GLUCONATE	4%W/V	SEV PHARMACEUTICALS LIMITEDPLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X1000.0 ML JERRYCAN	01/07/2012

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3730	NDA/MAL/HDP/7 544	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICAL S LIMITED	GLYCERIN OF BORAX	GLYCERINE+BORA X	12%W/V	SEV PHARMACEUTICALS LIMITEDPLOT 100 NALUKOLONGO	UGANDA	ORAL LIQUID ORDINARY LIQUIDS	1.0X22.0 ML BOTTLE	01/07/2013
3731	NDA/MAL/HDP/7 546	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICAL S LIMITED	HYDROGEN PEROXIDE	HYDROGEN PEROXIDE	6%W/V	SEV PHARMACEUTICALS LIMITEDPLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X200.0 ML BOTTLE,1.0X1.0 L JERRYCAN	01/07/2012

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3732	NDA/MAL/HDP/7 548	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICAL S LIMITED	IODINE TINCTURE	IODINE + POTASSIUM IODIDE	2.5%W/V+2.5%W/ V	SEV PHARMACEUTICALS LIMITEDPLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X22.0 ML BOTTLE	01/07/2013
3733	NDA/MAL/HDP/7 552	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICAL S LIMITED	MAGNESIUM TRISILICATE MIXTURE	MAGNESIUM TRISILICATE + LIGHT MAGNESIUM CARBONATE + SODIUM BICARBONATE	250MG + 250MG + 250MG/5ML	SEV PHARMACEUTICALS LIMITEDPLOT 100 NALUKOLONGO	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	01/07/2010

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3734	NDA/MAL/HDP/7 554	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICAL S LIMITED	POVIDONE IODINE BP	POVIDONE IODINE	10%W/V	SEV PHARMACEUTICALS LIMITEDPLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X200.0 ML BOTTLE,1.0X1000.0 ML JERRYCAN	01/07/2013
3735	NDA/MAL/HDP/7 556	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICAL S LIMITED	SEVASTAT	CETRIMIDE + CHLORHEXIDINE	3%W/V+0.3%W/V	SEV PHARMACEUTICALS LIMITEDPLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X1.0 L BOTTLE	01/07/2012

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3736	NDA/MAL/HDP/7 559	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICAL S LIMITED	SURGICAL SPIRIT	METHYL SALICYLATE	0.5%V/V	SEV PHARMACEUTICALS LIMITEDPLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL SPIRITS	1.0X100.0 ML BOTTLE	01/07/2011
3737	NDA/MAL/HDP/7 560	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICAL S LIMITED	VIOLGENT	CRYSTAL VIOLET	0.5%W/V	SEV PHARMACEUTICALS LIMITEDPLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X25.0 ML BOTTLE	01/07/2014

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3738	NDA/MAL/HDP/7 571	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	NEUROVIT FILM- COATED TABLET	THIAMINE MONONITRATE + PYRIDOXINE HCL + CYANOCOBALAMI NE	97MG + 50MG + 100MG	HOVID BHDLOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008
3739	NDA/MAL/HDP/7 586	OCHOA LABORATORIES	SUPER MEDIC LTD	CLEAR-T GEL	CLINDAMYCIN PHOSPHATE + TRETINOIN	1.0%W/W + 0.025%W/W	AUROCHEM LABORATORIES LTD PLOT 08 PALGHAR 401404 MAHARASHTRA, INDIA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE	29/11/2017

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3740	NDA/MAL/HDP/7 587	DAWA LIMITED	SUPER MEDIC LTD	NERVILIN 75	PREGABALIN	75 MG	DAWA LIMITED16633- 00620, RUARAKA, BABA DOGO ROAD, NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	21/11/2019
3741	NDA/MAL/HDP/7 588	OCHOA LABORATORIES LIMITED -	SUPER MEDIC LTD	EXEVATE-MF OINTMENT	BETAMETHASONE DIPROPIONATE + SALICYLIC ACID + UREA + LACTIC ACID + SODIUM LACTATE SOLUTION	0.05 % W/W + 3.0 % W/W + 10.0 % W/W + 3.0 % W/W + 2.0 % W/W	AUROCHEM LABORATORIES (I) PVT LTD8, PALGHAR TALUKA INDUSTRIAL CO - OPERATIVE ESTATE LIMITED PALGHAR, DISTRICT - PALGHAR, 401404	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE	29/11/2017

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3742	NDA/MAL/HDP/7 589	OCHOA LABORATORIES	SUPER MEDIC LTD	LACX SYRUP	LACTULOSE	10G/15ML	AUROCHEM LABORATORIES (I) PVT LTD-8 PALGHAR TALUKA INDUSTRIAL CO-OP ESTATE LTD PALGHAR 401 404 DIST THANE	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE,1.0X100.0 ML BOTTLE	29/11/2017
3743	NDA/MAL/HDP/7 590	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	MONTIGET	MONTELUKAST SODIUM	5MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	25/11/2021



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3744	NDA/MAL/HDP/7 595	AMMAN PHARMACEUTICAL S LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LOPROST	LATANOPROST	0.005% W/V	AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	JORDAN	OPHTHALMIC VIALS	1.0X2.5 ML VIAL	21/11/2019
3745	NDA/MAL/HDP/7 598	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	RABEFLUX-DSR	RABEPRAZOLE SODIUM + DOMPERIDONE	20MG + 30MG	STEDMAN PHARMACEUTICALS PVT. LTD.C-4, SIDCO PHARMACEUTICALS COMPLEX, ALATHUR, THIRUPORUR- 603 110, TAMIL NADU INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X3.0X10 .0 CAPSULE BLISTER	21/11/2019

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3746	NDA/MAL/HDP/7 605	GUFIC BIOSCIENCES LTD	EUROPA HEALTHCARE (U) LTD	STRIPOLE	PANTOPRAZOLE SODIUM SESQUIHYDRATE	40 MG	GUFIC BIOSCIENCES LIMITED (UNIT 2)SURVEY NO. 171, NATIONAL HIGHWAY NO. 8, NEAR GRID, AT & PO: KABILPORE, NAVSARI - 396424, GUJARAT - INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	27/11/2019
3747	NDA/MAL/HDP/7 607	FDC LTD	AIVEEN (U) LIMITED	TEARMAX EYE DROPS	CARMELLOSE SODIUM	5MG/ML	FDC LIMITED, WALUJ .PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD	INDIA	OPHTHALMIC LIQUIDS	1.0X1.0X10.0 ML VIAL	21/11/2019

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3748	NDA/MAL/HDP/7 610	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	TERBIDERM FORTE	TERBINAFINE HYDROCHLORIDE	250 MG	ATCO LABS LTD,B-18, S.I.T.E, KARACHI	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	21/11/2019
3749	NDA/MAL/HDP/7 611	FERRING GMBH	MACNAUGHTON LIMITED	PABAL	CARBETOCIN	100MCG/ML	FERRING GMBH.11, WITTLAND	GERMANY	PARENTERAL ORDINARY VIALS	1.0X5.0X1.0 ML VIAL	01/07/2017

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3750	NDA/MAL/HDP/7614	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS UGANDA LTD	TOPCLIN	CLINDAMYCIN PHOSPHATE	1 %W/W	KREMOINT PHARMA PVT LTD PLANT IIB-8, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST) DIST. THANE 421506	INDIA	TOPICAL EXTERNAL EMULSION GELS	1.0X25.0 G TUBE	21/11/2019
3751	NDA/MAL/HDP/7615	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVCLAV-625	AMOXICILLIN + CLAVULANIC ACID	500MG + 125MG	AMN LIFE SCIENCE PVT LTD-67/P-1, MALAV, AREA-BHILAD, VALSAD-396105, GUJARAT MEDICEF PHARMA-NO. 28, PHASE 1, EPIP, JHARRMAJRI, BADDI, DIST SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER, 1.0X2.0X7.0 TABLET BLISTER	21/11/2019

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3752	NDA/MAL/HDP/7 622	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	MONTELAIR 5	MONTELUKAST SODIUM	5MG	HOVID BHDLOT 56442,71/2 MILES JALAN IPOH,PERAK,MALAYS IA	MALAYSIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2018
3753	NDA/MAL/HDP/7 652	MSD (PTY) LTD	SURGIPHARM (U) LIMITED	JANUVIA 100	SITAGLIPTIN	100MG	MSD PTY LTD117 16TH ROAD, HALFWAY HOUSE 1685	SOUTH AFRICA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2017

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3754	NDA/MAL/HDP/7 653	MSD (PTY) LTD	SURGIPHARM (U) LIMITED	JANUVIA 50	SITAGLIPTIN	50MG	MSD PTY LTD117 16TH ROAD, HALFWAY HOUSE 1685	SOUTH AFRICA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2017
3755	NDA/MAL/HDP/7 656	A.MENARINI INDUSTRIE FARMACEUTICHE RIUNITE	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	SPASMOMEN	OTILONIUM BROMIDE	40MG	A.MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.LVIA CAMPO DI PILE, L'AQUILA (AQ), ITALY	ITALY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER,1.0X1.0X10 .0 TABLET BLISTER (FREE PHYSICIAN'S SAMPLE, NOT FOR SALE )	01/07/2017

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3756	NDA/MAL/HDP/7 674	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABLEVOX	LEVOFLOXACIN HEMIHYDRATE	5G/L	ABACUS PARENTERAL DRUGS LIMITEDBLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2017
3757	NDA/MAL/HDP/7 681	ZEE PHARMACEUTICAL S LTD	ZEE PHARMACEUTICAL S LIMITED	ZEECEL 200	CELECOXIB	200MG	THE MADRAS PHARMACEUTICALS.. NO. 137B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI 600096	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2017

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3758	NDA/MAL/HDP/7 683	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DELAREX	DES Loratadine	5MG	GLOBAL NAPI PHARMACEUTICALS - 2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	EGYPT	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2017
3759	NDA/MAL/HDP/7 686	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OPTIGENT EYE/EAR DROPS	GENTAMICIN SULPHATE	0.3W/V	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2017



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3760	NDA/MAL/HDP/7 687	ABACUS PHARMA (AFRICA) LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DI - QUIN	DIHYDROARTEMI SININ+PIPERAQUI NE PHOSPHATE	40MG + 320MG	SKANT HEALTH CARE LTD 1802-1805 GIDC PHASE III VAPI GUJARAT	CHINA	ORAL SOLID ORDINARY TABLETS	1X9 TABLET BLISTER,	09/07/2017
3761	NDA/MAL/HDP/7 688	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE 850MG TABLET	METFORMIN HYDROCHLORIDE	850MG	NKUNZI PHARMACEUTICALS2 59 DAVIDSON ROAD, WADEVILLEGERMIST ON, 1428 SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X300.0 TABLET CONTAINER,1.0X60. 0 TABLET CONTAINER,1.0X4.0 X15.0 TABLET BLISTER	01/07/2017

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3762	NDA/MAL/HDP/7 695	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	CORTUM 500	CEFUROXIME AXETIL	500MG	MALIK LIFESCIENCES PRIVATE LIMITED PLOT NO. 16, NH 58, VARDHMAN INDUTRIAL ESTATE, VILLAGE BAHADARPUR SAINI HARIDWAR, UTTARAKHAND- 247667	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017
3763	NDA/MAL/HDP/7 706	CACHET PHARMACEUTICAL S PVT LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CACEF 200	CEFPODOXIME PROXETIL	200MG	INNOVA CAPTAB PVT. LTD 1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER, 1.0X10.0 TABLET BLISTER	01/07/2017

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3764	NDA/MAL/HDP/7 714	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROXONE 1GM	CEFTRIAZONE SODIUM	1 G	ZEISS PHARMACEUTICALS PVT LTD - PLOT 72, EPIP, PHASE 1, JHARMAJRI BADDI, 173205, DIST: SOLAN HIMACHAL PRADESH, INDIA M/S SCOTT-EDIL ADVANCE RESEARCH LABORATORIES AND EDUCATION LIMITEDHILL-TOP, INDUSTRIAL AREA, BHATOLI KALAN, BADDI DISTT. SOLAN	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	07/11/2018
3765	NDA/MAL/HDP/7 715	JANSSEN-CILAG INTERNATIONAL NV	LABOREX UGANDA LIMITED	SIRTURO	BEDAQUILINE FUMARATE	100MG	RECIPHARM PHARMACEUTICALS PVT LTD34TH KM, TUMKUR ROAD, T- BEGUR, NELAMANGALA TALUK BENGALURU, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X188.0 TABLET BOTTLE	29/11/2017

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3766	NDA/MAL/HDP/7 716	CORE ACCESS LIMITED	CORE ACCESS LTD	ALRINAST 2.5 MG / 5 ML SYRUP	DES Loratidine	2.5 MG / 5 ML	NOBEL İLAÇ SAN. VE TİC. A.Ş.SANCAKLAR, DÜZCE, 81100	TURKEY	ORAL LIQUID ORDINARY SYRUPS	1.0X150.0 ML BOTTLE	29/11/2017
3767	NDA/MAL/HDP/7 724	FERRING GMBH	MACNAUGHTON LIMITED	MENOPUR	HIGHLY PURIFIED MENOTROPHIN [ CORRESPONDING TO FOLLICLE STIMULATING HORMONE ACTIVITY (FSH) 75 IU + LUTEINISING HORMONE ACTIVITY (LH) 75 IU]	75 IU + 75 IU/ 4ML VIAL	FERRING (PTY) LTD- WITTLAND II 24146 KIEL	GERMANY	PARENTERAL ORDINARY DRY VIALS	10.0X4.0 ML VIAL 10*1ML CLEAR COLOURLESS GLASS AMPOULES CONTAINING 9.0MG/ML OF NA CL	01/07/2017

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3768	NDA/MAL/HDP/7 726	NTICALS LTD.	VITACARE LIMITED	LOPINAVIR + RITONAVIR	LOPINAVIR + RITONAVIR	100MG + 25MG	MACLEODS PHARMACEUTICALS LTD(BLOCK N2)VILLAGE THEDA,P.O LODHI MAJRA,TEHSIL BADDI,HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2017
3769	NDA/MAL/HDP/7 735	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	IBUMOL 400	PARACETAMOL + IBUPROFEN	325MG + 400MG	AJANTA PHARMA LIMITED PAITHANMANUFACT URING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017

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3770	NDA/MAL/HDP/7 745	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	TAZOGARD	PIPERACILLIN +TAZOBACTAM	4G + 0.5G	AKUMS DRUGS & PHARMACEUTICALS LTD.2, 3, 4, & 5, SEC- 6B, I.I.E., SIDCUL, RANIPUR, HARIDWAR-249403 (INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X4.5 G VIAL ,2X10ML LDPE AMPOULES OF WFI	01/07/2017
3771	NDA/MAL/HDP/7 747	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	THERMODOL	PARACETAMOL	1.0%W/V	AKUMS DRUGS & PHARMACEUTICALS LTD.2, 3, 4, & 5, SEC- 6B, I.I.E., SIDCUL, RANIPUR, HARIDWAR-249403 (INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2017

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3772	NDA/MAL/HDP/7 751	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	UNODEX COUGH SYRUP	BROMHEXINE HYDROCHLORIDE + DEXTROMETHOR PHAN HYDROBROMIDE + AMMONIUM CHLORIDE	8MG + 10MG + 100MG	AKUMS DRUGS & PHARMACEUTICALS LTD-PLANT II PLOT NO.22, SECTOR 6-A, IIE, SIDCUL, RANIPUR, DISTRICT: HARIDWAR 249 403, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2017
3773	NDA/MAL/HDP/7 760	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	OZACE MD 10	OLANZAPINE	10MG	PSYCHOTROPICS INDIA LTD PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND PSYCHOTROPICS INDIA LTD PLOT-NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017

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3774	NDA/MAL/HDP/7784	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	LORATOL	LORATADINE	5MG/5ML	NOBEL ILAC DUZCESANAYIINVE TICARET A.S SANCAKLAR 81100 DUZCE	TURKEY	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2017
3775	NDA/MAL/HDP/7903	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MELMET-1000SR	METFORMIN HYDROCHLORIDE	1000MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID RETARD COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2009



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3776	NDA/MAL/HDP/7905	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	ACEFYL	ACEFYLINE PIPERAZINE + DIPHENHYDRAMINE HYDROCHLORIDE	45MG +8MG	NABIQASIM INDUSTRIES (PVT) LIMITED17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2016
3777	NDA/MAL/HDP/7907	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	HUCOG 5000 HP	CHORIONIC GONADOTROPHIN	5000 I.U/ VIAL	BHARAT SERUMS & VACCINES LIMITED PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (E) MAHARASHTRA STATE 421501	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X5000.0 I.U VIAL + 1*1ML 0.9%W/V NA CL AMBER GLASS AMPOULE	01/07/2017

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3778	NDA/MAL/HDP/8 015	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	D-FEN	DICLOFENAC SODIUM	25MG/ML	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X3.0 ML AMPOULE,1.0X10.0 X1.0X10.0X3.0 ML AMPOULE	01/07/2011
3779	NDA/MAL/HDP/8 023	DENK PHARMA GMB H &CO. KG	BENLE CONSULT LIMITED	AMOXICLAV- DENK 500/62.5	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500 MG + 62.5 MG	PENCEF PHARMA GMBHBRIENBACHS TR ASSE 13 D-13509 BERLIN	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X8.0 TABLET BLISTER	01/07/2011

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3780	NDA/MAL/HDP/8 043	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	RABEZOL	RABEPRAZOLE SODIUM	20MG	BİLİM PHARMACEUTICALS GOSB 41480 GEBZE- KOCAELİ/TURKE	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X14.0 TABLET BLISTER	01/07/2017
3781	NDA/MAL/HDP/8 073	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	TRILEPTAL	OXCARBAZEPINE	300MG	NOVARTIS PHARMA SPA,-TORRE ANNUNZIATA ITALY	ITALY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X50.0 TABLET CONTAINER	01/07/1997

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3782	NDA/MAL/HDP/8 085	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	CIPROL-500	CIPROFLOXACIN	500MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD PLOT NO. M444B, STRETCHER ROAD, NTINDA, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007
3783	NDA/MAL/HDP/8 089	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM-AMOXY	AMOXYCILLIN	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X10 0.0X10.0 CAPSULE BLISTER,1.0X500.0 CAPSULE CONTAINER,1.0X25 0.0 CAPSULE CONTAINER	01/07/1997

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3784	NDA/MAL/HDP/8 091	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEGEL SUSPENSION	ALUMINIUM HYDROXIDE+MAG NESIUM TRISILICATE	120MG+250MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2001
3785	NDA/MAL/HDP/8 092	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	KEMOXYL 250MG	AMOXYCILLIN	250MG	LABORATORY & ALLIED LTD PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER, 1.0X10. 0X10.0 CAPSULE BLISTER	01/07/1997

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3786	NDA/MAL/HDP/8 095	DENK PHARMA GMB H & CO. KG	BENLE CONSULT LIMITED	COLOSAR-DENK 100/12.5	LOSARTAN POTASSIUM + HYDROCHLOROT HIAZIDE	100MG + 12.5MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2016
3787	NDA/MAL/HDP/8 096	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	BENZALIN	BENZATHINE BENZYPENICILLI N SODIUM	2.4MEGA/ VIAL	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0 VIAL CARTON,1.0X100.0 X2.4 VIAL CARTON,1.0X10.0X 2.4 VIAL CARTON	01/07/2011

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3788	NDA/MAL/HDP/8 103	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	WELQUINE 500	LEVOFLOXACIN	500MG	AKUMS DRUGS & PHARMACEUTICALS LTD.PLANT III, PLOT NO. 19, 20, 21, SECTOR 6-A, IIE, SIDCUL, RANIPUR, DISTRICT: UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016
3789	NDA/MAL/HDP/8 104	ABACUS PHARMA (AFRICA) LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TELPRESS 40	TELMISARTAN	40MG	PSYCHOTROPICS INDIA LTD PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017

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3790	NDA/MAL/HDP/8 105	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	XERIN	LEVOCETIRIZINE HYDROCHLORIDE + MONTELUKAST SODIUM	5MG + 10MG	AKUMS DRUGS AND PHARMACEUTICALS LTD PLANT-1 PLOT NO.19, 20&21 SECTOR-6A, 11E, SIDCUL, RAHIPUR DISTT; HARIDWAR, 249403, (UTTRAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1.0X10 .0 TABLET BLISTER	01/07/2017
3791	NDA/MAL/HDP/8 107	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	WELRAB 20	RABEPRAZOLE SODIUM	20MG	AKUMS DRUGS & PHARMACEUTICALS LTD -19,20,21, SECTOR 6A, I.I.E, SIDCUL, RANIPUR, HARIDWAR 249403 DISTRICT: UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017



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3792	NDA/MAL/HDP/8 108	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	ORS	GLUCOSE ANHYDROUS+TRI SODIUM CITRATE+SODIUM CHLORIDE+POTAS SIUM CHLORIDE	6.75G + 1.45G + 1.3G + 0.75G	MEDIPHARM INDUSTRIES LTD PLOT 65, KAKAJJO ROAD, BWEYOGERERE POSTAL ADDRESS : P.O.BOX 5917, KAMPALA.	UGANDA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X10.0X25.0 G SACHET	01/07/2017
3793	NDA/MAL/HDP/8 109	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	IRON FOLATE	FERROUS SULPHATE + FOLIC ACI	200MG + 0.4MG	MEDICAMEN BIOTECH LTDSP- 1192, A &B, PHASE -IV, INDUSTRIAL AREA BHIWADI -301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET JAR	01/07/2017

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3794	NDA/MAL/HDP/8 110	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	R.B.TONE SYRUP	MULTI- INGREDIENT	N/A	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X200.0 ML BOTTLE, 1.0X1.0X10 0.0 ML BOTTLE	01/07/2017
3795	NDA/MAL/HDP/8 112	MEDOCHÉMIE LTD	LABOREX UGANDA LIMITED	MOXICLAV	AMOXICILLIN + CLAVULANIC ACID	156.25MG/5ML	MEDOCHÉMIE LTD – FACTORY B-PLOT 48, IAPETOU STREET, AGIOS ATHANASSIOS INDUSTRIAL; AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	ORAL SOLID ORDINARY POWDERS	1.0X100.0 ML BOTTLE	01/07/2016

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3796	NDA/MAL/HDP/8 113	MEDOCHÉMIE LTD	LABOREX UGANDA LIMITED	MOXICLAV FORTE	AMOXICILLIN + CLAVULANIC ACID	312.5MG/5ML	MEDOCHÉMIE LIMITED (FACTORY B- ORAL FACILITY)-PLOT 48, LAPETOU STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 41101 AGIOS ATHANASSIOS, LIMASSOL - CYPRUS	CYPRUS	ORAL SOLID ORDINARY POWDERS	1.0X100.0 ML BOTTLE	01/07/2016
3797	NDA/MAL/HDP/8 114	MEDOCHÉMIE LTD	LABOREX UGANDA LIMITED	RUPAN	IBUPROFEN	400MG	MEDOCHÉMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016

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3798	NDA/MAL/HDP/8 115	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	LAMIVUDINE	LAMIVUDINE	150MG	MACLEODS PHARMACEUTICALS LTD.PLOT NO. 25-27 SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN (UT) - 396210, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2017
3799	NDA/MAL/HDP/8 118	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	LOPINAVIR + RITONAVIR	LOPINAVIR + RITONAVIR	200MG + 50MG	MACLEODS PHARMACEUTICALS LTD .PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET BOTTLE	01/07/2013

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3800	NDA/MAL/HDP/8 119	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	HALOPERIDOL DECANOATE	HALOPERIDOL DECANOATE	50MG/ML	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE,1.0X10.0 X1.0 ML AMPOULE	01/07/2017
3801	NDA/MAL/HDP/8 121	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	SWISSQUINE	QUININE	300MG/ML	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2011

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3802	NDA/MAL/HDP/8 125	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO. LTD	GAMA PHARMACEUTICAL S (U) LIMITED	MATADOR	LEVOFLOXACIN	500MG	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO. LTD, NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET, AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X7.0 TABLET BLISTER	01/07/2009
3803	NDA/MAL/HDP/8 127	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE	2% W/V	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X30.0 ML VIAL	01/07/2016

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3804	NDA/MAL/HDP/8 130	DEVA HOLDING A.S	SHREEJI PHARMACEUTICAL S LIMITED	DEGRA 100	SILDENAFIL CITRATE	100MG	DEVA HOLDING A. S.ÇERKEZKÖY ORGANIZE SANAYI BOLGESI. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKIRDAĞ/ TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	30/05/2018
3805	NDA/MAL/HDP/8 131	DEVA HOLDING A.S	SHREEJI PHARMACEUTICAL S LIMITED	DEGRA	SILDENAFIL CITRATE	50MG	DEVA HOLDING A. S.ÇERKEZKÖY ORGANIZE SANAYI BOLGESI. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKIRDAĞ/ TURKEY	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	01/07/2017

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3806	NDA/MAL/HDP/8 133	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	MYHEP	SOFOSBUVIR	400MG	MYLAN LABORATORIES LIMITEDD ,F-4 & F- 12,MIDC, MALEGAON,SIRRRRA R, NASHIK -422113 MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X28.0 TABLET BOTTLE	01/07/2017
3807	NDA/MAL/HDP/8 142	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	XARELTO	RIVAROXABAN	2.5MG	BAYER PHARMA AG 51368 LEVERKUSENBAYER PHARMA AG 51368 LEVERKUSEN	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X14.0 TABLET BLISTER,1.0X2.0X14 .0 TABLET BLISTER	01/07/2017



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3808	NDA/MAL/HDP/8 143	NAARI LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	LYDIA POSTPIL	LEVONORGESTRE L	1.5MG	NAARI PHARMA PRIVATE LIMITEDPLOT NO. 14- 16, 55-57, SECTOR-5, IIE, PANT NAGAR RUDRAPUR-263153 DIST-U.S. NAGAR UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0 TABLET BLISTER	01/07/2013
3809	NDA/MAL/HDP/8 144	NAARI LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	MA KARE	MIFEPRISTONE + MISOPROSTOL	200MG+ 200MCG	NAARI PHARMA PRIVATE LIMITEDPLOT NO. 14- 16, 55-57, SECTOR-5, IIE, PANT NAGAR RUDRAPUR-263153 DIST-U.S. NAGAR UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0 TABLET BLISTER	01/07/2017

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3810	NDA/MAL/HDP/8 145	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DENK- AIR 10	MONTELUKAST SODIUM	10MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2017
3811	NDA/MAL/HDP/8 146	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DENK- AIR JUNIOR 4	MONTELUKAST SODIUM	4MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2017

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3812	NDA/MAL/HDP/8 147	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DENK- AIR JUNIOR 5	MONTELUKAST SODIUM	5 MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2017
3813	NDA/MAL/HDP/8 148	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	FLUCLOXACILLIN	FLUCLOXACILLIN	500MG	SPARSH BIO-TECH PVT. LTD.-PLOT NO. 1, SURVEY NO. 242/243/244, VILLAGE LAKHABAVAD POST KHODIYAR COLONY DISTRICT, JAMNAGAR – 361006 GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2017

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3814	NDA/MAL/HDP/8 150	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	JAKAVI	RUXOLITINIB	20MG	NOVARTIS PHARMA STEIN AGCH. 4002 STEIN, SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER	01/07/2017
3815	NDA/MAL/HDP/8 151	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGO-C	VITAMIN C	100MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET STRIP	01/07/2005

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3816	NDA/MAL/HDP/8 152	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	JAKAVI	RUXOLITINIB	15MG	NOVARTIS PHARMA STEIN AG.SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER	01/07/2017
3817	NDA/MAL/HDP/8 154	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOGCORT	HYDROCORTISON E ACETATE	1%W/W	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2013

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3818	NDA/MAL/HDP/8 155	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	JAKAVI	RUXOLITINIB	5MG	NOVARTIS PHARMA STEIN AG.SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER	01/07/2017
3819	NDA/MAL/HDP/8 156	TATA UGANDA LIMITED	GITTOES PHARMACEUTICAL S LIMITED	DIPHThERIA + TETANUS + PERTUSSIS + HEPATITIS B + HAEMOPHILUS TYPE B CONJUGATE VACCINE	DIPHThERIA + TETANUS + PERTUSSIS + HEPATITIS B + HAEMOPHILUS TYPE B CONJUGATE VACCINE	25 LF (≥ 30 IU)+5.5 LF (≥ 40 IU)+16 IOU (≥ 4.0 IU)+12.5MCG+11M CG	BIOLOGICAL E LTD PLOT NO.1, S.P BIOTECHNOLOGY PARK, PHASE II KOLThER (V), SHAMEERPET(M), RANGA REDDY(DIST), ANDHRA PRADESH, INDIA 500078	INDIA	PARENTERAL ORDINARY I M VIALS	1.0X48.0X0.5 ML VIAL (1 DOSE VIAL),1.0X24.0X5.0 ML VIAL (10 DOSE VIAL)	01/07/2014

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3820	NDA/MAL/HDP/8 157	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	D LYTE- PLAIN	ANHYDROUS GLUCOSE + SODIUM CHLORIDE + TRISODIUM CITRATE + POTASSIUM CHLORIDE	13.50G + 2.60G + 2.90G +1.50G/ 1L	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X20.5 G SACHET	01/07/2016
3821	NDA/MAL/HDP/8 159	AUROBINDO PHARMA LIMITED	GITTOES PHARMACEUTICAL S LIMITED	LOPINAVIR + RITONAVIR	LOPINAVIR + RITONAVIR	100MG + 25MG	AUROBINDO PHARMA LIMITED, UNIT IIISURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELENGANA (STATE)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2017

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3822	NDA/MAL/HDP/8 160	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ULGICID (CHERRY FLAVOUR)	ALGINIC ACID+ MAGNESIUM HYDROXIDE+ ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE +SIMETICONE	200MG+250MG+2 50MG+250MG+12 5MG/15ML	STEDMAN PHARMACEUTICALS PVT LTD...C-4, SIDCO PHARMACEUTICAL COMPLEX ALATHUR, THIRUPORUR	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	01/07/2017
3823	NDA/MAL/HDP/8 162	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	HUMOG 75 HP	HIGHLY PURIFIED MENOTROPHIN [ CORRESPONDING TO FOLLICLE STIMULATING HORMONE ACTIVITY (FSH) 75 IU + LUTEINISING HORMONE ACTIVITY (LH) 75 IU] /150 I.U	75 IU + 75 IU/ 150 I.U VIAL	BHARAT SERUMS AND VACCINES LTD PLOT NO. K-27 ADDITIONAL MIDC AMBERNATH (E ) 412 501	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1*1 ML AMPOULE OF 0.9%W/V NAACL	01/07/2017



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3824	NDA/MAL/HDP/8 163	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	BETADINE SURGICAL SCRUB	POVIDONE- IODINE	7.5%W/W	G,S PHARMBUTOR PVT LTD B-172 INDUSTRIAL AREA BEHROR 301701 RAJASTHAN	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X1.0X50.0 ML BOTTLE,1.0X500.0 ML BOTTLE	26/09/2018
3825	NDA/MAL/HDP/8 167	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	BETADINE STANDARDISED MICROBICIDAL SOLUTION 10% W/V	POVIDONE- IODINE	10%W/W	G,S PHARMBUTOR PVT LTD B-172 INDUSTRIAL AREA BEHROR 301701 RAJASTHAN	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X1.0X50.0 ML BOTTLE,1.0X1.0X10 0.0 ML BOTTLE,1.0X500.0 ML BOTTLE	01/07/1997

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3826	NDA/MAL/HDP/8 170	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ULGICID (PINEAPPLE FLAVOUR)	ALGINIC + MAGNESIUM HYDROXIDE +DRIED ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE +SIMETICONE	200MG+250MG+2 50MG+250MG+12 5MG/15ML	STEDMAN PHARMACEUTICALS PVT LTD...C-4, SIDCO PHARMACEUTICAL COMPLEX ALATHUR, THIRUPORUR	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	01/07/2017
3827	NDA/MAL/HDP/8 177	MEGA LIFSCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	CILZEC PLUS	TELMISARTAN + HYDROCHLOROT HIAZIDE	40MG + 12.5MG	MSN LABORATORIES PVT. LIMITED PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016

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3828	NDA/MAL/HDP/8 178	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	NYSTAGO TABLETS	NYSTATIN	500,000I.U	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.T HANE INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X100.0 TABLET BOTTLE,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2005
3829	NDA/MAL/HDP/8 185	AFRICURE PHARMACEUTICAL S (INDIA) LTD	AFRICURE PHARMACEUTICAL S U LIMITED	INDOSIM	INDOMETHACIN	25MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9- 12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/1997

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3830	NDA/MAL/HDP/8 194	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	SOLONEX-100	ISONIAZID	100MG	OXALIS LAB-VILLAGE THEDA, P.O. LODHIMAJRA, TEHSIL BADDI, DIST. SOLAN (HP) PIN CODE 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X24. 0X28.0 TABLET BLISTER	01/07/2005
3831	NDA/MAL/HDP/8 195	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	RH-COM	RIFAMPICIN & ISONIAZID	150MG +75MG	MACLEODS PHARMACEUTICALS LTD-BLOCK N3, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP,1.0X24.0X28. 0 TABLET BLISTER,1.0X3.0X28 .0 TABLET BLISTER	01/07/2005

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3832	NDA/MAL/HDP/8 197	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	AMIKACIN	AMIKACIN SULPHATE	500MG/2ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY VIALS	1.0X2.0 ML VIAL	01/07/2017
3833	NDA/MAL/HDP/8 198	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	XYMEX DROPS	MULTI- INGREDIENT	MULTI- INGREDIENT	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X15.0 ML BOTTLE	01/07/1999

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3834	NDA/MAL/HDP/8 199	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	XYMEX SYRUP	MULTI- INGREDIENT	MULTI- INGREDIENT	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2000
3835	NDA/MAL/HDP/8 200	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	ORS ORANGE	GLUCOSE ANHYDROUS + TRISODIUM CITRATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE	6.75G + 1.45G + 1.3G + 0.75G / SACHET	MEDIPHARM INDUSTRIES( EA) LTD PLOT 65 KAKAJJO ROAD BWEYOGERERE P.O.BOX 6218,KAMPALA,UGA NDA	UGANDA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X10.4 G SACHET	01/07/2017

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3836	NDA/MAL/HDP/8 201	CIRON DRUGS AND PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	CENTROZINE	CETIRIZINE HYDROCHLORIDE	5MG/5ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, 119 MIDC TARAPUR BOISAR DIST THANE 4011 506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2017
3837	NDA/MAL/HDP/8 202	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	ISONIAZID	ISONIAZID	300MG	OXALIS LABS- VILLAGE THEDA,P.O.LODHIM AJRA ,TEHSIL BADDI,DIST .SOLAN (HIMACHAL PRADESH) - 174101 INDIA MACLEODS PHARMACEUTICALS LTD.PLOT NO. 25-27 SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN (UT) - 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X28.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER,1.0X24.0X2 8.0 TABLET BLISTER	01/07/2017

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3838	NDA/MAL/HDP/8 206	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BRULEXIN	CEFALEXIN MONOHYDRATE	125MG/5ML	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2018
3839	NDA/MAL/HDP/8 207	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	ZOMETA	ZOLEDRONIC ACID	4MG/5ML	NOVARTIS PHARMA STEIN AG ;SCHAFFHAUSERSTR ASSE CH 4332 STEIN- SWITZERLAND	SWITZERLAND	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X5.0 ML VIAL	01/07/2017



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3840	NDA/MAL/HDP/8 210	CIRON DRUGS & PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	HYDROCORTISON E SODIUM SUCCINATE FOR INJECTION BP	HYDROCORTISON E	100MG	CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, 119 MIDC TARAPUR BOISAR DIST THANE 4011 506	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X100.0 MG VIAL	01/07/2007
3841	NDA/MAL/HDP/8 211	SHELYS PHARMACEUTICAL S LTD	BETA HEALTHCARE UGANDA LIMITED	MUCO-ASTHALIN SYRUP	SALBUTAMOL + BROMHEXINE	2MG/5ML + 4MG/5ML	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2010

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3842	NDA/MAL/HDP/8 212	FDC LIMITED -	AIVEEN (U) LIMITED	BACTIGEN EYE/EAR DROPS	GENTAMICIN	0.3%W/V	FDC LIMITED B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.☐	INDIA	OPHTHALMIC VIALS	1.0X5.0 ML VIAL,1.0X10.0 ML VIAL	01/07/1998
3843	NDA/MAL/HDP/8 213	FDC LTD	AIVEEN (U) LIMITED	ZOCON 200	FLUCONAZOLE	200MG	FDC LTD.L-56/L- 57,PHASE II-D, VERNA INDUSTRIAL ESTATE,VERNA- 403722, SALCETE,GOA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X2.0 TABLET BLISTER	01/07/2001

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3844	NDA/MAL/HDP/8 216	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	SEFOTAX	CEFOTAXIME SODIUM	1G	SWISS PARENTERALS LTD, UNIT- IIPLOT NO. 402,412-414 KERALA INDUSTRIAL ESTATE, GIDC, NEAR BAVLA, DIST: AHMEDABAD	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2017
3845	NDA/MAL/HDP/8 221	NATIONAL HEALTHCARE PVT LTD	VITACARE LTD	NEMADOL	TRAMADOL HYDROCHLORIDE	50MG/ML	NATIONAL HEALTHCARE PVT LTD-CHHATAPIPRA 3 BARA	NEPAL	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE	01/07/2017

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3846	NDA/MAL/HDP/8 224	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OPTIGENT OINTMENT	GENTAMICIN SULFATE	0.3%W/W	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B EGYPT	EGYPT	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE	01/07/2017
3847	NDA/MAL/HDP/8 226	DEVA HOLDING A.S	SHREEJI PHARMACEUTICAL S LIMITED	SALRES	SALBUTAMOL SULPHATE	120.5MCG/SPRAY	DEVA HOLDING A. S.ÇERKEZKÖY ORGANIZE SANAYI BOLGESI. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKİRDAĞ/ TURKEY	TURKEY	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER	01/07/2017

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3848	NDA/MAL/HDP/8 228	AFRICURE PHARMACEUTICAL S (INDIA) LTD	AFRICURE PHARMACEUTICAL S U LIMITED	VITAMIN B- COMPLEX (BEEKO)	VITAMINS B1 + B2 + B6 + NIACINAMIDE	1MG +1MG +1MG +15MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9- 12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017
3849	NDA/MAL/HDP/8 232	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICAL S LTD	MOMATE	MOMETASONE FUROATE MONOHYDRATE	50MCG/ SPRAY	GLENMARK PHARMACEUTICALS LTDVILLAGE, KISHANPURA, BADDI, NALAGARH ROAD, INDIA GLENMARK PHARMACEUTICALS LTDVILLAGE: KISHANPURA, BADDI NALAGARH DISTRICT SOLAN - 174101, INDIA	INDIA	NASAL SYSTEMIC METERED-DOSE LIQUIDS	1.0X120.0 METERED DOSE BOTTLE	01/07/2017

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3850	NDA/MAL/HDP/8 235	DAWA LIMITED-	SUPER MEDIC LTD	ACEPAR	ACECLOFENAC + SERRATIOPEPTID ASE + PARACETAMOL	100MG + 15MG + 500MG	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017
3851	NDA/MAL/HDP/8 243	OCHOA LABORATORIES LIMITED -	SUPER MEDIC LTD	TX-MF	TRANEXAMIC ACID + MEFENAMIC ACID	500MG + 250MG	AUROCHEM PHARMACEUTICALS INDIA PRIVATE LIMITED58, PALGHAR TALUKA INDUSTRIAL CO - OPERATIVE ESTATE LIMITED PALGHAR, DISTRICT - PALGHAR, 401 404	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017

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3852	NDA/MAL/HDP/8 252	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED	SURGIPHARM (U) LIMITED	PARACETAMOL FRESENIUS	PARACETAMOL	10MG/ML	FRESENIUS KABI DEUTSCHLAND GMBHFRESENIUSSTR ASSE 1, D-61169, FRIEDBERG	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X10.0X50.0 ML VIAL,1.0X10.0X100. 0 ML VIAL	01/07/2017
3853	NDA/MAL/HDP/8 253	REYOUNG PHARMACEUTICAL CO LTD	ROYAL PHARMA 2011 LIMITED	DICLOFENAC SODIUM	DICLOFENAC SODIUM	25MG/ML	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	10X10X3 ML AMPOULE	01/07/2017

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3854	NDA/MAL/HDP/8 254	MICRO LABS LTD	LABOREX UGANDA LIMITED	GRAMOCEF-CV	CEFIXIME TRIHYDRATE + CLAVULANIC ACID	200MG + 125MG	MICRO LABS LIMITED, BOMMASANDRA PLOT NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET STRIP	01/07/2017
3855	NDA/MAL/HDP/8 264	CACHET PHARMA PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	EMITINO ORAL SOLUTION	ONDANSETRON	2MG/5ML	CACHET PHARMACEUTICALS PVT LTD THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X30.0 ML BOTTLE	01/07/2017



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3856	NDA/MAL/HDP/8 274	HETERO LABS LTD	AIVEEN (U) LIMITED	BICATERO 50	BICALUTAMIDE	50MG	HETERO LABS LTD (UNIT-VI)"SY.NO. 439, 440 & 458,APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR DISTRICT ANDHRA PRADESH-509301 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2013
3857	NDA/MAL/HDP/8 275	HETERO LABS LTD	AIVEEN (U) LIMITED	LETERO	LETROZOLE	2.5MG	HETERO LABS LTD (UNIT-VI)"SY.NO. 439, 440 & 458,APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR DISTRICT ANDHRA PRADESH-509301 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2013

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3858	NDA/MAL/HDP/8 276	HETERO LABS LTD	AIVEEN (U) LIMITED	GEMTERO 1G	GEMCITABINE	1G	HETERO LABS (UNIT VI), INDIAAPIIC, FORMULATION SEZ, POLEPALLY (V),JEDCHERLA(M) MAHABOBNAGER DISTRICT ANDHRA PRADESH-509301, INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 G VIAL	01/07/2013
3859	NDA/MAL/HDP/8 277	HETERO LABS LTD	AIVEEN (U) LIMITED	GEMTERO 200MG	GEMCITABINE	200MG	HETERO LABS (UNIT VI), INDIAAPIIC, FORMULATION SEZ, POLEPALLY (V),JEDCHERLA(M) MAHABOBNAGER DISTRICT ANDHRA PRADESH-509301, INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X200.0 MG VIAL	01/07/2013

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3860	NDA/MAL/HDP/8 278	HETERO LABS LTD	AIVEEN (U) LIMITED	ANATERO	ANASTROZOLE	1MG	HETERO LABS LTD, UNIT VI, INDIAAPIO, FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGER DISTRICT ANDHRA PRADESH-509301, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1X30 TABLET BOTTLE	01/07/2013
3861	NDA/MAL/HDP/8 279	SAKAR HEALTHCARE PVT LTD	ROYAL PHARMA 2011 LIMITED	GENTACIN	GENTAMICIN SULPHATE	80MG/2ML	SAKAR HEALTH CARE PVT, LTD (BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ- BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA)	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X6.0X2.0 ML AMPOULE IN BLISTERS	25/10/2023

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3862	NDA/MAL/HDP/8 299	AFRICURE PHARMACEUTICAL S (INDIA) PRIVATELIMITED	AFRICURE PHARMACEUTICAL S U LIMITED	DICLOFENAC TABLETS BP	DICLOFENAC SODIUM	50MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9- 12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007
3863	NDA/MAL/HDP/8 300	AFRICURE PHARMACEUTICAL S (INDIA) PRIVATELIMITED	AFRICURE PHARMACEUTICAL S U LIMITED	CIPRONE-500	CIPROFLOXACIN HYDROCHLORIDE	500MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9- 12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007

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3864	NDA/MAL/HDP/8 307	NAME AFRICURE PHARMACEUTICAL S (INDIA) PRIVATELIMITED	AFRICURE PHARMACEUTICAL S U LIMITED	METFORMIN 500	METFORMIN	500MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9- 12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008
3865	NDA/MAL/HDP/8 308	NAME AFRICURE PHARMACEUTICAL S (INDIA) PRIVATELIMITED	AFRICURE PHARMACEUTICAL S U LIMITED	PREDNISOLONE 5MG	PREDNISOLONE	5MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9- 12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008

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3866	NDA/MAL/HDP/8 312	CADILA PHARMACEUTICAL S LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	TRICORT 40	TRIAMCINOLONE ACETONIDE	40MG/ML	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL	29/11/2017
3867	NDA/MAL/HDP/8 315	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	PREZISTA 75	DARUNAVIR	75MG	JANSSEN ORTHO LLC. STATE ROAD 933 KM 0.1 MARNEY WARD GURABO PUERTO RICO 00778	UNITED STATES	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X480.0 TABLET BOTTLE	01/07/2017

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3868	NDA/MAL/HDP/8 316	AUROBINDO PHARMA LIMITED	GITTOES PHARMACEUTICAL S LIMITED	DOLUTEGRAVIR 50 MG/ LAMIVUDINE 300 MG/ TENOFOVIR DISOPROXIL FUMARATE 300 MG TABLETS	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE	50MG + 300MG + 300MG	AUROBINDO PHARMA LTD, UNIT XNO. 16, APIIC MULTI PRODUCTS SEZ, MENAKUR VILLAGE, NAIDUPETA MANDAL, SPSR, NELLORE DISTRICT, ANDHRA PRADESH, PIN 524421 "AUROBINDO PHARMA LIMITEDUNIT –VII, SEZ, TSIIC, PLOT NO. SI,S. NO.'S 411/P, 425/P, 434/P, 435/P	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE	30/05/2018
3869	NDA/MAL/HDP/8 319	KOPRAN LIMITED	TATA UGANDA LIMITED	ERYKO-250	ERYTHROMYCIN STEARATE TABLETS BP	250MG	KOPRAN LTDVILLAGE SAVROLI TAL KHARAPUR DIST RAIGAD 410 202	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X50 0.0 TABLET CONTAINER	29/11/2017

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3870	NDA/MAL/HDP/8 321	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	PROSTAR- 200 CAPSULES	PROGESTERONE	200 MG	AKUMS DRUGS & PHARMACEUTICALS LTD .PLOT NO. 47, 48, SECTOR 6A, IIE, SIDCUL HARIDWAR, UTTRAKHAND – 249403, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X3.0X10 .0 CAPSULE BLISTER	31/01/2018
3871	NDA/MAL/HDP/8 322	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICAL S LTD	GLEMONT L	MONTELUKAST SODIUM+LEVOCE TIRIZINE DIHYDROCHLORID E	10 MG + 5 MG	GLENMARK PHARMACEUTICALS LIMITED-UNIT IIIVILLAGE KISHANPURA, BADDI- NALAGARH ROAD TEHSIL BADDI, DIST. SOLAN, BADDI 173205 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X7.0 TABLET BOTTLE	29/11/2017



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3872	NDA/MAL/HDP/8 324	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LOOBID TABLETS	OFLOXACIN + ORNIDAZOLE	200MG + 500 MG	CACHET PHARMACEUTICAL PVT LTD. HIMACHALTHANA, BADDI, HIMACHAL PRADESH-173 205, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	29/11/2017
3873	NDA/MAL/HDP/8 326	MEDOPHARM PRIVATE LIMITED	VITACARE LIMITED	MEDOMOX 250 DT	AMOXICILLIN	250MG	MEDOPHARM PVT LTD.NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER (EMBOSSSED WITH "GOU NOT FOR SALE" & NON- EMBOSSSED)	29/11/2017

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3874	NDA/MAL/HDP/8 331	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TORSINEX-20	TORSEMIDE	20MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/11/2017
3875	NDA/MAL/HDP/8 332	DEVA HOLDING A.S	SHREEJI PHARMACEUTICAL S LIMITED	AZITRO 500 MG	AZITHROMYCIN	500MG	DEVA HOLDING A. S.ÇERKEZKÖY ORGANIZE SANAYI BOLGESI. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKIRDAĞ/ TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	29/11/2017

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3876	NDA/MAL/HDP/8 333	MICRO LABS LTD 92 SIPCOT INDUSTRIAL	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	AVAS-20	ATORVASTATIN	20MG	MICRO LABS LTD 92 SIPCOT 92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/11/2017
3877	NDA/MAL/HDP/8 337	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ARTESUNATE 120 MG	ARTESUNATE	120 MG	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA BLISS INDAS LIFESCIENCE P. LTD..PLOT 73-76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X120.0 MG VIAL + 1*2 ML AMPOULE OF SODIUM BICARBONATE + 1*10 ML VIAL OF 0.9%W/V SODIUM CHLORIDE	29/11/2017

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3878	NDA/MAL/HDP/8 340	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	MONTEMAC 5	MONTELUKAST SODIUM	5 MG	MACLEODS PHARMACEUTICALS LTD(BLOCK N2)VILLAGE THEDA,P.O LODHI MAJRA,TEHSIL BADDI,HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/11/2017
3879	NDA/MAL/HDP/8 341	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	GENVOYA	ELVITEGRAVIR+C OBICISTAT+EMTRI CISTABINE+TEN FOVIR ALAFENAMIDE	150MG + 150MG + 200MG + 10MG	PATHEON INC.- TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9	CANADA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	31/01/2018

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3880	NDA/MAL/HDP/8 343	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	XYKAA EXTEND 1000	PARACETAMOL BP(IMMEDIATE RELEASE)+ PARACETAMOL BP(EXTENDED RELEASE)	325MG+675MG	TROIKAA PHARMACEUTICALS LTD .SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,2.0X10.0 TABLET BLISTER,1.0X4.0 TABLET BLISTER	29/11/2017
3881	NDA/MAL/HDP/8 344	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CELZA DRY SYRUP	CEFUROXIME AXETIL USP	125 MG/5 ML	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X50.0 ML BOTTLE	29/11/2017

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3882	NDA/MAL/HDP/8 345	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CELZA 500	CEFUROXIME AXETIL USP	500 MG	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	29/11/2017
3883	NDA/MAL/HDP/8 346	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ADERAN 8	CANDESARTAN CILEXETIL	8MG	AJANTA PHARMA LIMITEDB-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/11/2017

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3884	NDA/MAL/HDP/8 347	YICHANGHUMANW ELL PHARMACEUTICAL CO., LTD.	KAIYUANTANG (U) LIMITED	FENTWELL 0.05MG/ML	FENTANYL CITRATE	0.05MG/ML	YICHANGHUMANWE LL PHARMACEUTICAL CO., LTD.NO.19,DALIAN ROAD, YICHANG DEVELOPING ZONE,HUBEI PROVINCE ,CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X10.0 ML AMPOULE	30/05/2018
3885	NDA/MAL/HDP/8 348	İLKO İLAÇ SANAYI VE TICARET A. Ş.	CORE ACCESS LIMITED	IRBECOR PLUS 300MG/12.5MG	İRBESARTAN + HYDROCHLOROT HIAZIDE	300MG + 12.5MG	İLKO İLAÇ SANAYI VE TICARET A. Ş3. ORGANIZE SANAYI BÖLGESİ KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	29/11/2017

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3886	NDA/MAL/HDP/8 350	YICHANGHUMANW ELL PHARMACEUTICAL CO., LTD.	KAIYUANTANG (U) LIMITED	FENTWELL 0.05MG/ML	FENTANYL CITRATE	0.05MG/ML	YICHANGHUMANWE LL PHARMACEUTICAL CO., LTD.NO.19,DALIAN ROAD, YICHANG DEVELOPING ZONE,HUBEI PROVINCE ,CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	30/05/2018
3887	NDA/MAL/HDP/8 352	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	KETESSE	DEKXETOPROFEN TROMETAMOL	50MG/2ML	A. MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.LVIA SETTE SANTI 3, 50131 FIRENZE	ITALY	PARENTERAL ORDINARY AMPOULES	1.0X1.0 AMPOULE CARTON,1.0X6.0 AMPOULE CARTON,1.0X20.0 AMPOULE CARTON,1.0X5.0 AMPOULE CARTON	21/11/2019



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3888	NDA/MAL/HDP/8 353	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	FEDATE CAPSULES	CARBONYL IRON + FOLIC ACID + VITAMIN B12 + VITAMIN C + ZINC SULFATE MONOHYDRATE	100MG+1.5 MG + 15 MCG + 75 MG + 61.8 MG	AJANTA PHARMA LIMITEDPLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT- 392130 AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	29/11/2017
3889	NDA/MAL/HDP/8 354	MEGA LIFSCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	ZORUXA	ZOLEDRONIC ACID	5MG/100ML	GLAND PHARMA LIMITED 143-148D P PALLY, QUTHUBULLAPUL MANDAL, RANDA REDDY DIST, HYBERABAD, IN-500 043, INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	29/11/2017

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3890	NDA/MAL/HDP/8 356	UNOSOURCE PHARMA LTD	MEDVIN PHARMA LIMITED	LORFACT-D	DESLORATIDINE	5MG,	AKUMS DRUGS & PHARMACEUTICALS LTD19, 20,21 SECTOR 6A IIE SIDCUL RANIPUR HARIDWAR 249 403	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/11/2017
3891	NDA/MAL/HDP/8 392	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	IRBECOR PLUS 150MG/12.5MG	IRBESARTAN + HYDROCHLOROT HIAZIDE	150MG + 12.5MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş3. ORGANİZE SANAYİ BÖLGESİ KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	29/11/2017

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3892	NDA/MAL/HDP/8394	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	RIFAMPICIN 75 MG ISONIAZID 50 MG AND PYRAZINAMIDE 150 MG DISPERSIBLE TABLETS	RIFAMPICIN + ISONIAZID + PYRAZINAMIDE	75MG + 50MG + 150MG	MACLEODS PHARMACEUTICALS LTD., NO. 25-27PLOT NO. 25-26-27, SURVEY NO.366, PREMIER INDUSTRIAL ESTATE ., DAMAN - 396210, KACHIGAM, DAMAN	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X100.0 TABLET CONTAINER,1.0X3.0X28.0 TABLET BLISTER,1.0X24.0X28.0 TABLET BLISTER	29/11/2017
3893	NDA/MAL/HDP/8395	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	RIFAMPICIN 75 MG ISONIAZID 50 MG DISPERSABLE TABLETS	RIFAMPICIN + ISONIAZID	75MG + 50MG	OXALIS LABVILLAGE THEDA, P.O. LODHIMAJRA, TEHSIL BADDI, DIST. SOLAN (HP) PIN CODE 174101 MACLEODS PHARMACEUTICALS LTD., NO. 25-27PLOT NO. 25-26-27, SURVEY NO.366, PREMIER INDUSTRIAL ESTATE ., DAMAN - 396210, KACHIGAM, DAMAN	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X100.0 TABLET CONTAINER,1.0X3.0X28.0 TABLET BLISTER	29/11/2017

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3894	NDA/MAL/HDP/8 396	MARIE STOPE INTERNATIONAL	MARIE STOPE UGANDA LIMITED	BACK-UP	LEVONORGESTRE L	1.5MG	ACME FORMULATION PVT LTD. ROPAR ROAD NALAGARH DIST SOLAN (H.P) -174 101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0 TABLET BLISTER	29/11/2017
3895	NDA/MAL/HDP/8 407	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	TORTAS 20	TORSEMIDE	20MG	INTAS PHARMACEUTICALS LTD CAMP ROAD, SELAQUI – 248 197 DEHRADUN (UK)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/11/2017

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3896	NDA/MAL/HDP/8 411	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	RHEUMAC GEL	DICLOFENAC	1%W/W	LABORATORY & ALLIED LTD-PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE	29/11/2017
3897	NDA/MAL/HDP/8 419	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	VB COMPLEX	VIT B1+ VIT B2 +VIT B3 + NICOTINAMIDE+P ANTOTHENOL	10MG +1MG +1MG +16MG +0.5MG	SCOTT-EDIL PHARMACIA LTD (UNIT I)-56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE,1.0X100. 0X2.0 ML AMPOULE	01/07/2018

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3898	NDA/MAL/HDP/8 434	DAWA LIMITED	SUPER MEDIC LTD	DACINAZOLE	MICONAZOLE NITRATE	2%W/W	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2009
3899	NDA/MAL/HDP/8 468	THEON PHARMACEUTICAL S LIMITED	AIVEEN (U) LIMITED	THEOMOX-500	AMOXICILLIN	500 MG	THEON PHARMACEUTICALS LIMITED. VILLAGE SAINI MAJRA, TEHSIL NALAGARH, DISTT. SOLAN, HIMACHAL PRADESH 174 101 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1X10X10 CAPSULE BLISTER	31/01/2018

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3900	NDA/MAL/HDP/8 477	WOCKHARDT LTD	ABACUS PHARMA (AFRICA) LIMITED	GLARITUS 100IU/ML	INSULIN GLARGINE	100IU/ML	WOCKHARDT LIMITED - WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY CARTRIDGES	1.0X10.0 ML VIAL	31/01/2018
3901	NDA/MAL/HDP/8 485	CACHET PHARMACEUTICAL S PVT LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CACHMAX-400	CEFIXIME	400MG	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0 TABLET BLISTER	31/01/2018

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3902	NDA/MAL/HDP/8 489	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	MEDOL	TRAMADOL HYDROCHLORIDE	100 MG / 2 ML	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE,1.0X5.0X 2.0 ML AMPOULE	31/01/2018
3903	NDA/MAL/HDP/8 490	ALTHEA PHARMA PVT LTD.	JOINT MEDICAL STORE (UPMB - UCMB)	SODIUM CHLORIDE	SODIUM CHLORIDE	0.9% W/V	ALTHEA PHARMA PVT LTD -PLOT NO. 374 SHED NO. E.,ALPHA INDUSTRIAL PARK , ATHIYAWAD DABHEL ,NANI DAMAN (U.T) 396210, INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	31/01/2018



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3904	NDA/MAL/HDP/8 491	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CETROTIDE 0.25MG	CETRORELIX	0.25MG	PIERRE FABRE MEDICAMENT AQUITAINE PHARM INTERNATIONAL SITE 1 ABBOTT BIOLOGICALS B.V VEERWEG 12,NL- 8121 AA OLST THE NETHERLANDS	FRANCE	PARENTERAL ORDINARY COMBINATION PACK VIALS	1.0X1.0 VIAL CARTON,1.0X1.0 PREFILLED SYRINGE CARTON	31/01/2018
3905	NDA/MAL/HDP/8 493	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	DESCOVY 200MG/25MG	EMTRICITABINE/T ENOFOVIR ALAFENAMIDE	200MG + 25 MG	PATHEON INC.-- TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9	CANADA GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	31/01/2018

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3906	NDA/MAL/HDP/8 497	TWENTY FIRST CENTURY PHARMACEUTICAL S PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYOXIM 500	CEFUROXIME AXETIL	500 MG	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD - UNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE-247668. DIST.-HARIDWAR, UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	31/01/2018
3907	NDA/MAL/HDP/8 499	YELURI FORMULATIONS PVT LTD	SUPER MEDIC	SOLOCEF 1000 MG	CEFTRIAZONE SODIUM	1000MG	YELURI FORMULATIONS PVT. LTD-SY. NO. 296 / 7 / 6 IDA BOLLARAM,MEDAK DIST.502325, TELANGANA,INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	31/01/2018

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3908	NDA/MAL/HDP/8 522	PLANET PHARMACEUTICAL S UGANDA LTD	PLANET PHARMACEUTICAL S UGANDA LTD	DAYPENAM	MEROPENEM	500MG	ZEISS PHARMACEUTICALS PRIVATE LIMITED- PLOT NO. 72 EPIP- PHASE-1 JHARMAJRI BADDI DISTRICT SOLAN (H.P.) - INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X500.0 MG VIAL	07/01/2017
3909	NDA/MAL/HDP/8 566	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	AZINOWEL	AZITHROMYCIN	200MG/5ML	AKUMS DRUGS & PHARMACEUTICALS LTDPLANT II, PLOT NO. 22, SECTOR- 6A, IIE, SIDCUL, RANIPUR, DISTT.: HARIDWAR, UTTARAKHAND	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X15.0 ML BOTTLE	21/11/2019

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3910	NDA/MAL/HDP/8 569	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	TERBINOL®	TERBINAFINE HYDROCHLORIDE	1%W/W	NOBEL İLAÇ SAN. VE TIC. A.ŞSANC AKLAR, DÜZCE, 81100	TURKEY	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	21/11/2019
3911	NDA/MAL/HDP/8 602	KIMSY MEDS LTD	KIMSY MEDS LTD	KOFLIN COUGH FLU LINCTUS	CHLOPHENIRAMI NE	2MG	MAVID PHARMACEUTICAL INDUSTRIES LIMITEDPLOT 490 BIRONGO, KITIICO	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2005

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3912	NDA/MAL/HDP/8 603	KIMSY MEDS LTD	KIMSY MEDS LTD	MAAGA	SODIUM BICARBONATE + LIGHT MAGNESIUM CARBONATE + MAGNESIUM	250 MG + 250 MG + 250 MG	MAVID PHARMACEUTICAL INDUSTRIES LIMITEDPLOT 490 BIRONGO, KITIIKO	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	01/07/2005
3913	NDA/MAL/HDP/8 637	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	AGYCIN	AZITHROMYCIN DIHYDRATE	40MG/ML	BLISS GVS PHARMA LTD PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA- INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X15.0 ML BOTTLE	28/03/2018

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3914	NDA/MAL/HDP/8 639	MSD (PTY) LTD	SURGIPHARM (U) LIMITED	ISENTRESS 100MG	RALTEGRAVIR POTASSIUM	100MG	PATHEON PHARMACEUTICALS INC.-2110 E. GALBRAITH ROAD CINCINNATI, OH 45237-1625, USA MSD (PTY) LTD. -117- 16TH ROAD, HALFWAY HOUSE, 1685 SOUTH AFRICA	SOUTH AFRICA UNITED STATES OF AMERICA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X60.0 TABLET BOTTLE	28/03/2018
3915	NDA/MAL/HDP/8 639	MSD (PTY) LTD	SURGIPHARM (U) LIMITED	ISENTRESS 100MG	RALTEGRAVIR POTASSIUM	100MG	MERCK SHARP & DOHME BV.- WAARDERWEG 39 HAARLEM, - 2031 BN, NETHERLANDS	SOUTH AFRICA UNITED STATES OF AMERICA NETHERLANDS	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X60.0 TABLET BOTTLE	28/03/2018

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3916	NDA/MAL/HDP/8 641	CADILA PHARMACEUTICAL S LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	TELI H	TELMISARTAN + HYDROCHLOROT HIAZIDE	40MG + 12.5MG	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/03/2018
3917	NDA/MAL/HDP/8 643	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ARTESUNATE 60MG	ARTESUNATE	60MG	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA BLISS INDAS LIFESCIENCE P. LTD..PLOT 73-76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X60.0 MG VIAL + 1*1*5ML AMPOULE OF 0.9%W/V NACL + 1*1*1ML AMPOULE OF 5%W/V NAHCO3	28/03/2018

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3918	NDA/MAL/HDP/8 648	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	UNODEX PLUS	TERBUTALINE SULPHATE + BROMHEXINE HYDROCHLORIDE + GUAIFENESIN	2.5MG + 8MG + 100MG	AKUMS DRUGS & PHARMACEUTICALS LTD-PLANT II PLOT NO.22, SECTOR 6-A, IIE, SIDCUL, RANIPUR,DISTRICT: HARIDWAR 249 403, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	28/03/2018
3919	NDA/MAL/HDP/8 649	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	CEFCARE	CEFTRIAZONE SODIUM	1G	INJECTCARE PARENTERALS PVT. LTD.PLOT130 SILVASSA ROAD GIDC VAPI 396195 GUJARAT	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	31/01/2018



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3920	NDA/MAL/HDP/8 650	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	CEFDIA 400MG	CEFIXIME TRIHYDRATE	400MG	NOBEL İLAÇ SAN. VE TİC. A.Ş.81100 SANCAKLAR, DÜZCE- TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X5.0 TABLET BLISTER,1.0X2.0X1. 0X5.0 TABLET BLISTER	28/03/2018
3921	NDA/MAL/HDP/8 655	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE XR 1000MG	METFORMIN HYDROCHLORIDE	1000MG	MERCK SANTÉ S.A.S.2 RUE DU PRESOIR VERT 45400 SEMOY FRANCE MERCK KGAA-PHARMA PRODUCTION DARMSTADT FRANKFURTER STRABE 250, D- 64293, DARMSTADT	GERMANY FRANCE	ORAL SOLID RETARD TABLETS	1.0X4.0X15.0 TABLET BLISTER,1.0X6.0X10 .0 TABLET BLISTER	28/03/2018

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3922	NDA/MAL/HDP/8 660	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	VEMLIDY	TENOFOVIR ALAFENAMIDE	25MG	PATHEON INC.- TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9	CANADA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE	28/03/2018
3923	NDA/MAL/HDP/8 661	AUROBINDO PHARMA LIMITED	GITTOES PHARMACEUTICAL S LIMITED	DOLUTEGRAVIR TABLETS 50MG	DOLUTEGRAVIR SODIUM	50MG	AUROBINDO PHARMA LTD UNIT VII (SEZ) APIICPLOT NO. S1 SURVEY NO. 411,425,434,435 & 458 GREEN INDUSTRIAL PARK POLEPALLY VILLAGE MAHABOBNAGAR DISTRICT ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE	28/03/2018

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3924	NDA/MAL/HDP/8 662	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	AMOXIREN-DS	AMOXICILLIN TRIHYDRATE	250MG/5ML	RENE INDUSTRIES LTD .PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X100.0 ML BOTTLE	28/03/2018
3925	NDA/MAL/HDP/8 665	CACHET PHARMACEUTICAL S PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	PAMAGIN-C	CETIRIZINE HYDROCHLORIDE + DEXTROMETHOR PHAN HYDROBROMIDE + ACETAMINOPHEN + PHENYLEPHRINE HYDROCHLORIDE + ZINC GLUCONATE	5.0 MG +15 MG + 500 MG + 5 MG + 7.5 MG	CACHET PHARMACEUTICALS PVT LTDVILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	28/03/2018

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3926	NDA/MAL/HDP/8 684	TENTH OF RAMADAN FOR PHARMACEUTICAL S INDUSTRIES AND DIAGNOSTICS REAGENTS(RAMED A)	GAMA PHARMACEUTICAL S (U) LIMITED	MEGAFEN N	IBUPROFEN	100MG/5ML	TENTH OF RAMADAN FOR PHARMACEUTICAL INDUSTRIES & DIAGNOSTIC REAGENTS (RAMEDA)SECOND INDUSTRIAL ZONE, PLOT NO.5 SIXTH OF OCTOBER- EGYPT	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	26/11/2019
3927	NDA/MAL/HDP/8 685	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	RANCV 500	RANOLAZINE	500 MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	30/05/2018

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3928	NDA/MAL/HDP/8 688	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	DURART 600	DARUNAVIR	600 MG	MYLAN LABORATORIES LTD - H-12 & H-13, MIDC, WALUJ,AURANGABA D- 431136 MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	30/05/2018
3929	NDA/MAL/HDP/8 689	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	DURART 800	DARUNAVIR	800 MG	MYLAN LABORATORIES LTD - H-12 & H-13, MIDC, WALUJ,AURANGABA D- 431136 MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	30/05/2018

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3930	NDA/MAL/HDP/8 691	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	QUETRA 1000	LEVETIRACETAM	1000MG	REMEDICA LTD.AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE,3056 LIMASSOL CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	30/05/2018
3931	NDA/MAL/HDP/8 694	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ERBITUX	CETUXIMAB	5MG/ML	MERCK KGAA-250 FRANKFURTERSTRAS SE, D-6100 DARMSTADT	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X20.0 ML VIAL	07/11/2018

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3932	NDA/MAL/HDP/8 699	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	ACETAZOLAMIDE	ACETAZOLAMIDE	250 MG	REMEDICA LTD.AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE,3056 LIMASSOL CYPRUS	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	30/05/2018
3933	NDA/MAL/HDP/8 778	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVCEF-250	CEFUROXIME AXETIL	250MG	ASSOCIATED BIOTECHKRISHANPU RA, P. O GURUMAJRA, BADDI, DIST. SOLAN	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	26/11/2019

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3934	NDA/MAL/HDP/8 779	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	STATINOR 20	ROSUVASTATIN	20MG	HETERO LABS LIMITED UNIT VTSIIC FORMULATION SEZ, S.NO 439, 440, 441 & 458 POLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOB NAGAR (DIST) -509301, TELANGANA INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/05/2019
3935	NDA/MAL/HDP/8 780	HETERO DRUGS LTD	AIVEEN (U) LIMITED	STATINOR 10	ROSUVASTATIN CALCIUM	10 MG	HETERO LABS LIMITED UNIT VTSIIC FORMULATION SEZ, S.NO 439, 440, 441 & 458 POLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOB NAGAR (DIST) -509301, TELANGANA INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/03/2019



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3936	NDA/MAL/HDP/8781	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVXIM-400	CEFIXIME	400MG	ASSOCIATED BIOTECH- KRISHANPURA, P. O GURUMAJRA, BADDI, DIST. SOLAN	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X6.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER,1.0X10.0X1.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	21/11/2019
3937	NDA/MAL/HDP/8783	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVCLAV-375	AMOXICILLIN + CLAVULANIC ACID	250MG + 125MG	AMN LIFE SCIENCE PVT LTD-67/P-1, MALAV, AREA- BHILAD, VALSAD- 396105, GUJARAT MEDICEF PHARMA- NO. 28, PHASE 1, EPIP, JHARRMAJRI, BADDI, DIST SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER	21/11/2019

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3938	NDA/MAL/HDP/8 784	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVCEF-500	CEFUROXIME AXETIL	500MG	ASSOCIATED BIOTECH- KRISHANPURA, P. O GURUMAJRA, BADDI, DIST. SOLAN	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	21/11/2019
3939	NDA/MAL/HDP/8 785	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVCEF SUSPENSION	CEFUROXIME AXETIL	125MG/5ML	ASSOCIATED BIOTECH- KRISHANPURA, P. O GURUMAJRA, BADDI, DIST. SOLAN	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE	21/11/2019

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3940	NDA/MAL/HDP/8 786	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVXIM	CEFIXIME TRIHYDRATE	100MG	ASSOCIATED BIOTECHKRISHANPU RA, P. O GURUMAJRA, BADDI, DIST. SOLAN	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X12.0 TABLET BLISTER, 1.0X1.0X10.0 TABLET BLISTER, 1.0X6.0 TABLET BLISTER	26/11/2019
3941	NDA/MAL/HDP/8 787	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVXIM-200	CEFIXIME	200MG	ASSOCIATED BIOTECH- KRISHANPURA, P. O GURUMAJRA, BADDI, DIST. SOLAN	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	21/11/2019

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3942	NDA/MAL/HDP/8 788	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVPOD-200	CEFPODOXIME PROXETIL	200MG	ASSOCIATED BIOTECH- KRISHANPURA, P. O GURUMAJRA, BADDI, DIST. SOLAN	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	21/11/2019
3943	NDA/MAL/HDP/8 795	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN 60/360	ARTEMETHER + LUMEFANTRINE	60MG + 360MG	AJANTA PHARMA LIMITEDPLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT- 392130 AJANTA PHARMA LIMITEDB- 4/5/6 MIDC PAITHAN DISTRICT AURANGABAD MAHARASHTRA STATE INDIA 431 128	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0X1.0X6.0 TABLET BLISTER	26/11/2019

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3944	NDA/MAL/HDP/8 796	PSYCHOTROPICS INDIA LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	AMITRIP-25	AMITRIPTYLINE HYDROCHLORIDE	25MG	PSYCHOTROPICS INDIA LTD PLOT NO. 46 & 49, SECTOR- 6A, IIE, SIDCUL, HARIDWAR - 249403( UTTARAKHARD)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	21/11/2019
3945	NDA/MAL/HDP/8 797	TENTH OF RAMADAN FOR PHARMACEUTICAL S INDUSTRIES AND DIAGNOSTICS REAGENTS (RAME DA)	GAMA PHARMACEUTICAL S (U) LIMITED	COLONA	MEBEVERINE HYDROCHLORIDE + SULPIRIDE	100MG + 25MG	TENTH OF RAMADAN FOR PHARMACEUTICAL INDUSTRIES & DIAGNOSTIC REAGENTS (RAMEDA) SECOND INDUSTRIAL ZONE, PLOT NO.5 SIXTH OF OCTOBER- EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	26/11/2019

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3946	NDA/MAL/HDP/8 803	SQUARE PHARMACEUTICAL S LTD.(CHEMICALS DIVISION)	GAMA PHARMACEUTICAL S (U) LIMITED	SYNERGEX 625MG	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500MG + 125MG	SQUARE PHARMACEUTICALS LIMITED.SQUARE ROAD, SALGARIA, PABNA	BANGLADESH	ORAL SOLID ORDINARY TABLETS	1.0X3.0X6.0 TABLET BLISTER, 1.0X5.0X6.0 TABLET BLISTER	26/11/2019
3947	NDA/MAL/HDP/8 814	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ACRIPTEGA	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFIVIR DISOPROXIL FUMARATE	50MG + 300MG + 300MG	MYLAN LABORATORIES LIMITEDD ,PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE-II, SECTOR-III, PITHAMPUR-454775 DIST. DHAR, MADHYA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE,1.0X180.0 TABLET BOTTLE	30/05/2018

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3948	NDA/MAL/HDP/8 815	ZIM LABORATORIES LTD	REDDYS PHARMA LIMITED	ZIMAGRA – ODS 50	SLIDENAFIL CITRATE	50 MG	ZIM LABORATORIES LTDB-21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA,	INDIA	OTHER SYSTEMIC SPECIAL SOLIDS	1.0X1.0X10.0 SACHET CARTON	30/05/2018
3949	NDA/MAL/HDP/8 816	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABPARA	PARACETAMOL	1%W/V	ABACUS PARENTERAL DRUGS LIMITEDBLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION BAGS	1.0X1.0X100.0 ML BOTTLE	30/05/2018

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3950	NDA/MAL/HDP/8 817	MEDIPHARM INDUSTRIES (E.A) LTD	MEDIPHARM INDUSTRIES (E.A) LTD	MEDISOLONE-15	PREDNISOLONE SODIUM PHOSPHATE	15MG/5ML	MEDIPHARM INDUSTRIES( EA) LTD PLOT 65 KAKAJJO ROAD BWEYOGERERE P.O.BOX 6218,KAMPALA,UGA NDA	UGANDA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X5.0 ML BOTTLE	30/05/2018
3951	NDA/MAL/HDP/8 818	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	LEVOTOP-PF	LEVOFLOXACIN HEMIHYDRATE	1.5%W/V	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML VIAL	30/05/2018



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3952	NDA/MAL/HDP/8 819	UNOSOURCE PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	LORFACT-D SYRUP	DES Loratadine	5MG/5ML	AKUMS DRUGS & PHARMACEUTICALS LTD-PLANT II PLOT NO.22, SECTOR 6-A, IIE, SIDCUL, RANIPUR, DISTRICT: HARIDWAR 249 403, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	30/05/2018
3953	NDA/MAL/HDP/8 820	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	T-DOL P RAPID	TRAMADOL HYDROCHLORIDE + PARACETAMOL	37.5MG + 325MG	TROIKAA PHARMACEUTICALS LTD .C-1 SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	30/05/2018

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3954	NDA/MAL/HDP/8 823	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	EPCLUSA	SOFOSBUVIR + VELPATASIR	400MG + 100MG	PATHEON INC.- TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9	CANADA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X28.0 TABLET BOTTLE	30/05/2018
3955	NDA/MAL/HDP/8 824	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	NEPAFLAM	NEPAFENAC	0.1% W/V	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	OPHTHALMIC SUSPENSIONS	1.0X1.0X5.0 ML VIAL	30/05/2018

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3956	NDA/MAL/HDP/8 826	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ABACAVIR SULFATE AND LAMIVUDINE TABLETS FOR ORAL SUSPENSION 120/60 MG	ABACAVIR SULFATE + LAMIVUDINE	120MG + 60MG	CIPLA LIMITED PLOT NO A – 33, A – 2 (UNIT – I), MIDC PATALGANGA, DISTRICT RAIGAD, 410 220 MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X1.0X60.0 TABLET BOTTLE	30/05/2018
3957	NDA/MAL/HDP/8 827	HETERO LABS LTD	AIVEEN (U) LIMITED	SOFGEN	SOFOSBUVIR	400 MG	HETERO LABS LIMITED UNIT-VI - APIIC FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOB NAGAR DIST -509301, TELANGANA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X28.0 TABLET BOTTLE	30/05/2018

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3958	NDA/MAL/HDP/8 829	HETERO LABS LTD	AIVEEN (U) LIMITED	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFVIR DISOPROXIL FUMARATE	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFVIR DISOPROXIL FUMARATE	50 MG + 300 MG + 300 MG	M/S. ANNORA PHARMA PRIVATE LIMITEDSY. NO. 261, ANNARAM VILLAGE, GUMMADIDALA MANDAL, SANGAREDDY DISTRICT, TELENGANA STATE – 502313, INDIA HETERO LABS PRIVATE LIMITED UNIT IISURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X90 TABLET BOTTLE	20/12/2018
3959	NDA/MAL/HDP/8 830	HETERO LABS LTD	AIVEEN (U) LIMITED	IRBIS-HT	IRBESARTAN + HYDROCHLOROT HIAZIDE	300MG + 12.5MG	HETERO LABS LIMITED (UNIT V)SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019

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3960	NDA/MAL/HDP/8 831	HETERO LABS LTD	AIVEEN (U) LIMITED	PREGA 75	PREGABALIN	75MG	HETERO LABS PRIVATE LIMITED UNIT IISURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) JEEDIMETLA, HYDERABAD-500 055, TELANGANA STATE HETERO LABS LIMITED (UNIT I)VILLAGE KALYANPUR, CHAKKAN ROAD, BADDI, DIST. SOLAN, HIMACHAL	INDIA	ORAL SOLID ORDINARY CAPSULES	1X3X10 CAPSULE BLISTER	26/11/2019
3961	NDA/MAL/HDP/8 836	EXPHAR S.A. ZONING INDUSTRIEL DE NIVELLES SUD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	GASTRICID	FAMOTIDINE BP + MAGNESIUM HYDROXIDE BP + CALCIUM CARBONATE BP	10 MG + 165 MG + 800 MG	MILAN LABORATORIES (INDIA ) PVT LTD PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTR A-410209,INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X4.0 TABLET STRIP	07/11/2018

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3962	NDA/MAL/HDP/8 839	MACK BROWN PHARMACEUTICAL S PVT LIMITED	SHURIK LTD	HEALTH RICH	FERRIC AMMONIUM CITRATE + FOLIC ACID + VITAMIN B1 HCL + VITAMIN B6 HCL + NICOTINAMIDE + VITAMIN B12	900MG + 10MG + 20MG + 40MG + 200MG + 360MG /5ML	TORQUE PHARMACEUTICALS PVT LTD VILL. ISSAPUR, P.O. DAPPAR, PUNJAB- 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1X100 ML BOTTLE, 1X1X100 ML BOTTLE	26/11/2019
3963	NDA/MAL/HDP/8 843	SQUARE PHARMACEUTICAL S LTD.	GAMA PHARMACEUTICAL S (U) LIMITED	CEFOTIL 500	CEFUROXIME AXETIL	500MG	SQUARE PHARMACEUTICALS LIMITED - DHAKA UNIT (KALIAKOIR GAZIPUR)	BANGLADESH	ORAL SOLID ORDINARY TABLETS	1.0X2.0X6.0 TABLET	26/11/2019

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3964	NDA/MAL/HDP/8 844	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VENAXAN 500 MG	LEVOFLOXACIN HEMIHYDRATE	500 MG	SOUTH EGYPT DRUG INDUSTRIES CO-1ST INDUSTRIAL ZONE, 6 OCTOBER CITY, EGYPT.	EGYPT	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X5.0 TABLET BLISTER	07/11/2018
3965	NDA/MAL/HDP/8 845	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	FUROSEMIDE	FUROSEMIDE	10MG/ML	SWISS PARENTERALS PVT LTD ..809, KERALA INDUSTRIAL ESTAE, GIDC NEAR BAVLA, AHMEDABAD 382220, GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	21/11/2019

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3966	NDA/MAL/HDP/8 914	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	PEFLOREN 400	PEFLOXACIN MESILATE DIHYDRATE	400 MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER	25/07/2018
3967	NDA/MAL/HDP/8 915	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ATOXIA 120 MG	ETORICOXIB	120 MG	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD-P.O. BOX 69 AMMAN 11591 - AL- RAGEEM SAHAB - JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X7.0 TABLET BLISTER	25/07/2018



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3968	NDA/MAL/HDP/8 916	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	TAMSUMAC 0.4	TAMSULOSIN HYDROCHLORIDE	0.4MG	MACLEODS PHARMACEUTICALS LIMITED BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH - 174101 INDIA	INDIA	ORAL SOLID RETARD CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	25/07/2018
3969	NDA/MAL/HDP/8 917	OXIMIO LIMITED	GITTOES PHARMACEUTICAL S LIMITED	SCC-2 LLW TABLETS	RIFAMPICIN + ISONIAZID	150MG + 75MG	SVIZERA LABS PRIVATE LIMITED PLOT D-16/6 TTC INDUSTRIAL AREA MIDC TURBHE NAVI MUMBAI 400703, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X24.0X28.0 TABLET BLISTER	25/07/2018

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3970	NDA/MAL/HDP/8 918	OXIMIO LIMITED	GITTOES PHARMACEUTICAL S LIMITED	SCC-3 LLW TABLETS	RIFAMPICIN + ISONIAZID + ETHAMBUTOL HYDROCHLORIDE	150MG + 75MG + 275MG	SVIZERA LABS PRIVATE LIMITEDPLOT D-16/6 TTC INDUSTRIAL AREA MIDC TURBHE NAVI MUMBAI 400703, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X24.0X28.0 TABLET BLISTER	25/07/2018
3971	NDA/MAL/HDP/8 919	OXIMIO LIMITED	GITTOES PHARMACEUTICAL S LIMITED	SCC-4 TABLETS	RIFAMPICIN + ISONIAZID + PYRAZINAMIDE + ETHAMBUTOL HYDROCHLORIDE	150MG + 75MG + 400MG + 275MG	SVIZERA LABS PRIVATE LIMITEDPLOT D-16/6 TTC INDUSTRIAL AREA MIDC TURBHE NAVI MUMBAI 400703, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X24.0X28.0 TABLET BLISTER	25/07/2018

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3972	NDA/MAL/HDP/8 920	MERCK	UNITED HEALTHCARE DISTRIBUTORS LTD	CRINONE 8% GEL	PROGESTERONE	90MG/APPLICATO R	DENDRON BRANDS LIMITED94 RICKMANSWORTH ROAD,WATFORD , WD18 7JJ, UNITED KINGDOM	UNITED KINGDOM	VAGINAL GELS AND SOLS	1.0X1.0X15.0 POUCH CARTON	25/07/2018
3973	NDA/MAL/HDP/8 926	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GLUSIS 1000 ER	METFORMIN HYDROCHLORIDE	1000 MG	MSN LABORATORIES PRIVATE LIMITED (FORMULATIONS DIVISION) - PLOT NO.: 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, 502 325, INDIA	INDIA	ORAL SOLID RETARD TABLETS	1X3X10 TABLET BLISTER	25/07/2018

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3974	NDA/MAL/HDP/8 927	BIOLOGICAL E. LTD	GITTOES PHARMACEUTICALS LIMITED	DIPHThERIA AND TETANUS VACCINE (ADSORBED REDUCED ANTIGEN(S) CONTENT)	DIPHThERIA TOXOID + TETANUS TOXOID	2 LF ( NOT LESS THAN 2 IU) + 8.8 LF (NOT LESS THAN 20 IU)/ 0.5ML	BIOLOGICAL E. LIMITED-PLOT NO.1 SHAPOORJI PALLONJI BIOTECH PARK PHASE II, KOLTHUR VILLAGE, SHAMEERPET, MANDAL, R.R. DISTRICT, ANDRA PRADESH 500078, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X24.0X1.0X10.0 DOSE VIAL,1.0X48.0X1.0 DOSE VIAL	25/07/2018
3975	NDA/MAL/HDP/8 929	OCTAPHARMA AG	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ALBUNORM	HUMAN ALBUMIN	20%W/V	OCTAPHARMA PRODUKTIONSGESEL LSCHAFT DEUTSCHLAND MBH- WOLFGANG- MARGUERRE-ALLEE 1 31832 SPRINGE GERMANY	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X50.0 ML BOTTLE,1.0X1.0X10 0.0 ML BOTTLE	25/07/2018

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3976	NDA/MAL/HDP/8 931	CARITAS HEALTHCARE PVT. LTD	REDDYS PHARMA LIMITED	SODIUM CHLORIDE INTRAVENOUS INFUSION BP	SODIUM CHLORIDE	0.9%W/V	SICHUAN KELUN PHARMACEUTICAL CO., LTDSOUTH OF NO.2 ROAD, XINDU SATELLITE CITY INDUSTRIAL DEVELOPMENT ZONE, CHENGDU, SICHUAN PROVINCE 610500, P. R. CHINA	CHINA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	25/07/2018
3977	NDA/MAL/HDP/8 933	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	Q-TIB	SULFAMETHOXAZ OLE + TRIMETHOPRIM + ISONIAZID + PYRIDOXINE HYDROCHLORIDE	800MG + 160MG + 300MG +25MG	CIPLA LTD ,PLOT NO. A-33, A-2 (UNIT 1), A42 (UNIT II), MIDC PATALGANGA, DISTRICT-RAIGAD MAHARASHTRA, 410220 INDIA CIPLA LIMITED>A-33, A- 37/2/2 & A-2, M.I.D.C, PATALANGA 410 220, DISTRICT RAIGAD, M.S, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X30.0 TABLET BOTTLE	25/07/2018

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3978	NDA/MAL/HDP/8 934	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	CYCLO P EYE DROPS	CYCLOPENTOLATE HYDROCHLORIDE	1.0%W/V	ABACUS PARENTERAL DRUGS LIMITEDBLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	25/07/2018
3979	NDA/MAL/HDP/8 936	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD	HEALTHCARE LTD.	ESOFOLE	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40MG	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD-PLOT 20,21,22- DEFENCE INDUSTRIAL ZONE- MOMAN PURA, 16KM SHEIKHUPURA ROAD, (LAHORE) - PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER	25/07/2018

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3980	NDA/MAL/HDP/8939	FREDUN PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	RHINOCOLD	PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + CHLORPHENIRAMINE MALEATE + CAFFEINE (ANHYDROUS)	500MG + 10MG + 2MG + 30MMG	FREDUN PHARMACEUTICALS LTD -14, 15, 16, ZORABIAN INDUSTRIAL COMPLEX, VILLAGE, VEOOR, PALGHAR (EAST) DIST: THANE – 401 404 - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X1.0X4.0 TABLET BLISTER	25/07/2018
3981	NDA/MAL/HDP/8940	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	RABIZA 20MG	RABEPRAZOLE SODIUM	20MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.3. 42050 SELÇUKLU / KONYA TURKEY	TURKEY	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	25/07/2018

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3982	NDA/MAL/HDP/8 941	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	LIVERCOL 20MG	ROSUVASTATİN CALCIUM	20MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.3. 42050 SELÇUKLU / KONYA TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	25/07/2018
3983	NDA/MAL/HDP/8 943	HETERO LABS LTD	AIVEEN (U) LIMITED	IRBIS-HT 150/12.5	IRBESARTAN + HYDROCHLOROT HIAZIDE	150MG + 12.5MG	HETERO LABS LIMITED (UNIT V)SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019



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3984	NDA/MAL/HDP/8 944	B&O PHARM	TRIDEM PHARMA UGANDA LIMITED	GAMOK 625MG	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	500MG + 125MG	SINOPHARM WEIQIDA PHARMACEUTICAL CO., LTD-OSD WORKSHOP OF ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, SECOND MEDICAL ZONE DATONG, SHANXI, CHINA	CHINA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	25/07/2018
3985	NDA/MAL/HDP/8 946	B & O PHARM ZAC	TRIDEM PHARMA UGANDA LIMITED	GAMOK 0.6G	AMOXICILLIN SODIUM + CLAVULANATE POTASSIUM	500MG + 100MG	SINOPHARM WEIQIDA PHARMACEUTICAL CO., LTD-OSD WORKSHOP OF ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, SECOND MEDICAL ZONE DATONG, SHANXI, CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X0.6 G VIAL	25/07/2018

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3986	NDA/MAL/HDP/8 947	B & O PHARM ZAC	TRIDEM PHARMA UGANDA LIMITED	GAMOK 1.2G	AMOXICILLIN SODIUM + CLAVULANATE POTASSIUM	1G + 0.2G	SINOPHARM WEIQIDA PHARMACEUTICAL CO., LTD-OSD WORKSHOP OF ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, SECOND MEDICAL ZONE DATONG, SHANXI, CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X1.2 G VIAL	25/07/2018
3987	NDA/MAL/HDP/8 949	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CETAL SUPOSITORIES	PARACETAMOL	120MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B1, EGYPT	EGYPT	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY BLISTER	25/07/2018

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3988	NDA/MAL/HDP/8 952	THEON PHARMACEUTICAL S LTD	AIVEEN (U) LIMITED	THEOFLEX -500	CEFALEXIN MONOHYDRATE	500 MG	THEON PHARMACEUTICALS LIMITED. VILLAGE SAINI MAJRA, TEHSIL NALAGARH, DISTT. SOLAN, HIMACHAL PRADESH 174 101 INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1X10X10 CAPSULE BLISTER	25/07/2018
3989	NDA/MAL/HDP/8 953	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	BENYLIN CHILDREN'S WET COUGH	GUAIFENESIN	100MG PER 10ML	JOHNSON&JOHNSO N PTY LTD.EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE	25/07/2018

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3990	NDA/MAL/HDP/8954	JOHNSON & JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN WET COUGH	GUAIFENESIN	200MG PER 10ML	JOHNSON&JOHNSON PTY LTD.EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X50.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE,1.0X1.0X200.0 ML BOTTLE	25/07/2018
3991	NDA/MAL/HDP/9053	F. HOFFMANN LA-ROCHE	LABOREX UGANDA LIMITED	MABTHERA® 100MG/10ML	RITUXIMAB	100MG/10ML	ROCHE DIAGNOSTICS GMBH MANNHEIM-SANDHOFER STRASSE 116 -68305 MANNHEIM GERMANY.	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X2.0X10.0 ML VIAL	26/09/2018

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3992	NDA/MAL/HDP/9054	F. HOFFMANN LA-ROCHE	LABOREX UGANDA LIMITED	MABTHERA® 500MG/50ML	RITUXIMAB	500MG/50ML	ROCHE DIAGNOSTICS GMBH MANNHEIM- SANDHOFER STRASSE 116 -68305 MANNHEIM GERMANY.	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X50.0 ML VIAL	26/09/2018
3993	NDA/MAL/HDP/9057	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP®	DIHYDROARTEMI SININ + PIPERAQUINE PHOSPHATE	60MG + 480MG	GUILIN PHARMACEUTICAL CO LTD-NO. 43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER,1.0X6.0X25 .0 TABLET BLISTER	26/09/2018

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3994	NDA/MAL/HDP/9 058	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP® DISPERSIBLE	DIHYDROARTEMI SININ + PIPERAQUINE PHOSPHATE	30MG + 240MG	GUILIN PHARMACEUTICAL CO LTD-NO. 43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X2.0X3.0 TABLET BLISTER,1.0X3.0X25 .0 TABLET BLISTER	26/09/2018
3995	NDA/MAL/HDP/9 059	CRATUS PHARMA PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	CLASSMOX DROPS	AMOXICILLIN TRIHYDRATE	125MG/ML	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD - UNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE-247668. DIST.-HARIDWAR, UTTARAKHAND	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X10.0 ML BOTTLE	26/09/2018

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3996	NDA/MAL/HDP/9 062	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ADERAN 32	CANDESARTAN CILEXETIL	32 MG	AJANTA PHARMA LIMITEDB-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	26/09/2018
3997	NDA/MAL/HDP/9 063	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	TENOFOVIR DISOPROXIL FUMARATE TABLETS 300 MG	TENOFOVIR DISOPROXIL FUMARATE	300 MG	LAURUS LABS LIMITED, (UNIT-2) - PLOT NO:19, 20 & 21,WESTERN SECTOR, APSEZ, ATCHUTAPURAM MANDAL, VISAKHAPATNAM- DISTRICT-531011, ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE	26/09/2018

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3998	NDA/MAL/HDP/9064	THEON PHARMACEUTICALS LTD	AIVEEN (U) LIMITED	THEOMOX-250	AMOXICILLIN TRIHYDRATE	250 MG	THEON PHARMACEUTICALS LIMITED. VILLAGE SAINI MAJRA, TEHSIL NALAGARH, DISTT. SOLAN, HIMACHAL PRADESH 174 101 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1X10X10 CAPSULE BLISTER	26/09/2018
3999	NDA/MAL/HDP/9065	THEON PHARMACEUTICALS LTD	AIVEEN (U) LIMITED	THEOFLEX -250	CEFALEXIN MONOHYDRATE	250 MG	THEON PHARMACEUTICALS LIMITED. VILLAGE SAINI MAJRA, TEHSIL NALAGARH, DISTT. SOLAN, HIMACHAL PRADESH 174 101 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1X10X10 CAPSULE BLISTER	26/09/2018



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4000	NDA/MAL/HDP/9066	THEON PHARMACEUTICALS LTD	AIVEEN (U) LIMITED	THEOFIX-200	CEFIXIME TRIHYDRATE	200 MG	THEON PHARMACEUTICALS LIMITED. VILLAGE SAINI MAJRA, TEHSIL NALAGARH, DISTT. SOLAN, HIMACHAL PRADESH 174 101 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1X2X10 TABLET BLISTER	26/09/2018
4001	NDA/MAL/HDP/9067	MEDISEL(K) LTD	AIVEEN (U) LIMITED	BRONCHOWIN	DOXOFYLLINE	400 MG	CORONA REMEDIES PVT LIMITEDVILLAGE JATOLI, POST OFFICE OACHGHAT, TEHSIL SOLAN, DIST. SOLAN HIMACHAL PRADESH – 173223. INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	26/09/2018

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4002	NDA/MAL/HDP/9 068	MEDISEL(K) LTD	AIVEEN (U) LIMITED	MOXIDOC TABLET	MOXIFLOXACIN HYDROCHLORIDE	400 MG	CORONA REMEDIES PVT LIMITEDVILLAGE JATOLI, POST OFFICE OACHGHAT, TEHSIL SOLAN, DIST. SOLAN HIMACHAL PRADESH – 173223. INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X1X10 TABLET BLISTER	26/09/2018
4003	NDA/MAL/HDP/9 130	AUROLAB	SWASTIK PHARMACEUTICAL LTD	MFLOX-DM	MOXIFLOXACIN + DEXAMETHASON E SODIUM PHOSPHATE	0.5%W/V + 0.1%W/V	AUROLAB LIMITEDNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU INDIA	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	21/11/2019

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4004	NDA/MAL/HDP/9 137	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	DOM R	RABEPRAZOLE SODIUM + DOMPERIDONE SR	20MG + 30MG	CORONA REMEDIES PVT. LTDVILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	21/11/2019
4005	NDA/MAL/HDP/9 140	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	CLOMIPHENE CITRATE	CLOMIPHENE CITRATE	50MG	CORONA REMEDIES PVT. LTDVILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	21/11/2019

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4006	NDA/MAL/HDP/9 141	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	RABZOLE	RABEPRAZOLE SODIUM + LEVOSULPIRIDE	20MG + 75MG	CORONA REMEDIES PVT. LTDVILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	21/11/2019
4007	NDA/MAL/HDP/9 142	THEON PHARMACEUTICAL S LIMITED	AIVEEN (U) LIMITED	THEOFIX -50 DS	CEFIXIME TRIHYDRATE	50MG/5ML	THEON PHARMACEUTICALS LTD ,VILLAGE SAINI MAJRA, TEHSIL, NALAGARH, DIST. SOLAN HP	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1X60 ML BOTTLE	26/11/2019

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4008	NDA/MAL/HDP/9 146	MICRO LABS LTD	LABOREX UGANDA LIMITED	ISONIAZID	ISONIAZID	300MG	MICRO LABS LIMITED .,92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X24.0X2 8.0 TABLET BLISTER,1.0X1000.0 TABLET BOTTLE	21/11/2019
4009	NDA/MAL/HDP/9 165	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	VAGID-100	CLOTRIMAZOLE	100 MG	M/S BLISS GVS PHARMA LIMITED PLOT 10, SURVEY NO. 38/1, DEWAN UDYOG NAGAR, ALIYALI VILLAGE PALGHAR, DIST. THANE - 401404	INDIA	VAGINAL SUPPOSITORIES	1.0X1.0X7.0 PESSARY BLISTER,1.0X1.0X6. 0 PESSARY BLISTER	21/11/2019

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4010	NDA/MAL/HDP/9 166	HETERO LABS LTD	AIVEEN (U) LIMITED	VIRDAC 30	DACLATASVIR DIHYDROCHLORID E	30 MG	HETERO LABS LIMITED (UNIT V)SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X28.0 TABLET BOTTLE	27/11/2019
4011	NDA/MAL/HDP/9 172	PROFARMA .SH.A	JOINT MEDICAL STORE (UPMB - UCMB)	DOXYDERMA	DOXYCYCLINE MONOHYDRATE	100MG	PROFARMA SH.AMYSLYM KETA,TIRANA	ALBANIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	27/08/2019

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4012	NDA/MAL/HDP/9 173	PROFARMA .SH.A	JOINT MEDICAL STORE (UPMB - UCMB)	PRODEXA-T	DEXAMETHASON E	0.5MG	PROFARMA SH.AMYSLYM KETA,TIRANA	ALBANIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	27/08/2019
4013	NDA/MAL/HDP/9 174	PROFARMA .SH.A	JOINT MEDICAL STORE (UPMB - UCMB)	ULCOZOL 20MG	OMEPRAZOLE	20MG	PROFARMA SH.AMYSLYM KETA,TIRANA	ALBANIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	21/11/2019

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4014	NDA/MAL/HDP/9 175	PROFARMA .SH.A	JOINT MEDICAL STORE (UPMB - UCMB)	ERITROMICINE	ERYTHROMYCIN ESTOLATE	250MG	PROFARMA SH.AMYSLYM KETA,TIRANA	ALBANIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	21/11/2019
4015	NDA/MAL/HDP/9 176	PROFARMA .SH.A	JOINT MEDICAL STORE (UPMB - UCMB)	PIROCUTAN	PIROXICAM	20MG	PROFARMA SH.AMYSLYM KETA,TIRANA	ALBANIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019



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4016	NDA/MAL/HDP/9 177	PROFARMA .SH.A	JOINT MEDICAL STORE (UPMB - UCMB)	TETRA	TETRACYCLINE HYDROCHLORIDE	1%W/V	PROFARMA SH.AMYSLYM KETA,TIRANA	ALBANIA	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE	21/11/2019
4017	NDA/MAL/HDP/9 178	PROFARMA .SH.A	JOINT MEDICAL STORE (UPMB - UCMB)	LORADE	LORATADINE	10MG	PROFARMA SH.AMYSLYM KETA,TIRANA	ALBANIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	21/11/2019

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4018	NDA/MAL/HDP/9 189	SAGA LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	ESOFLUX 40	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40 MG	SAGA LIFESCIENCES LIMITEDSURVEY NO. 198/2 & 198/3, CHACHRAWADI VASNA, TA-SANAND, DIST. AHMEDABAD - 382210, INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	28/09/2020
4019	NDA/MAL/HDP/9 190	SAKAR HEALTHCARE LIMITED	TATA UGANDA LIMITED	RABEKAR	RABEPRAZOLE SODIUM	20MG	SAKAR HEALTH CARE PVT LTD-10/13 CHONGODAR SARKHEJ BAVLA ROAD DIST AHEMABAD 382213 GUJARATI	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 MG VIAL + 1*5ML WFI IN LDPE	15/02/2023

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4020	NDA/MAL/HDP/9 191	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANDOX-DS 50	CEFPODOXIME PROXETIL	50 MG/5ML	SANCE LABORATORIES PVT LTDVI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	08/09/2020
4021	NDA/MAL/HDP/9 192	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANDOX- 200	CEFPODOXIME PROXETIL	200 MG	SANCE LABORATORIES PVT LTDVI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	08/09/2020

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4022	NDA/MAL/HDP/9 193	SHANGHAI DESANO BIO- PHARMACEUTICAL CO., LTD	TATA UGANDA LIMITED	LAMIVUDINE AND ZIDOVUDINE TABLETS 150 MG/300 MG	LAMIVUDINE + ZIDOVUDINE	150 MG + 300 MG	SHANGHAI DESANO BIO- PHARMACEUTICAL CO., LTD1479 ZHANGHENG ROAD, CHINA (SHANGHAI) PILOT FREE TRADE ZONE SHANGHAI, CHINA	CHINA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X60.0 TABLET CONTAINER	08/09/2020
4023	NDA/MAL/HDP/9 194	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MAGNABIOTIC	AMOXICILLINTRIH YDRATE + POTASSIUM CLAVULANATE	875 MG + 125 MG	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)-1ST INDUSTRIAL ZONE, 6 OCTOVER CITY, P.O. BOX 43	EGYPT	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BOTTLE	08/09/2020

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4024	NDA/MAL/HDP/9 195	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	SOBISIS	SODIUM BICARBONATE	500 MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRIA L AREA,MEHATPUR- 174 315, HIMACHAL PRADESH.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/09/2020
4025	NDA/MAL/HDP/9 196	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	SOBISIS FORTE	SODIUM BICARBONATE	1000 MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRIA L AREA,MEHATPUR- 174 315, HIMACHAL PRADESH.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/09/2020

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4026	NDA/MAL/HDP/9 197	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	SEVLAREN 400	SEVELAMER CARBONATE	400 MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRIA L AREA,MEHATPUR- 174 315, HIMACHAL PRADESH.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/09/2020
4027	NDA/MAL/HDP/9 198	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	PBREN 75	PREGABALIN	75 MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRIA L AREA,MEHATPUR- 174 315, HIMACHAL PRADESH.	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	08/09/2020

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4028	NDA/MAL/HDP/9 199	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	KCHEK	CALCIUM POLYSTYRENE SULPHONATE	15 MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRIA L AREA,MEHATPUR- 174 315, HIMACHAL PRADESH.	INDIA	ORAL LIQUID ORDINARY OTHER POWDERS/GRANU LES	1.0X15.0 G SACHET	08/09/2020
4029	NDA/MAL/HDP/9 200	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	LEVIGRESS 250	LEVETIRACETAM	250 MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRIA L AREA,MEHATPUR- 174 315, HIMACHAL PRADESH.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/09/2020

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4030	NDA/MAL/HDP/9 201	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	LEVIGRESS 500	LEVETIRACETAM	500MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRIA L AREA,MEHATPUR- 174 315, HIMACHAL PRADESH.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/09/2020
4031	NDA/MAL/HDP/9 202	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	ESCIGRESS 5	ESCITALOPRAM OXALATE	5MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRIA L AREA,MEHATPUR- 174 315, HIMACHAL PRADESH.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/09/2020



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4032	NDA/MAL/HDP/9 203	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	ESCIGRESS 10	ESCITALOPRAM OXALATE	10MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRIA L AREA,MEHATPUR- 174 315, HIMACHAL PRADESH.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/09/2020
4033	NDA/MAL/HDP/9 204	SUN PHARMACEUTICAL INDUSTRIES LTD	STAR PHARMACEUTICAL S LTD	CHERIFLU PLUS WITH VITAMIN C	CHLORPHENAMIN E MALEATE + PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE +VITAMIN C	4 MG + 650 MG + 10 MG + 30 MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED INDUSTRIAL AREA 3, A.B. ROAD, DEWAS 455001, MADHYA PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	08/09/2020

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4034	NDA/MAL/HDP/9 205	SYNOKEM PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GASTROSYN	ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE	250 MG + 250 MG + 50 MG / 5ML	SYNOKEM PHARMACEUTICALS LTD-PLOT NO.- 35- 36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL)	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	08/09/2020
4035	NDA/MAL/HDP/9 210	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VIVAZAC	IRBESARTAN	300 MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/09/2020

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4036	NDA/MAL/HDP/9 211	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HI DEE 10000 IU	CHOLECALCIFERO L	10,000IU	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X1.0X30.0 CAPSULE CONTAINER	08/09/2020
4037	NDA/MAL/HDP/9 212	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HI DEE 50000 IU	CHOLECALCIFERO L	50,000IU	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X1.0X8.0 CAPSULE CONTAINER	08/09/2020

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4038	NDA/MAL/HDP/9 213	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	COMBIART SUSPENSION	ARTEMETHER + LUMEFANTRINE	15 MG + 90 MG/5ML	MADRAS PHARMACEUTICALS 137-B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI – 600 096, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE	08/09/2020
4039	NDA/MAL/HDP/9 214	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HI DEE 2000 IU	CHOLECALCIFERO L	2000IU	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X1.0X30.0 CAPSULE CONTAINER	08/09/2020

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4040	NDA/MAL/HDP/9 215	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HI DEE 2000 IU/5 DROPS	CHOLECALCIFERO L	2000IU/ 5 DROPS	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL LIQUID ORDINARY DROPS	1.0X1.0X10.0 ML BOTTLE	08/09/2020
4041	NDA/MAL/HDP/9 217	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	ABACAVIR, DOLUTEGRAVIR AND LAMIVUDINE TABLETS	ABACAVIR SULFATE + DOLUTEGRAVIR SODIUM + LAMIVUDINE	600 MG + 50 MG + 300 MG	LAURUS LABS LTD (UNIT 2)PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	08/09/2020

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4042	NDA/MAL/HDP/9 219	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TESS	TRIAMCINOLONE ACETONIDE	0.1% W/W	TROIKAA PHARMACEUTICALS LTDBLOCK NO. 2019, 2020, 2023, VILLAGE VIROCHANNAGAR, TAL-SANAND CITY: AHMEDABAD, DIST. AHMEDABAD- 382170, GUJARAT STATE	INDIA	TOPICAL EXTERNAL PASTES	1.0X1.0X5.0 G TUBE	08/09/2020
4043	NDA/MAL/HDP/9 222	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	DARUNAVIR TABLETS	DARUNAVIR	800 MG	LAURUS LABS LTD (UNIT 2)PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	08/09/2020

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4044	NDA/MAL/HDP/9 223	WALLACE PHARMACEUTICAL S PVT. LTD	STAR PHARMACEUTICAL S LTD	LAXIWAL	LACTULOSE	10 G/15 ML	WALLACE PHARMACEUTICALS PVT LTDBHATIAN, NALAGARH, DIST. SOLAN HP 174101	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X20 0.0 ML BOTTLE	08/09/2020
4045	NDA/MAL/HDP/9 225	ZIM LABORATORIES LTD	ROYAL PHARMA 2011 LIMITED	ZIMADOL 50	TRAMADOL HYDROCHLORIDE	50 MG	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	08/09/2020

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4046	NDA/MAL/HDP/9 228	LIFEWAY PHARMACEUTICAL INDUSTRIES LIMITED	LIFEWAY PHARMACEUTICAL INDUSTRIES LIMITED	SUREDOL	PARACETAMOL	500MG	LIFEWAY PHARMACEUTICAL INDUSTRIES LIMITED- BLOCK 198, PLOT 478,	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/09/2020
4047	NDA/MAL/HDP/9 229	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	TRADMIN	TRAMADOL HYDROCHLORIDE	50MG	AKUMS DRUGS & PHARMACEUTICALS LTD19-20,21, SECTOR 6-4, SIDCUL, IIE, RANIPUR HARIDWAR-249403	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	08/09/2020



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4048	NDA/MAL/HDP/9 237	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	AZITHRO-DENK 250 MG	AZITHROMYCIN MONOHYDRATE	250MG	ARTESAN PHARMA GMBH & CO. KGWENDLANDSTR.1, 29439, LUCHOW	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	08/09/2020
4049	NDA/MAL/HDP/9 238	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	AZITHRO-DENK 500 MG	AZITHROMYCIN MONOHYDRATE	500MG	ARTESAN PHARMA GMBH & CO. KGWENDLANDSTR.1, 29439, LUCHOW	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	08/09/2020

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

4050	NDA/MAL/HDP/9 241	BKRS PHARMA PVT. LTD.	VEERAM HEALTHCARE (U) LIMITED	LEXAR	LEVOFLOXACIN HEMIHYDRATE	500MG	HIGGS HEALTHCARE PVT. LIMITED KHASRA NO. 480/1, BHATOLIKALAN BADDI, DIST SOLAN, (H.P) - INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	08/09/2020
4051	NDA/MAL/HDP/9 246	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	CLAMOXIN	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500 MG + 125 MG	MEDOPHARM PVT LIMITEDNO. 50 KAYARAMBEDU VILLAGE, GUDUVANCHERY- 603202	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER,1.0X2.0X10 .0 TABLET BLISTER	19/02/2021

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

4052	NDA/MAL/HDP/9 248	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	ESOFAG-D	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE + DOMPERIDONE	40MG + 30MG	MICRO LABS LIMITED .,92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE STRIP	08/09/2020
4053	NDA/MAL/HDP/9 252	BKRS PHARMA PVT. LTD.	VEERAM HEALTHCARE (U) LIMITED	FLUCO-BKRS	FLUCONAZOLE	0.2% W/V	HIGGS HEALTHCARE PVT. LIMITED KHASRA NO. 480/1, BHATOLIKALAN BADDI, DIST SOLAN, (H.P) - INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	08/09/2020

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4054	NDA/MAL/HDP/9 262	REDDYS PHARMA LIMITED	REDDYS PHARMA LIMITED	DOMIPAN	PANTOPRAZOLE SODIUM SESQUIHYDRATE + DOMPERIDONE	40 MG + 30 MG	FREDUN PHARMACEUTICALS LIMITED <sup>14,15,16</sup> , ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PA LGHAR (E), DIST: PALGHAR-401 404	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	08/09/2020
4055	NDA/MAL/HDP/9 263	FREDUN PHARMACEUTICAL S LTD	REDDYS PHARMA LIMITED	ETCOX-90	ETORICOXIB	90MG	FREDUN PHARMACEUTICALS LIMITED <sup>14,15,16</sup> , ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PA LGHAR (E), DIST: PALGHAR-401 404	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/09/2020

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4056	NDA/MAL/HDP/9 264	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	APRITANT IV	FOSAPRIPITANT DIMEGLUMINE	150 MG/VIAL	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 VIAL VIAL	08/09/2020
4057	NDA/MAL/HDP/9 266	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ABACAVIR (AS SULFATE) / LAMIVUDINE DISPERSIBLE TABLETS	ABACAVIR SULFATE + LAMIVUDINE	120 MG + 60 MG	MYLAN LABORATORIES LTD PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR - 454775; DIST; DHAR; MADHYA PRADESH; MYLAN LABORATORIES LIMITED NO. H-12 & H-13, MIDC, WALUJ INDUSTRIAL AREA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X30.0 TABLET CONTAINER, 1.0X60. 0 TABLET CONTAINER	08/09/2020

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4058	NDA/MAL/HDP/9 278	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	CANDIFORCE-100	ITRACONAZOLE	100 MG	RA CHEM PHARMA LTD PLOT NO. A- 19/C, ROAD NO. 18, IDA NACHARAM, HYDERABAD- 500076, TELENGANA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	08/09/2020
4059	NDA/MAL/HDP/9 279	RAPTAKOS, BRETT & CO. LTD.	EUROPA HEALTHCARE (U) LTD	SILVIRIN	SILVER SULFADIAZINE	1% W/W	RAPTAKOS BRETT & CO.LTD 1ST POKHRAN ROAD, THANE 400 606	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	08/09/2020

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4060	NDA/MAL/HDP/9 280	RAPTAKOS, BRETT & CO. LTD.	EUROPA HEALTHCARE (U) LTD	NORASH	DIMETHICONE + ZINC OXIDE + CALAMINE + CETRIMIDE	20% W/W + 7.5% W/W + 1.5% W/W + 1.125% W/W	RAPTAKOS BRETT & CO.LTD1ST POKHRAN ROAD,THANE 400 606	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	08/09/2020
4061	NDA/MAL/HDP/9 286	GALENTIC PHARMA LTD	VITACARE LIMITED	SELDRUF	SELENIUM SULFIDE	2.5% W/V	GALENTIC PHARMA (INDIA) LTD .R-673, MIDC, TTC, RABALE, THANE-BELAPUR ROAD, NAVI MUMBAI	INDIA	TOPICAL EXTERNAL SUSPENSIONS	1.0X100.0 ML BOTTLE	08/09/2020

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4062	NDA/MAL/HDP/9 287	GLENMARK PHARMACEUTICAL S LTD	ABACUS PHARMA (AFRICA) LIMITED	CANDID-V3	CLOTRIMAZOLE	200MG	GLENMARK PHARMACEUTICALS LTD .PLOT E-37, 39, D ROAD, MIDC, SATPUR, NASHIK 422007, MAHARASHTRA STATE	INDIA	VAGINAL TABLETS	1.0X1.0X3.0 TABLET STRIP	08/09/2020
4063	NDA/MAL/HDP/9 288	HETERO DRUGS LTD	AIVEEN (U) LIMITED	VIRDAC 60	DACLATASVIR DIHYDROCHLORID E	60 MG	HETERO LABS LIMITED (UNIT V)SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X28.0 TABLET BOTTLE	28/09/2020



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4064	NDA/MAL/HDP/9 290	INFUGEN PHARMA PVT. LTD.	TATA UGANDA LIMITED	INFIXIME 200	CEFIXIME TRIHYDRATE	200MG	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	08/09/2020
4065	NDA/MAL/HDP/9 291	INTAS PHARMACEUTICAL S LIMITED	STAR BIOTECH UGANDA LTD	SARTEL-80 LH	TELMISARTAN + HYDROCHLOROT HIAZIDE	80 MG + 12.5 MG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI- 248197, DEHRADUN (UTTARAKHAND)	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/09/2020

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4066	NDA/MAL/HDP/9 294	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	BENYLIN WET COUGH MENTHOL	GUAIFENESIN	200 MG/10 ML	JOHNSON & JOHNSON (PTY) LTD241 MAIN ROAD, RETREAT, 7945, CAPE TOWN	SOUTH AFRICA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	08/09/2020
4067	NDA/MAL/HDP/9 295	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	TRIMIC	METRONIDAZOLE + MICONAZOLE NITRATE	500 MG + 100 MG	BLISS GVS PHARMA LIMITED10,11 & 12,DEWAN UDYOG NAGAR,ALIYALI,PALG HAR,MAHARASHTRA 401404,INDIA	INDIA	VAGINAL SUPPOSITORIES	1.0X2.0X7.0 SUPPOSITORY STRIP	25/09/2020

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4068	NDA/MAL/HDP/9 296	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	VAGID-CL	CLINDAMYCIN + CLOTRIMAZOLE	100 MG + 200 MG	BLISS GVS PHARMA LIMITED 10,11 & 12, DEWAN UDYOG NAGAR, ALIYALI, PALG HAR, MAHARASHTRA 401404, INDIA	INDIA	VAGINAL SUPPOSITORIES	1.0X1.0X3.0 SUPPOSITORY STRIP	08/09/2020
4069	NDA/MAL/HDP/9 305	KOPRAN LIMITED	TATA UGANDA LIMITED	CELEKOP-200	CELECOXIB	200MG	KOPRAN LIMITED VILLAGE - SAVROLI (KHOPOLI), TALUKA - KHALAPUR, DIST. RAIGAD 410202, MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	08/09/2020

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4070	NDA/MAL/HDP/9 306	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	FUNBACT-A	CLOTRIMAZOLE + BETAMETHASONE DIPROPIONATE + NEOMYCIN SULFATE	1.0 % W/W + 0.05 % W/W + 0.5 % W/W	KREMOINT PHARMA PVT LTD. B-8, ADDITIONAL AMBERNATH M.I.D.C, OPP. ANAND NAGIAR POLICE CHECK POST, AMBERNATH (E), DIST. THANE.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	08/09/2020
4071	NDA/MAL/HDP/9 313	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GSUNATE-30	ARTESUNATE	30 MG/VIAL	BLISS INDAS LIFESCIENCE P. LTD..PLOT 73-76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 VIAL CARTON + 0.5 ML OF 5.0 %W/V SODIUM BICARBONATE VIAL + 2.5 ML OF 0.9% W/V SODIUM CHLORIDE VIAL	08/09/2020

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4072	NDA/MAL/HDP/9 314	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	GVITHER FORTE INJECTION	ARTEMETHER	80 MG/ML	BLISS INDAS LIFESCIENCE P. LTD.- PLOT 73-76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE,1.0X6.0X 1.0 ML AMPOULE	08/09/2020
4073	NDA/MAL/HDP/9 315	CENTAUR PHARMACEUTICAL S PVT. LTD	GITTOES PHARMACEUTICAL S LIMITED	ACETAMOX	ACETAZOLAMIDE	250 MG	CENTAUR PHARMACEUTICALS PVT. LTD (PLANT 1)PLOT 3,5B, 2C TIVIM INDUSTRIAL ESTATE, KARASVADA, MAPUSA, GOA 403526	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/09/2020

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4074	NDA/MAL/HDP/9 316	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	TERBIDERM	TERBINAFINE HYDROCHLORIDE	1% W/W	ATCO LABS LTD,B-18, S.I.T.E, KARACHI	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE	08/09/2020
4075	NDA/MAL/HDP/9 318	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD	HEALTHCARE LTD.	FLOTIZOL	CLOTRIMAZOLE	1%W/W	AL FAZAL PHARMA INDUSTRIES (PVT) LTD-PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	25/09/2020

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4076	NDA/MAL/HDP/9 322	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	DOLUTEGRAVIR, LAMIVUDINE AND TENOFIVIR DISOPROXIL FUMARATE TABLETS	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFIVIR DISOPROXIL FUMARATE	50 MG + 300 MG + 300 MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED (CIPLAQCIL)PLOT 1- 7, 1ST RING ROAD, LUZIRA INDUSTRIAL PARK	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER,1.0X90. 0 TABLET CONTAINER,1.0X18 0.0 TABLET CONTAINER	08/09/2020
4077	NDA/MAL/HDP/9 324	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	PROP PLUS	IBUPROFEN + PARACETAMOL	400 MG + 325 MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,10.0X1.0X1 0.0 TABLET BLISTER	08/09/2020

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4078	NDA/MAL/HDP/9 325	BESINS HEALTHCARE SA	SURGIPHARM (U) LIMITED	OESTROGEL	ESTRADIOL HEMIHYDRATE	0.06W/W	BESINS MANUFACTURING BELGIUM (BMB)GROOT BIJGAARDENSTRAAT, 128. 1620	BELGIUM	TOPICAL EXTERNAL GELS AND SOLS	1.0X1.0X80.0 G CONTAINER	08/09/2020
4079	NDA/MAL/HDP/9 327	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	OXCIN-D	MOXIFLOXACIN + DEXAMETHASON E SODIUM PHOSPHATE	0.5%W/V + 0.1% W/V	ATCO LABS LTD,B-18, S.I.T.E, KARACHI	PAKISTAN	OPHTHALMIC DROPS	1.0X1.0X5.0 ML CONTAINER	08/09/2020



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4080	NDA/MAL/HDP/9 331	BKRS PHARMA PVT. LTD.	VEERAM HEALTHCARE (U) LIMITED	PARA-BKRS	PARACETAMOL	1.0%W/V	HIGGS HEALTHCARE PVT. LIMITEDKHASRA NO. 480/1, BHATOLIKALAN BADDI, DISTT SOLAN, (H.P) - INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	26/10/2020
4081	NDA/MAL/HDP/9 345	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	FLUCONAZOLE INJECTION USP (2MG/ML)	FLUCONAZOLE	2MG/ML	ABARIS HEALTHCARE PVT. LTDSURVEY NO. 1407/11, VILLAGE RAJPUR, TAL KADI DIST. MEHSANA, GUJARAT-382740	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1X100 ML BOTTLE	22/12/2020

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4082	NDA/MAL/HDP/9 350	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICAL S LIMITED	NUROFEN	IBUPROFEN LYSINE	684MG	ASTRA ZENECA TURKEYNOTTINGHA M SITE, THANE ROAD, NOTTINGHAM, NOTTINGHAMSHIRE, NG90 2DB, UNITED KINGDOM	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X12.0 TABLET BLISTER	09/12/2020
4083	NDA/MAL/HDP/9 353	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	LUMITER DT	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	OXALIS LABS LIMITEDVILLAGE THEDA, P.O LODHIMAJRA, TEHSIL,BADDI, DIST.SOLAN, INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X6.0 TABLET BLISTER,1.0X2.0X6. 0 TABLET BLISTER,1.0X30.0X6 .0 TABLET BLISTER,1.0X30.0X2 .0X6.0 TABLET BLISTER,1.0X1.0X12 .0 TABLET BLISTER,30.0X1.0X1 2.0 TABLET BLISTER	09/12/2020

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4084	NDA/MAL/HDP/9 355	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	PLATINEX	CISPLATIN	1MG/ML	KHANDELWAL LABORATORIES PVT. LTDB-1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1X1X10 ML VIAL	22/12/2020
4085	NDA/MAL/HDP/9 356	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	IRIS	DESLORATADINE	5MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/12/2020

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4086	NDA/MAL/HDP/9 365	HETERO BIOPHARMA LIMITED,	AIVEEN (U) LIMITED	BEVAAS 100	BEVACIZUMAB	100MG/4ML	HETERO BIOPHARMA LIMITEDSY. NO. 458 (PART), TSIC- FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL MAHABOONAGAR DISTRICT – 509 301, TELANGANA STATE, INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X4.0 ML VIAL	09/12/2020
4087	NDA/MAL/HDP/9 366	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TOBRASON	TOBRAMYCIN + DEXAMETHASON E	3 MG + 1 MG/1G	AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	JORDAN	OPHTHALMIC OINTMENTS	1.0X1.0X5.0 MG TUBE	09/12/2020

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4088	NDA/MAL/HDP/9 368	HETERO BIOPHARMA LIMITED,	AIVEEN (U) LIMITED	BEVAAS 400	BEVACIZUMAB	400MG/16ML	HETERO BIOPHARMA LIMITEDSY. NO. 458 (PART), TSIIC- FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL MAHABOBNAGAR DISTRICT – 509 301, TELANGANA STATE, INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X16.0 ML VIAL	09/12/2020
4089	NDA/MAL/HDP/9 370	RAINBOW LIFE SCIENCES PVT.LTD.	EUROPA HEALTHCARE (U) LTD	MONTLIV	MONTELUKAST + LEVOCETIRIZINE DIHYDROCHLORID E	10 MG+ 5 MG	GLOBELA PHARMA PVT.LTD.357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	09/12/2020

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4090	NDA/MAL/HDP/9 371	MEDINOVATION ENTERPRISES LTD	MEDINOVATION ENTERPRISES LTD	MEDSUNATE- 60	ARTESUNATE	60MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA BLISS INDASI LIFESCIENCE PRIVATE LIMITED PLOT NO. 73 TO 76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN- 396 210	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + (1*5 ML AMPOULE OF 0.9%W/V NACL + 1*1 ML AMPOULE OF 5%W/V NAHCO3)	09/12/2020
4091	NDA/MAL/HDP/9 376	KOPRAN LIMITED	TATA UGANDA LIMITED	AZ-1 500	AZITHROMYCIN DIHYDRATE	500 MG	KOPRAN LIMITED VILLAGE - SAVROLI (KHOPOLI), TALUKA - KHALAPUR, DIST. RAIGAD 410202, MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X1.0X3.0 TABLET BLISTER	09/12/2020

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4092	NDA/MAL/HDP/9 377	KOPRAN LIMITED	TATA UGANDA LIMITED	AMYN DT 250	AMOXICLLIN TRIHYDRATE	250 MG	KOPRAN LIMITEDVILLAGE - SAVROLI (KHOPOLI), TALUKA - KHALAPUR, DIST. RAIGAD 410202, MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X3.0X15.0 TABLET STRIP,10.0X10.0 TABLET STRIP	09/12/2020
4093	NDA/MAL/HDP/9 379	KOPRAN LIMITED	TATA UGANDA LIMITED	AMYN DT 125	AMOXICILLIN TRIHYDRATE	125 MG	KOPRAN LIMITEDVILLAGE - SAVROLI (KHOPOLI), TALUKA - KHALAPUR, DIST. RAIGAD 410202, MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X3.0X15.0 TABLET STRIP,10.0X10.0 TABLET STRIP	09/12/2020

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4094	NDA/MAL/HDP/9 381	POPULATION SERVICES INTERNATIONAL, UGANDA (PSIU)	POPULATION SERVICES INTERNATIONAL - UGANDA	PRONTA 1	LEVONORGESTRE L	1.5 MG	MYLAN LABORATORIES LIMITED PLOT NO. 20 & 21, PHARMEZ, SARKHEJ - BAVLA, NATIONAL HIGHWAY NO. 8 - A, NEAR VILLAGE - MATODA, TAL - SANAND, DIST., AHMEDABAD - 382213	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X1.0 TABLET BLISTER	09/12/2020
4095	NDA/MAL/HDP/9 383	SUN PHARMACEUTICAL INDUSTRIES LTD	STAR PHARMACEUTICAL S LTD	DOLUTEGRAVIR, LAMIVUDINE, TENOFIVIR DISOPROXIL FUMARATE TABLETS	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFIVIR DISOPROXIL FUMARATE	50 MG + 300 MG + 300 MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED) VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER, 1.0X1.0 X90.0 TABLET CONTAINER	09/12/2020



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4096	NDA/MAL/HDP/9 385	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BRUZOLIN	XYLOMETAZOLINE HYDROCHLORIDE	0.05% W/V	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	NASAL SYSTEMIC DROPS	1.0X1.0X15.0 ML BOTTLE	09/12/2020
4097	NDA/MAL/HDP/9 388	CONCEPT PHARMACEUTICAL S LTD	JEET PHARMACEUTICAL S LIMITED	IRON SUCROSE INJECTION USP 20 MG/ML	FERRIC HYDROXIDE + SUCROSE	20 MG /ML	CONCEPT PHARMACEUTICALS LIMITEDKISHANPUR JAMALPUR ROORKEE DIST HARIDWAR - 247667 UTTARAKHAND, INDIA.	INDIA	PARENTERAL ORDINARY INFUSION AMPOULES	1.0X5.0X10.0 ML AMPOULE	18/12/2020

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4098	NDA/MAL/HDP/9 393	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	LESS-K	CALCIUM POLYSTYRENE SULFONATE	5 GM/SACKET	MEGA LIFESCIENCES PUBLIC COMPANY LTDPLANT 2; 515/1 MOO 4, SOI 8 BANGPOO INDUSTRIAL ESTATE PATTANA 3 ROAD, PHRAEKSA, MUEANG, SAMUTPRAKARN 10280, THAILAND	THAILAND	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0X5.0 G SACHET	09/12/2020
4099	NDA/MAL/HDP/9 394	HETERO LABS LTD	AIVEEN (U) LIMITED	TEMOTERO 100	TEMOZOLOMIDE	100MG	HETERO LABS LIMITED (UNIT VI)APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGER DISTRICT ANDHRA PRADESH-509301	INDIA	ORAL SOLID ORDINARY CAPSULES	1X1X5 CAPSULE BOTTLE	22/12/2020

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4100	NDA/MAL/HDP/9 395	HETERO LABS LTD	AIVEEN (U) LIMITED	TEMOTERO 250	TEMOZOLOMIDE	250MG	HETERO LABS LIMITED (UNIT VI)APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGER DISTRICT ANDHRA PRADESH-509301	INDIA	ORAL SOLID ORDINARY CAPSULES	1X1X5 CAPSULE BOTTLE	22/12/2020
4101	NDA/MAL/HDP/9 401	BESINS HEALTHCARE SA	SURGIPHARM (U) LIMITED	UTROGESTAN	PROGESTERONE	100 MG	CYNDEA PHARMA, S.LPOLIGONO INDUSTRIAL EMILIANO REVILLA SANZ. AVDA. DE AGREDA, 31 OLVEGA 42110 (SORIA)	SPAIN	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X15.0 CAPSULE BLISTER	09/12/2020

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4102	NDA/MAL/HDP/9 403	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	LARTEM	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	S KANT HEALTHCARE LIMITED1802 – 1805, G.I.D.C., PHASE III, VAPI -396195 GUJARAT, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X24.0 TABLET BLISTER	09/12/2020
4103	NDA/MAL/HDP/9 404	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SOFTDROPS	CARBOXYMETHYL CELLULOSE SODIUM + GLYCERIN	0.5% W/V + 0.5% W/V	CIRON DRUGS AND PHARMACEUTICALS PVT LTD .N-118, 118/1, 119, 119/1, 119/2, 113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, MAHARASHTRA STATE AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML BOTTLE	09/12/2020

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4104	NDA/MAL/HDP/9 408	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	ZIRIN	CETIRIZINE DIHYDROCHLORID E	10 MG	MEGA LIFESCIENCES PUBLIC COMPANY LTDPLANT 2; 515/1 MOO 4, SOI 8 BANGPOO INDUSTRIAL ESTATE PATTANA 3 ROAD, PHRAEKSA, MUEANG, SAMUTPRAKARN 10280, THAILAND	THAILAND	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X5.0X10.0 CAPSULE BLISTER	09/12/2020
4105	NDA/MAL/HDP/9 409	HETERO LABS LTD	AIVEEN (U) LIMITED	STAVANCE 500	VANCOMYCIN HYDROCHLORIDE	500 MG/VIAL	ASPIRO PHARMA LIMITEDSY. NO. 321, BIOTECH PARK, PHASE-III, KARKAPATLA, MARKOOK MANDAL, SIDDIPET DISTRICT- 502 281, TELANGANA, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X500.0 MG VIAL	09/12/2020

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4106	NDA/MAL/HDP/9 410	HETERO LABS LTD	AIVEEN (U) LIMITED	STAVANCE 1	VANCOMYCIN HYDROCHLORIDE	1G/VIAL	ASPIRO PHARMA LIMITEDSY. NO. 321, BIOTECH PARK, PHASE-III, KARKAPATLA, MARKOOK MANDAL, SIDDIPET DISTRICT- 502 281, TELANGANA, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL	09/12/2020
4107	NDA/MAL/HDP/9 411	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CONCOR AMLO 5 +5	BISOPROLOL FUMARATE + AMLODIPINE BESILATE	5MG + 5MG	EGIS PHARMACEUTICALS PLCBOKENYFOLDI UT 118-120, 1165 BUDAPEST	HUNGARY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/12/2020

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4108	NDA/MAL/HDP/9 412	SAGA LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	EBASTO - 10	EBASTINE	10 MG	SAGA LIFESCIENCES LIMITEDSURVEY NO. 198/2 & 198/3, CHACHRAWADI VASNA, TA-SANAND, DIST. AHMEDABAD - 382210, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	09/12/2020
4109	NDA/MAL/HDP/9 413	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CONCOR AMLO 10 + 5	BISOPROLOL FUMARATE + AMLODIPINE BESILATE	10MG + 5MG	EGIS PHARMACEUTICALS PLCBOKENYFOLDI UT 118-120, 1165 BUDAPEST	HUNGARY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/12/2020

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4110	NDA/MAL/HDP/9 415	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CONCOR AMLO 10 + 10	BISOPROLOL FUMARATE + AMLODIPINE BESILATE	10MG + 10MG	EGIS PHARMACEUTICALS PLCBOKENYFOLDI UT 118-120, 1165 BUDAPEST	HUNGARY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/12/2020
4111	NDA/MAL/HDP/9 416	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CONCOR AMLO 5 + 10	BISOPROLOL FUMARATE + AMLODIPINE BESILATE	5MG + 10MG	EGIS PHARMACEUTICALS PLCBOKENYFOLDI UT 118-120, 1165 BUDAPEST	HUNGARY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/12/2020



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4112	NDA/MAL/HDP/9 418	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	EFAVIRENZ, LAMIVUDINE AND TENOFIVIR DISOPROXIL FUMARATE TABLETS	EFAVIRENZ + LAMIVUDINE + TENOFIVIR DISOPROXIL FUMARATE	400 MG + 300 MG + 300 MG	LAURUS LABS LTD (UNIT 2)PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTAM, ANDRA PRADESH,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER,1.0X90. 0 TABLET CONTAINER,1.0X18 0.0 TABLET CONTAINER	09/12/2020
4113	NDA/MAL/HDP/9 421	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MUCOSIL AM	TERBUTALINE SULFATE + GUAIFENESIN + AMBROXOL HYDROCHLORIDE + MENTHOL	1.25 MG + 50 MG + 15 MG + 2.5 MG/5 ML	RAVIAN LIFE SCIENCE PVT LTD PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	09/12/2020

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4114	NDA/MAL/HDP/9 424	PHARCO B INTERNATIONAL,	GAMA PHARMACEUTICAL S (U) LIMITED	CEFAXONE 1G I.V.	CEFTRIAZONE SODIUM HYDRATE	1G	PHARCO-B INTERNATIONAL PHARMACEUTICALS ORG EL-ARAB 3D INDUSTRIAL ZONE, BLOCK 18 AREA, 10, 11, ALEXANDRIA EGYPT	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	09/12/2020
4115	NDA/MAL/HDP/9 426	PHARCO B INTERNATIONAL,	GAMA PHARMACEUTICAL S (U) LIMITED	CEFAXONE 2G I.V.	CEFTRIAZONE SODIUM HYDRATE	2G	PHARCO-B INTERNATIONAL PHARMACEUTICALS ORG EL-ARAB 3D INDUSTRIAL ZONE, BLOCK 18 AREA, 10, 11, ALEXANDRIA EGYPT	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X2.0 G VIAL	09/12/2020

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4116	NDA/MAL/HDP/9 428	LUPIN LIMITED	AIVEEN (U) LIMITED	RIFAMPIN AND ISONIAZID DISPERSIBLE TABLETS	RIFAMPIN + ISONIAZID	75 MG + 50 MG	LUPIN LIMITED A- 28/1 MIDC CHIKALTHANA AURANGABAD	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X14.0X6.0 TABLET STRIP	09/12/2020
4117	NDA/MAL/HDP/9 430	SAGA LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	VALK PLUS SP	ACECLOFENAC + PARACETAMOL+ SERRATIOPEPTID ASE	100 MG + 500 MG +10 MG	SAGA LIFESCIENCES LIMITEDSURVEY NO. 198/2 & 198/3, CHACHRAWADI VASNA, TA-SANAND, DIST. AHMEDABAD - 382210, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1.0X10 .0 TABLET BLISTER	09/12/2020

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4118	NDA/MAL/HDP/9 431	INTAS PHARMACEUTICAL S LIMITED	NORVIK ENTERPRISES LIMITED	NALTRAS 50	NALTREXONE HYDROCHLORIDE	50 MG	INTAS PHARMACEUTICALS LTD.PLOT NO. 457, 458, & 191/218P,VILLAGE: MATODA, TAL. SANAND, AHMEDABAD, GUJARAT, 382210 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	09/12/2020
4119	NDA/MAL/HDP/9 432	MEDISEL(K) LTD	SUPER MEDIC LTD	ECOFREE 120	ETORICOXIB	120MG	CORONA REMEDIES PVT. LTDVILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	22/12/2020

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4120	NDA/MAL/HDP/9 433	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ADACIN	ADAPALENE + CLINDAMYCIN PHOSPHATE	0.1 %W/W + 1.0% W/W	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X1.0X15.0 G TUBE	09/12/2020
4121	NDA/MAL/HDP/9 434	INFUGEN PHARMA PVT. LTD.	TATA UGANDA LIMITED	LAVAGEM	BISACODYL	5MG	FREDUN PHARMACEUTICALS LIMITED14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PA LGHAR (E), DIST: PALGHAR-401 404	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	09/12/2020

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4122	NDA/MAL/HDP/9 436	SAKAR HEALTHCARE PVT LTD	TATA UGANDA LIMITED	SEFIXI-200	CEFIXIME TRIHYDRATE	200MG	SAKAR HEALTHCARE PVT LIMITED PLOT 10/13 SARKHEJ- BAVLA ROAD, AHMEDABAD, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	09/12/2020
4123	NDA/MAL/HDP/9 439	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	HYFRESH	SODIUM HYALURONATE	0.2% W/V	JAMJOOM PHARMACEUTICALS CO. PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	OPHTHALMIC LIQUIDS	1.0X1.0X10.0 ML BOTTLE	18/12/2020

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4124	NDA/MAL/HDP/9 440	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	XOLAMOL	DORZOLAMIDE HYDROCHLORIDE + TIMOLOL MALEATE	2%W/V + 0.5%W/V/ML	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	09/12/2020
4125	NDA/MAL/HDP/9 444	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	LATANOCOM	LATANOPROST + TIMOLOL MALEATE	0.005% W/W + 0.5% W/W	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	OPHTHALMIC DROPS	1.0X1.0X2.5 ML BOTTLE	18/12/2020

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4126	NDA/MAL/HDP/9 445	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	SURECURE GEL	ADAPALENE	0.1% W/W	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	TOPICAL EXTERNAL GELS AND SOLS	1X1X30 G TUBE	18/12/2020
4127	NDA/MAL/HDP/9 446	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	FUSIBACT	SODIUM FUSIDATE	2%W/W	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X15.0 G TUBE	18/12/2020



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4128	NDA/MAL/HDP/9 447	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	FUSIBACT-B	FUSIDIC ACID + BETAMETHASONE VALERATE	2% W/W + 0.1% W/W	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	09/12/2020
4129	NDA/MAL/HDP/9 448	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	ELICA	MOMETASONE FUROATE	0.1%W/W	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X30.0 G TUBE	18/12/2020

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4130	NDA/MAL/HDP/9 449	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	ELICASAL	MOMETASONE FUROATE + SALICYLIC ACID	0.1% W/W + 5.0% W/W	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X30.0 G TUBE	18/12/2020
4131	NDA/MAL/HDP/9 452	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BNOXIPARIN 40	ENOXAPARIN SODIUM	40 MG/0.4 ML	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X0.4 ML PRE- FILLED SYRINGE	09/12/2020

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4132	NDA/MAL/HDP/9 453	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BNOXIPARIN 60	ENOXAPARIN SODIUM	60 MG/0.6 ML	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X0.6 ML PRE- FILLED SYRINGE	09/12/2020
4133	NDA/MAL/HDP/9 455	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	BISPEC-5	SOLIFENACIN SUCCINATE	5MG	CIPLA LTD, GOA UNIT V & UNIT XL-139, S- 103&M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	09/12/2020

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4134	NDA/MAL/HDP/9 456	CIPLA LTD	ABACUS PHARMA (AFRICA) LIMITED	BISPEC-10	SOLIFENACIN SUCCINATE	10MG	CIPLA LTD, GOA UNIT V & UNIT XL-139, S- 103&M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	09/12/2020
4135	NDA/MAL/HDP/9 481	BKRS PHARMA PVT. LTD.	VEERAM HEALTHCARE (U) LIMITED	OFLO-BKRS	OFLOXACIN	0.2% W/V	HIGGS HEALTHCARE PVT. LIMITED KHASRA NO. 480/1, BHATOLIKALAN BADDI, DIST SOLAN, (H.P) - INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	09/12/2020

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4136	NDA/MAL/HDP/9 490	INFUGEN PHARMA PVT. LTD.	TATA UGANDA LIMITED	IPEN-CIL	IMIPENEM + CILASTATIN	500 MG + 500 MG/VIAL	ZEISS PHARMACEUTICALS PVT LTD - PLOT 72, EPIP, PHASE 1, JHARMAJRI BADDI, 173205, DIST: SOLAN HIMACHAL PRADESH, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	09/12/2020
4137	NDA/MAL/HDP/9 494	ZIM LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	ONDANSET ODS 8	ONDANSETRON HYDROCHLORIDE	8 MG/STRIP	ZIM LABS LTD.B 21/22, MIDC AREA, KALMESHWAR 441501, DIST- NAGPUR	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0X1.0 TABLET STRIP	24/02/2021

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4138	NDA/MAL/HDP/9 500	POPULATION SERVICES INTERNATIONAL, UGANDA (PSIU)	POPULATION SERVICES INTERNATIONAL - UGANDA	MEURI	DESOGESTREL + ETHINYLESTRADI OL	150MCG + 30MCG	MYLAN LABORATORIES LIMITED PLOT NO. 20 & 21, PHARMEZ, SARKHEJ - BAVLA, NATIONAL HIGHWAY NO. 8 - A, NEAR VILLAGE - MATODA, TAL - SANAND, DIST., AHMEDABAD - 382213	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X28.0 TABLET BLISTER	24/02/2021
4139	NDA/MAL/HDP/9 501	BESINS HEALTHCARE SA	SURGIPHARM (U) LIMITED	UTROGESTAN VAGINAL 100 MG	PROGESTERONE	100 MG	CYNDEA PHARMA, S.L.POLIGONO INDUSTRIAL EMILIANO REVILLA SANZ. AVDA. DE AGREDA, 31 OLVEGA 42110 (SORIA)	SPAIN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X15.0 CAPSULE BLISTER	24/02/2021

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4140	NDA/MAL/HDP/9 502	BESINS HEALTHCARE SA	SURGIPHARM (U) LIMITED	UTROGESTAN VAGINAL 200 MG	PROGESTERONE	200 MG	CYNDEA PHARMA, S.LPOLIGONO INDUSTRIAL EMILIANO REVILLA SANZ. AVDA. DE AGREDA, 31 OLVEGA 42110 (SORIA)	SPAIN	VAGINAL CAPSULES	1.0X1.0X7.0X1.0X8. 0 CAPSULE BLISTER	24/02/2021
4141	NDA/MAL/HDP/9 503	BESINS HEALTHCARE SA	SURGIPHARM (U) LIMITED	UTROGESTAN 200 MG SOFT CAPSULES	PROGESTERONE	200 MG	CYNDEA PHARMA, S.LPOLIGONO INDUSTRIAL EMILIANO REVILLA SANZ. AVDA. DE AGREDA, 31 OLVEGA 42110 (SORIA)	SPAIN	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X8.0X3.0X7. 0 CAPSULE BLISTER	24/02/2021

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4142	NDA/MAL/HDP/9 504	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	BETA COOL DOUBLE ACTION ANTACID SUSPENSION	SODIUM ALGINATE + SODIUM BICARBONATE	(500 MG + 267 MG)/10 ML	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO LR 209/6534 MOGADISHU ROAD	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	24/02/2021
4143	NDA/MAL/HDP/9 505	CADILA HEALTHCARE LIMITED "ZYDUS TOWER" -	ABACUS PHARMA (AFRICA) LIMITED	ODIMONT-LC	LEVOCETIRIZINE DIHYDROCHLORID E + MONTELUKAST	5 MG + 10 MG	RAVIAN LIFE SCIENCE PVT LTD PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/02/2021



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4144	NDA/MAL/HDP/9 506	TROIKAA PHARMACEUTICAL S LTD	ABACUS PHARMA (AFRICA) LIMITED	TROFENTYL	FENTANYL CITRATE	50 MCG/ML	TROIKAA PHARMACEUTICALS LIMITED,,C-1, SARA INDUSTRIAL ESTATE, SELAQUI, DEHRADUN-248197, UTTARAKHAND	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE	24/02/2021
4145	NDA/MAL/HDP/9 510	PLANET PHARMACEUTICAL S UGANDA LTD	PLANET PHARMACEUTICAL S UGANDA LTD	GEODERM	BETAMETHASONE DIPROPIONATE + GENTAMICIN SULFATE + CLOTRIMAZOLE	(0.5 MG + 1.0 MG + 10.0 MG)/G	KREMOINT PHARMA PVT LTD PLANT IIB-8, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST) DIST. THANE 421506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE,1.0X30.0 G TUBE	24/02/2021

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4146	NDA/MAL/HDP/9 511	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	SPASNIL FORTE TABLET	MEFENAMIC ACID + DICYCLOMINE HYDROCHLORIDE	250 MG + 10 MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/02/2021
4147	NDA/MAL/HDP/9 513	ALTHEA PHARMA PVT LTD.	JOINT MEDICAL STORE (UPMB - UCMB)	METRONIDAZOLE INFUSION BP	METRONIDAZOLE	0.5% W/V	ALTHEA PHARMA PRIVATE LIMITEDWORKS: PLOT NO. 374, SHED NO. 'E', ALPHA INDL. PARK, ATHIAWAD, DABHEL, NANI DAMAN - 396210 (U.T.), INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	24/02/2021

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4148	NDA/MAL/HDP/9 514	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	BACTAFUZ	FUSIDIC ACID	2% W/W	ENCUBE ETHICALS PVT LTD PLOT C-1, MADKAIM INDUSTRIAL ESTATE, MADKAIM, POST: MARDOL, PONDA GOA-403404	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	24/02/2021
4149	NDA/MAL/HDP/9 515	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	BACTAFUZ-B	FUSIDIC ACID + BETAMETHASONE VALERATE	2% W/W + 0.1%W/W	ENCUBE ETHICALS PVT LTD PLOT C-1, MADKAIM INDUSTRIAL ESTATE, MADKAIM, POST: MARDOL, PONDA GOA-403404	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	24/02/2021

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4150	NDA/MAL/HDP/9 525	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	SPAQ-CO DISP	(SULFADOXINE + PYRIMETHAMINE) + AMODIAQUINE HYDROCHLORIDE	(250 MG + 12.5 MG) +76.5 MG	GUILIN PHARMACEUTICAL CO LTD .NO. 43, QULIDIAN ROAD, GUILIN 541004	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X1.0X4.0 TABLET BLISTER, 1.0X25.0X1.0X12.0 TABLET BLISTER	24/02/2021
4151	NDA/MAL/HDP/9 526	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	SPAQ-CO DISP	(SULFADOXINE + PYRIMETHAMINE) + AMODIAQUINE HYDROCHLORIDE	(500 MG + 25 MG) +153 MG	GUILIN PHARMACEUTICAL CO LTD .NO. 43, QULIDIAN ROAD, GUILIN 541004	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X1.0X4.0 TABLET BLISTER	24/02/2021

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4152	NDA/MAL/HDP/9 533	LUPIN LTD	AIVEEN (U) LIMITED	ISONIAZID TABLETS BP 100MG	ISONIAZID	100 MG	LUPIN LTDA-28/1, M.I.D.C., CHIKALTHANA, AURANGABAD- 431210, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	24/02/2021
4153	NDA/MAL/HDP/9 534	B&O PHARM	TRIDEM PHARMA UGANDA LIMITED	PHLORO-G	PHLOROGLUCINO L DIHYDRATE	80MG	GUILIN PHARMACEUTICAL CO LTD .NO. 43, QULIDIAN ROAD, GUILIN 541004	CHINA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X1.0X10.0 TABLET BLISTER	24/02/2021

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4154	NDA/MAL/HDP/9 535	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO DURATAZ INJECTION 4.5 G	PIPERACILLIN + TAZOBACTAM	(4 G + 0.5 G)/VIAL	ARISTO PHARMACEUTICALS PVT LTD PLOT 208, NEW INDUSTRIAL AREA NO. 2, MANDIDEEP 462046 DIST. RAISEN (MP)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X4.5 G VIAL	24/02/2021
4155	NDA/MAL/HDP/9 537	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	SENSOCAIN SPINAL 0.5% INJECTION	BUPIVACAINE HYDROCHLORIDE	5MG/ML	BROOKES PHARMA (PRIVATE) LIMITED 58 59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X5.0X4.0 ML AMPOULE	24/02/2021

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4156	NDA/MAL/HDP/9 538	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	ECZEMUS 0.1 % OINTMENT	TACROLIMUS MONOHYDRATE	0.1% W/W	BROOKES PHARMA (PRIVATE) LIMITED58 59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	TOPICAL EXTERNAL OINTMENTS	1.0X10.0 G TUBE	24/02/2021
4157	NDA/MAL/HDP/9 541	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	ERLOCIP 25	ERLOTINIB HYDROCHLORIDE	25MG	CIPLA LTDUNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	24/02/2021

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4158	NDA/MAL/HDP/9 542	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	ERLOCIP 100	ERLOTINIB HYDROCHLORIDE	100MG	CIPLA LTDUNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	24/02/2021
4159	NDA/MAL/HDP/9 543	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	ERLOCIP 150	ERLOTINIB HYDROCHLORIDE	150MG	CIPLA LTDUNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	24/02/2021



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4160	NDA/MAL/HDP/9 549	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	DUOSKIN	ISOCONAZOLE NITRATE + DIFLUCORTOLON E VALERATE	1% W/W + 0.1% W/W	BILIM ILAC SAN.VE TIC.A.SGEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY	TURKEY	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	04/03/2021
4161	NDA/MAL/HDP/9 550	OCTOBER PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BRONCHOPRO	AMBROXOL HYDROCHLORIDE	7.5MG/ML	OCTOBER PHARMA1ST INDUSTRIAL ZONE, STREET 25 PLOT 190, 6TH OCTOBER CITY CAIRO, ARAB REPUBLIC OF EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X30.0 ML BOTTLE	24/02/2021

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4162	NDA/MAL/HDP/9 551	DEVA HOLDING A.S	SHREEJI PHARMACEUTICAL S LIMITED	LUXAT	MONTELUKAST SODIUM	10MG	DEVA HOLDING A.SCERKEZKOY ORGANIZE SANAYI BOLGESI, KARAAGAC MAH., ATATURK CAD., NO.: 32 KAPAKLI TEKIRDAG	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	24/02/2021
4163	NDA/MAL/HDP/9 552	INFUGEN PHARMA PVT. LTD.	TATA UGANDA LIMITED	HOPEIN 1000 MG	MEROPENEM TRIHYDRATE	1000MG	ZEISS PHARMACEUTICALS PVT LTD - PLOT 72, EPIP, PHASE 1, JHARMAJRI BADDI, 173205, DIST: SOLAN HIMACHAL PRADESH, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	24/02/2021

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4164	NDA/MAL/HDP/9557	MEDIPHARM INDUSTRIES (E.A) LTD	MEDIPHARM INDUSTRIES (E.A) LTD	MEDIACTIN	CYPROHEPTADINE HYDROCHLORIDE	2 MG/5 ML	MEDIPHARM INDUSTRIES (E.A.) LTD (PLOT 65 KAKAJJO ROAD, BWEYOGERERE)	UGANDA	ORAL LIQUID ORDINARY LIQUIDS	1.0X60.0 ML Bottle	04/03/2021
4165	NDA/MAL/HDP/9576	SAVA HEALTHCARE LIMITED -	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	FLUTIAIR	FLUTICASONE PROPIONATE	0.05%W/V	SAVA HEALTHCARE LIMITED.PLOT NO 507B -512, G.I.D.C. ESTATE, WADHWANCITY-363 035 SURENDRANAGAR, GUJARAT, INDIA	INDIA	NASAL TOPICAL SPRAYS WITHOUT GAS	1.0X1.0X10.0 ML VIAL	24/02/2021

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4166	NDA/MAL/HDP/9 586	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	AMVA DENK 5/160 MG	AMLODIPINE + VALSARTAN	5 MG + 160 MG	BALKANPHARMA- DUPNITSA AD3, SAMOKOVSKO SHOSSE STR. 2600 DUPNITSA	BULGARIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	02/06/2021
4167	NDA/MAL/HDP/9 588	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	AMVA DENK 10/160 MG	AMLODIPINE BESILATE + VALSARTAN	10 MG + 160 MG	BALKANPHARMA- DUPNITSA AD3, SAMOKOVSKO SHOSSE STR. 2600 DUPNITSA	BULGARIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	02/06/2021

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4168	NDA/MAL/HDP/9 589	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	CLOFAZIMINE TABLETS 100MG	CLOFAZIMINE	100 MG	OXALIS LABVILLAGE THEDA, P.O. LODHIMAJRA, TEHSIL BADDI, DIST. SOLAN (HP) PIN CODE 174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	02/06/2021
4169	NDA/MAL/HDP/9 590	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	AMVA DENK 5/80 MG	AMLODIPINE BESILATE + VALSARTAN	5 MG + 80 MG	BALKANPHARMA- DUPNITSA AD3, SAMOKOVSKO SHOSSE STR. 2600 DUPNITSA	BULGARIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	02/06/2021

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4170	NDA/MAL/HDP/9 591	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	AZITIZ-500	AZITHROMYCIN DIHYDRATE	500 MG	ZOTA HEALTHCARE LIMITED PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY STATION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X1X3 TABLET BLISTER	04/06/2021
4171	NDA/MAL/HDP/9 594	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	ROSUVASTATIN DENK 10 MG	ROSUVASTATIN CALCIUM	10 MG	PHARMACEUTICAL WORKS POLPHARMA SA (ZAKLADY FARMACEUTYCZNE POLPHARMA SA)-19 PELPLINSKA STREET, 83-200 STAROGARD GDANSKI	POLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/06/2021

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4172	NDA/MAL/HDP/9 595	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	ROSUVASTATIN DENK 20 MG	ROSUVASTATIN CALCIUM	20 MG	PHARMACEUTICAL WORKS POLPHARMA SA (ZAKLADY FARMACEUTYCZNE POLPHARMA SA)-19 PELPLINSKA STREET, 83-200 STAROGARD GDANSKI	POLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/06/2021
4173	NDA/MAL/HDP/9 596	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	ROSUVASTATIN DENK 5 MG	ROSUVASTATIN CALCIUM	5 MG	PHARMACEUTICAL WORKS POLPHARMA SA (ZAKLADY FARMACEUTYCZNE POLPHARMA SA)-19 PELPLINSKA STREET, 83-200 STAROGARD GDANSKI	POLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/06/2021

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4174	NDA/MAL/HDP/9 597	S KANT HEALTHCARE LTD -	ABACUS PHARMA (AFRICA) LIMITED	MALACURE	SULFADOXINE + PYRIMETHAMINE	500 MG + 25 MG	S KANT HEALTHCARE LIMITED1802 – 1805, G.I.D.C., PHASE III, VAPI -396195 GUJARAT, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	03/06/2021
4175	NDA/MAL/HDP/9 600	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VIVAZAC 150 MG	IRBESARTAN	150 MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/06/2021



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4176	NDA/MAL/HDP/9 601	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SENERGY 5/160MG	AMLODIPINE BESYLATE + VALSARTAN	5 MG + 160 MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/06/2021
4177	NDA/MAL/HDP/9 602	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SENERGY 10/160MG	AMLODIPINE BESYLATE + VALSARTAN	10 MG + 160 MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/06/2021

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4178	NDA/MAL/HDP/9 603	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	KOCITAF	DOLUTEGRAVIR SODIUM + EMTRICITABINE + TENOFVIR ALAFENAMIDE FUMARATE	50 MG + 200 MG + 25 MG	MYLAN LABORATORIES LTD PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR - 454775; DIST; DHAR; MADHYA PRADESH;	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	02/06/2021
4179	NDA/MAL/HDP/9 609	ZIM LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	CETRIZIM L ODS	LEVOCETIRIZINE DIHYDROCHLORID E	5 MG	ZIM LABORATORIES LIMITED B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0 TABLET STRIP	02/06/2021

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4180	NDA/MAL/HDP/9 610	REDDYS PHARMA LIMITED	REDDYS PHARMA LIMITED	LASOFLOX-O	OFLOXACIN + ORNIDAZOLE	200 MG + 500 MG	FREDUN PHARMACEUTICALS LIMITED14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PA LGHAR (E), DIST: PALGHAR-401 404	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	02/06/2021
4181	NDA/MAL/HDP/9 611	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	ESOMAC-40 MUPS	ESOMEPRAZOLE MAGNESIUM DIHYDRATE	40 MG	CIPLA LIMITED.PLOT NO. L-139, S-103 & M-62, VERNA INDUSTRIAL ESTATE, VERNA SALCETTE, GOA, PIN 403722	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	02/06/2021

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4182	NDA/MAL/HDP/9 612	CIPLA LTD	ABACUS PHARMA (AFRICA) LIMITED	ESOMAC-20 MUPS	ESOMEPRAZOLE MAGNESIUM DIHYDRATE	20 MG	CIPLA LIMITED.PLOT NO. L-139, S-103 & M-62, VERNA INDUSTRIAL ESTATE, VERNA SALCETTE, GOA, PIN 403722	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	02/06/2021
4183	NDA/MAL/HDP/9 613	CIPLA LTD	ABACUS PHARMA (AFRICA) LIMITED	IVABEAT 5	IVABRADINE HYDROCHLORIDE	5 MG	CIPLA LTDUNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X14.0 TABLET BLISTER	02/06/2021

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4184	NDA/MAL/HDP/9 614	CIPLA LTD	ABACUS PHARMA (AFRICA) LIMITED	IVABEAT 7.5	IVABRADINE HYDROCHLORIDE	7.5 MG	CIPLA LTD UNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X14.0 TABLET BLISTER	02/06/2021
4185	NDA/MAL/HDP/9 615	ARTEPHARM CO., LTD.,	BHL HEALTHCARE LIMITED	ARTEQUICK	ARTEMISININ + PIPERAQUINE	62.5 MG + 375 MG	ARTEPHARM CO. LTD 4 ROAD STREET AVENUE ECONOMY DEVELOPMENT ZONE OF FENGSHUN COUNTY MEIZHOU CITY GUANGDONG PRONVINCE	CHINA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	02/06/2021

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4186	NDA/MAL/HDP/9 619	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROMIDE PLUS	TROPICAMIDE + PHENYLEPHRINE HYDROCHLORIDE	0.8% W/V + 5%W/V	AUROLAB LIMITEDNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU INDIA	INDIA	OPHTHALMIC LIQUIDS	1.0X1.0X5.0 ML CONTAINER	02/06/2021
4187	NDA/MAL/HDP/9 620	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICAL S LTD	DOLUTEGRAVIR TABLETS	DOLUTEGRAVIR SODIUM	50 MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	02/06/2021

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4188	NDA/MAL/HDP/9 621	FDC LIMITED -	AIVEEN (U) LIMITED	ELECTRAL-Z KIT	ZINC SULPHATE MONOHYDRATE + (SODIUM CHLORIDE + POTASSIUM CHLORIDE + SODIUM CITRATE + ANHYDROUS GLUCOSE)	20 MG + (2.6 G + 1.5 G + 2.9 G + 13.5 G)/SACHET	FDC LTD.L-56&L-57, PHASE II- D, VERNA INDUSTRIAL ESTATE, VERNA-403 722, SALCETE, GOA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X1.0X10.0 TABLET BLISTER,1.0X2.0X21 .8 G SACHET COMBIPACK	02/06/2021
4189	NDA/MAL/HDP/9 624	ADCOCK INGRAM LIMITED	SURGIPHARM (U) LIMITED	ADCO-IBUPROFEN 400 MG	IBUPROFEN	400 MG	ADCOCK INGRAM LIMITED 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE  560099, KARNATAKA STATE, INDIA	INDIA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X1.0X12.0 TABLET BLISTER	02/06/2021

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

4190	NDA/MAL/HDP/9 625	ACME FORMULATION PVT. LTD.	POPULATION SERVICES INTERNATIONAL - UGANDA	AVERTISO	MISOPROSTOL	200 MCG	ACME FORMULATION PVT. LTDROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X4.0 TABLET BLISTER	02/06/2021
4191	NDA/MAL/HDP/9 626	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	BIKTARVY	BICTEGRAVIR SODIUM + EMTRICITABINE + TENOFIVIR ALAFENAMIDE	50 MG + 200 MG + 25 MG	GILEAD SCIENCES IRELAND UC,CORKIDA BUSINESS & TECHNOLOGY PARK, CARRIGTOHILL, COUNTY CORK,	IRELAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	02/06/2021



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4192	NDA/MAL/HDP/9 628	UNICHEM LABORATORIES LIMITEDv	EUROPA HEALTHCARE (U) LTD	MPLIFY 20	TADALAFIL	20 MG	UNICHEM LABORATORIES LTD PLOT NO. 15,16,17,17A & 18, PILERNE INDUSTRIAL ESTATE, PILERNE, BARDEZ, GOA- 403511 UNICHEM LABORATORIES BADI- UNIT IIVILLAGE BHATAULI, BADDI HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X1.0 TABLET BLISTER,1.0X1.0X4. 0 TABLET BLISTER	02/06/2021
4193	NDA/MAL/HDP/9 629	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DECOZAL	XYLOMETAZOLINE HYDROCHLORIDE	0.5 MG/ML	AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	JORDAN	NASAL SYSTEMIC METERED-DOSE LIQUIDS	1.0X1.0X10.0 ML BOTTLE	02/06/2021

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

4194	NDA/MAL/HDP/9 631	DAWA LIMITED	SUPER MEDIC LTD	DAWASOLONE	PREDNISOLONE SODIUM PHOSPHATE	5 MG/5 ML	DAWA LIMITED PLOT NO. 7879/8 BABADOGO ROAD, RUARAKA P. O. BOX 16633-00620 NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X60.0 ML BOTTLE	02/06/2021
4195	NDA/MAL/HDP/9 632	AGIO PHARMACEUTICAL S LIMITED	ROYAL PHARMA 2011 LIMITED	CANISON VAGINAL 100	CLOTRIMAZOLE	100 MG	AGIO PHARMACEUTICALS LIMITED.T- 81, 82, MIDC, BHOSARI, PUNE - 411 026 INDIA	INDIA	VAGINAL TABLETS	1.0X1.0X6.0 TABLET STRIP	02/06/2021

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

4196	NDA/MAL/HDP/9 633	AGIO PHARMACEUTICAL S LIMITED	ROYAL PHARMA 2011 LIMITED	AGILAX	LACTULOSE SOLUTION	3.35G/5ML	AGIO PHARMACEUTICALS LIMITED.T- 81, 82, MIDC, BHOSARI, PUNE - 411 026 INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE	02/06/2021
4197	NDA/MAL/HDP/9 636	ALTHEA PHARMA PVT LTD.	JOINT MEDICAL STORE (UPMB - UCMB)	ALTHEMOL	PARACETAMOL	1.0 % W/V (1G/100 ML)	ALTHEA PHARMA PRIVATE LIMITEDWORKS: PLOT NO. 374, SHED NO. 'E', ALPHA INDL. PARK, ATHIAWAD, DABHEL, NANI DAMAN - 396210 (U.T.), INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	02/06/2021

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4198	NDA/MAL/HDP/9 638	LUPIN LIMITED-	AIVEEN (U) LIMITED	RIFAMPICIN AND ISONIAZID TABLETS	RIFAMPICIN + ISONIAZID	150 MG + 75 MG	LUPIN LTDA-28/1, M.I.D.C., CHIKALTHANA, AURANGABAD- 431210, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X24.0X28.0 TABLET BLISTER	02/06/2021
4199	NDA/MAL/HDP/9 639	ZOTA HEALTHCARE LTD	HARLEYS UGANDA LIMITED	ZOMEPR-ES-40	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40 MG	ZOTA HEALTHCARE LIMITED PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY STATION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1X3X10 TABLET BLISTER	03/06/2021

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

4200	NDA/MAL/HDP/9 640	BERLIN-CHEMIE AG -	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	PRILIGY 30 MG	DAPOXETINE HYDROCHLORIDE	30 MG	MENARINI - VON HEYDEN GMBHLEIPZIGER STRABE 7-13, 01097 DRESDEN	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	02/06/2021
4201	NDA/MAL/HDP/9 641	BERLIN-CHEMIE AG -	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	PRILIGY 60 MG	DAPOXETINE HYDROCHLORIDE	60 MG	MENARINI - VON HEYDEN GMBHLEIPZIGER STRABE 7-13, 01097 DRESDEN	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	02/06/2021

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

4202	NDA/MAL/HDP/9 642	GLENMARK PHARMACEUTICAL S LTD	ABACUS PHARMA (AFRICA) LIMITED	OFLOMIL	AMOROLFINE HYDROCHLORIDE	5% W/V	GLENMARK PHARMACEUTICALS LTD .PLOT E-37, 39, D ROAD, MIDC, SATPUR, NASHIK 422007, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X1.0X2.5 ML VIAL + 1*12, ISOPROPYL ALCOHOL 70% SWAB SACHETS	03/06/2021
4203	NDA/MAL/HDP/9 643	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	ABACAVIR (AS SULFATE) AND LAMIVUDINE TABLETS	ABACAVIR SULFATE + LAMIVUDINE	600MG + 300 MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X90.0 TABLET CONTAINER	02/06/2021

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4204	NDA/MAL/HDP/9 645	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	HALOPERIDOL INJECTION BP 5 MG/ML	HALOPERIDOL	5 MG/ML	SWISS PARENTERALS PVT LTD ..809, KERALA INDUSTRIAL ESTAE, GIDC NEAR BAVLA, AHMEDABAD 382220, GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE,1.0X10.0 X1.0 ML AMPOULE	02/06/2021
4205	NDA/MAL/HDP/9 648	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	FUSIBACT CREAM	FUSIDIC ACID	2%W/W	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	TOPICAL EXTERNAL CREAMS	1X1X15 G TUBE	04/06/2021

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4206	NDA/MAL/HDP/9 651	PT SANBE FARMA	MEDVIN PHARMA LIMITED	SANTOCYN	OXYTOCIN	10 IU/ML	PT SANBE FARMA UNIT 3.JL INDUSTRI CIMAREME NO.8 PADALARANG 40533 BANDUNG	INDONESIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE	02/06/2021
4207	NDA/MAL/HDP/9 652	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICAL S LTD	LAMIVUDINE AND TENOFIVIR DISOPROXIL FUMARATE 300 MG/300 MG TABLETS	LAMIVUDINE + TENOFIVIR DISOPROXIL FUMARATE	300 MG + 300 MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BLISTER	02/06/2021



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4208	NDA/MAL/HDP/9 653	LABORATE PHARMACEUTICAL S INDIA LIMITED	HEALTHCARE LTD.	FERROUS SULPHATE WITH FOLIC ACID TABLETS	FERROUS SULPHATE + FOLIC ACID	60 MG + 0.6 MG	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	02/06/2021
4209	NDA/MAL/HDP/9 655	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	METOCLOPRAMID E INJECTION BP 5 MG/ML	METOCLOPRAMI DE HYDROCHLORIDE	5 MG/ML	PSYCHOTROPICS INDIA LTD PLOT NO. 12 & 12A, INDUSTRIAL PARK-II, PHASE-1, VILLAGE SALEMPUR, MEHDOOD-2 HARIDWAR-249403, UTTARAKHAND INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE	02/06/2021

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4210	NDA/MAL/HDP/9 663	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	POVIREN	POVIDONE + IODINE	10% W/V	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X200.0 ML BOTTLE, 1.0X1000.0 ML BOTTLE	02/06/2021
4211	NDA/MAL/HDP/9 665	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYNAC-SP	ACECLOFENAC + PARACETAMOL + SERRATIOPEPTID ASE	100 MG + 325 MG + 15 MG	RAVIAN LIFE SCIENCE PVT. LIMITED PLOT NO. 34, SECTOR: 8A, SIDCUL, IIE, HARIDWAR - 249403, UTTARAKHAND	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/06/2021

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4212	NDA/MAL/HDP/9 666	SCOTT-EDIL PHARMACIA LTD.,	ROYAL PHARMA 2011 LIMITED	VOLIGESIC-GEL	DICLOFENAC DIETHYLAMINE	1.0 % W/W	SCOTT-EDIL PHARMACIA LTD (UNIT I)56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X1.0X30.0 G TUBE	04/06/2021
4213	NDA/MAL/HDP/9 667	NATIONAL PHARMACEUTICAL INDUSTRIES CO.	MEDVIN PHARMA LIMITED	SPECTROMAX 500	CLARITHROMYCIN	500MG	NATIONAL PHARMACEUTICAL INDUSTRIES COMPANY OMANP.O.BOX 120, RUSAYL, POSTAL CODE-124, SULTANATE OF OMAN	OMAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X2X7 TABLET BLISTER	04/06/2021

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4214	NDA/MAL/HDP/9 668	LABORATE PHARMACEUTICAL S INDIA LIMITED	HEALTHCARE LTD.	AZILAB-200	AZITHROMYCIN DIHYDRATE	200MG/5ML	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X30.0 ML CONTAINER + 30 ML WFI IN LDPE CONTAINER	02/06/2021
4215	NDA/MAL/HDP/9 669	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	ZOCOLD	PARACETAMOL + CHLORPHENAMIN E MALEATE + PHENYLEPHRINE HYDROCHLORIDE	500 MG + 2 MG + 5 MG	ZOTA HEALTHCARE LIMITED PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY SATTION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1X25X4 TABLET STRIP	04/06/2021

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4216	NDA/MAL/HDP/9 670	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	CDGREL-75	CLOPIDOGREL BISULFATE	75MG	ZOTA HEALTHCARE LIMITEDPLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY SATTION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X3X10 TABLET BLISTER	04/06/2021
4217	NDA/MAL/HDP/9 671	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	RISOPINE	CARBAMAZEPINE	200 MG	SUNRISE INTERNATIONAL LABS LTD PLOT NO. 100, LANE-5, SECTOR II, PHASE-II, IDA, CHERLAPALLY INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	02/06/2021

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4218	NDA/MAL/HDP/9 672	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	NASO B12	METHYLCOBALA MIN	250 MCG/ACTUATION	TROIKAA PHARMACEUTICALS LIMITED..SANAND - KADI ROAD, THOL, CITY: THOL - 382 728, DIST. MEHSANA, GUJARAT STATE - INDIA	INDIA	NASAL SYSTEMIC UNIT DOSE AEROSOLS	1.0X1.0X2.3 ML BOTTLE	02/06/2021
4219	NDA/MAL/HDP/9 675	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	OD-TAM 0.4	TAMSULOSIN HYDROCHLORIDE	0.4 MG	AUROBINDO PHARMA LTD, UNIT VIISY. NO. 411/P, 425/P, 434/P, 435/P & 458/P, PLOT NO. S1 (PART), SPECIAL ECONOMIC ZONE (SEZ), TSIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHRLA MANDAL, MAHABOOB NAGA DISTRICT, PIN CODE: 509302,	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	04/06/2021

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4220	NDA/MAL/HDP/9 678	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	AXABAN-DENK 2.5 MG	APIXABAN	2.5 MG	COMBINO PHARM (MALTA) LIMITEDHF60 HAL FAR INDUSTRIAL ESTATE BBG3000	MALTA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X60.0 TABLET CONTAINER	02/06/2021
4221	NDA/MAL/HDP/9 679	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	AXABAN-DENK 5 MG	APIXABAN	5MG	COMBINO PHARM (MALTA) LIMITEDHF60 HAL FAR INDUSTRIAL ESTATE BBG3000	MALTA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X60.0 TABLET CONTAINER	02/06/2021

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4222	NDA/MAL/HDP/9 681	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	MISSROL-200	MISOPROSTOL	200MCG	SYNOKEM PHARMACEUTICALS LTD-PLOT NO.- 35- 36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP,10.0X1.0X10. 0 TABLET BLISTER	02/06/2021
4223	NDA/MAL/HDP/9 683	GLOBELA PHARMA PVT. LTD.	ROYAL PHARMA 2011 LIMITED	CAPTOGLO	CAPTOPRIL	25 MG	GLOBELA PHARMA PVT.LTD.357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1X10X10 TABLET STRIP,	23/06/2021



## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

4224	NDA/MAL/HDP/9688	FREDUN PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	FREDNISOL TABLETS	PREDNISOLONE	5MG	FREDUN PHARMACEUTICALS LIMITED14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PALGHAR (E), DIST: PALGHAR-401 404	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X2.0X5.0X10.0 TABLET BLISTER	19/07/2021
4225	NDA/MAL/HDP/9712	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	QUININE DIHYDROCHLORIDE INJECTION	QUININE DIHYDROCHLORIDE	600MG/2ML	SCOTT-EDIL PHARMACIA LTD (UNIT I)56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE	13/09/2021

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4226	NDA/MAL/HDP/9 713	I CARE PHARMA LIMITED	SUPER MEDIC LTD	AZOL 400	ALBENDAZOLE	400MG	MEDICO REMEDIES PVT LTD,-8 & 9 DEWAN AND SONS, UDYOG NAGAR, PALGHAR, DIST. THANE-401404, MAHARSHITRA	INDIA	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X1.0 TABLET BLISTER	15/09/2021
4227	NDA/MAL/HDP/9 714	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	ROVISTA	ROSUVASTATIN	20MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	29/09/2021

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4228	NDA/MAL/HDP/9 717	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	ESOME	ESOMEPRAZOLE	40MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER	29/09/2021
4229	NDA/MAL/HDP/9 719	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	ESOME	ESOMEPRAZOLE	20MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER	29/09/2021

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4230	NDA/MAL/HDP/9 721	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	MONTIGET	MONTELUKAST SODIUM	4MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY GRANULES	1.0X14.0 SACHET CARTON	29/09/2021
4231	NDA/MAL/HDP/9 722	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	SEKROL 30 MG/5 ML	AMBROXOL HYDROCHLORIDE	30 MG/5 ML	BILIM ILAC SAN.VE TIC.A.SGEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY	TURKEY	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X150.0 ML BOTTLE	02/06/2021

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4232	NDA/MAL/HDP/9 723	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	SEKROL 15MG/5 ML	AMBROXOL HYDROCHLORIDE	15MG/5ML	BILIM ILAC SAN.VE TIC.A.SGEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY	TURKEY	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	05/10/2021
4233	NDA/MAL/HDP/9 725	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	MOCIN	MOXIFLOXACIN HYDROCHLORIDE	0.5%W/V	ABACUS PARENTERAL DRUGS LTD (APDL)PLOT 114, BLOCK 191, KINGA - MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML VIAL	05/10/2021

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4234	NDA/MAL/HDP/9726	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	ABLEPT – 300	GABAPENTIN	300MG	MICRO LABS LIMITED .,92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	05/10/2021
4235	NDA/MAL/HDP/9728	ENCORE HEALTHCARE PVT. LTD.	REDDYS PHARMA LIMITED	ATONL 100	ATENOLOL	100MG	ENCORE HEALTHCARE PVT LTDD-5, MIDC AREA, PAITHAN- 431148, DIST. AURANGABAD, MAHARASHTRA - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1X10X10 TABLET BLISTER,	12/10/2021

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4236	NDA/MAL/HDP/9729	ENCORE HEALTHCARE PVT. LTD.	REDDYS PHARMA LIMITED	ATONL 50	ATENOLOL	50MG	ENCORE HEALTHCARE PVT LTDD-5, MIDC AREA, PAITHAN- 431148, DIST. AURANGABAD, MAHARASHTRA - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1X10X10 TABLET BLISTER,	12/10/2021
4237	NDA/MAL/HDP/9731	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MELANOV-M	GLICLAZIDE + METFORMIN HYDROCHLORIDE	80MG + 500MG	MICRO LABS LIMITED .,92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	05/10/2021

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4238	NDA/MAL/HDP/9 747	SHANGHAI FOSUN PHARMACEUTICAL INDUSTRIAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	ARGESUN 60 MG	ARTESUNATE	60MG	GUILIN PHARMACEUTICAL CO LTD .NO. 43, QULIDIAN ROAD, GUILIN 541004	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X60.0 MG VIAL 1 CLEAR GLASS AMPOULE OF SODIUM BICARBONATE	05/10/2021
4239	NDA/MAL/HDP/9 748	SHANGHAI FOSUN PHARMACEUTICAL INDUSTRIAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	ARGESUN 30 MG	ARTESUNATE	30MG	GUILIN PHARMACEUTICAL CO LTD .NO. 43, QULIDIAN ROAD, GUILIN 541004	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X30.0 MG VIAL 1 CLEAR GLASS AMPOULE OF SODIUM BICARBONATE	05/10/2021



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4240	NDA/MAL/HDP/9 749	SHANGHAI FOSUN PHARMACEUTICAL INDUSTRIAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	ARGESUN 120 MG	ARTESUNATE	120MG	GUILIN PHARMACEUTICAL CO LTD .NO. 43, QULIDIAN ROAD, GUILIN 541004	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X120.0 MG VIAL 1 CLEAR GLASS AMPOULE OF SODIUM BICARBONATE	05/10/2021
4241	NDA/MAL/HDP/9 754	PROFARMA .SH.A	JOINT MEDICAL STORE (UPMB - UCMB)	LUMINAL	PHENOBARBITAL SODIUM	200 MG/2 ML	PROFARMA SH.AMYSLYM KETA,TIRANA	ALBANIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X2.0 ML AMPOULE	05/10/2021

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4242	NDA/MAL/HDP/9755	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	ORILAM ODT-100	LAMOTRIGINE	100MG	MICRO LABS LIMITED .,92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	05/10/2021
4243	NDA/MAL/HDP/9756	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	ORILAM ODT-25	LAMOTRIGINE	25MG	MICRO LABS LIMITED .,92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	05/10/2021

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4244	NDA/MAL/HDP/9 757	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	GLYFERON 850	METFORMIN HYDROCHLORIDE	850MG	BILIM ILAC SAN.VE TIC.A.SGEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	05/10/2021
4245	NDA/MAL/HDP/9 758	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SKUDEXA	TRAMADOL HYDROCHLORIDE + DEKKETOPROFEN	75MG + 25MG	MENARINI - VON HEYDEN GMBHLEIPZIGER STRABE 7-13, 01097 DRESDEN	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	12/10/2021

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4246	NDA/MAL/HDP/9759	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	EZITA	EZETIMIBE	10MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	29/09/2021
4247	NDA/MAL/HDP/9760	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	ADVANT	CANDESARTAN	16MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1X2X7 TABLET BLISTER	29/09/2021

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4248	NDA/MAL/HDP/9761	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	LOPICARD 10MG	AMLODIPINE BESILATE	10MG	GETZ PHARMA (PVT) LIMITED 29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	29/09/2021
4249	NDA/MAL/HDP/9762	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	ADVANTEC	CANDESARTAN CILEXETIL + HYDROCHLOROT HIAZIDE	16MG + 12.5MG	GETZ PHARMA (PVT) LIMITED 29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER	29/09/2021

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4250	NDA/MAL/HDP/9 763	RAINE INDUSTRIES	HEALTH LINK PHARMACY LIMITED	ROLXIN 40/320	DIHYDROARTEMI SININ + PIPERAQUINE PHOSPHATE	40 MG + 320 MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X9.0 TABLET BLISTER	05/10/2021
4251	NDA/MAL/HDP/9 765	PANACEA BIOTEC LTD	VITACARE LIMITED	LIVOLUK	LACTULOSE	10.0 G/15 ML	PANACEA BIOTEC PHARMA LIMITED MALPURI BADDI, DISTRICT SOLAN, HIMACHAL PRADESH-173205 - INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE, 1.0X450.0 ML BOTTLE	05/10/2021

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4252	NDA/MAL/HDP/9 766	S KANT HEALTHCARE LTD -	ABACUS PHARMA (AFRICA) LIMITED	NEOMYCIN SULFATE CREAM USP	NEOMYCIN SULPHATE	0.5%W/W	S KANT HEALTHCARE LIMITED1802 – 1805, G.I.D.C., PHASE III, VAPI -396195 GUJARAT, INDIA.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	05/10/2021
4253	NDA/MAL/HDP/9 767	IND SWIFT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	PREZEL 75	PREGABALIN	75MG	IND-SWIFT LIMITED ,,PHASE 1, INDUSTRIAL GROWTH CENTRE, SAMBA-184121, JAMMU & KASHMIR	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	05/10/2021

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4254	NDA/MAL/HDP/9768	LABORATE PHARMACEUTICALS INDIA LIMITED	HEALTHCARE LTD.	MALAREST	QUININE DIHYDROCHLORIDE	600MG/2ML	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	FRANCE	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0X2.0 ML AMPOULE	05/10/2021
4255	NDA/MAL/HDP/9773	GLOBELA PHARMA PVT. LTD.	SHREEJI CARE LIMITED	LOPERAGLOBE	LOPERAMIDE HYDROCHLORIDE	2MG	GLOBELA PHARMA PVT.LTD.357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	11/10/2021



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4256	NDA/MAL/HDP/9774	I-CARE PHARMA LTD	AIVEEN (U) LIMITED	DOLOFIT	PARACETAMOL + DICLOFENAC SODIUM	500MG + 50MG	MEDICO REMEDIES PVT LTD.,8 & 9 DEWAN AND SONS, UDYOG NAGAR, PALGHAR, DIST. THANE-401404, MAHARSHITRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	05/10/2021
4257	NDA/MAL/HDP/9775	LABORATOIRE AGUETTANT	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	PHENYLEPHRINE AGUETTANT	PHENYLEPHRINE HYDROCHLORIDE	500µG/10ML	LABORATOIRE AGUETTANT1 RUE ALEXANDER FLEMING 69007, LYON - FRANCE	FRANCE	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X10.0X10.0 ML PRE- FILLED SYRINGE	05/10/2021

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4258	NDA/MAL/HDP/9776	FAES FARMA S.A	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DEFAL DROPS	DEFLAZACORT	22.75MG/ML	FAES FARMA SAMAXIMO AGUIRRE 14. 48940 LEIOA – SPAIN	SPAIN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X13.0 ML BOTTLE	05/10/2021
4259	NDA/MAL/HDP/9777	FAES FARMA S.A	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DEFAL 30 MG	DEFLAZACORT	30MG	FAES FARMA SAMAXIMO AGUIRRE 14. 48940 LEIOA – SPAIN	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	05/10/2021

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4260	NDA/MAL/HDP/9 778	FAES FARMA S.A	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DEFAL 6MG	DEFLAZACORT	6 MG	FAES FARMA SAMAXIMO AGUIRRE 14. 48940 LEIOA – SPAIN	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	05/10/2021
4261	NDA/MAL/HDP/9 779	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	EYLEA	AFLIBERCEPT	40 MG/ML	BAYER AG, BERLINMULLERSTRA BE 178, 13353 BERLIN - GERMANY	GERMANY	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL	05/10/2021

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4262	NDA/MAL/HDP/9 780	IND SWIFT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	CLARIE DS 125	CLARITHROMYCIN	125 MG/5 ML	IND-SWIFT LIMITED ,PHASE 1, INDUSTRIAL GROWTH CENTRE, SAMBA-184121, JAMMU & KASHMIR	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X50.0 ML BOTTLE	12/10/2021
4263	NDA/MAL/HDP/9 781	IND SWIFT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	CLARIE DS 250	CLARITHROMYCIN	250 MG/5 ML	IND-SWIFT LIMITED ,PHASE 1, INDUSTRIAL GROWTH CENTRE, SAMBA-184121, JAMMU & KASHMIR	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X50.0 ML BOTTLE	12/10/2021

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4264	NDA/MAL/HDP/9 782	LUPIN LIMITED-	AIVEEN (U) LIMITED	ATAZANAVIR SULFATE AND RITONAVIR TABLETS 300 MG AND 100 MG	ATAZANAVIR SULFATE + RITONAVIR	300 MG + 100 MG	LUPIN LTD PLOT NO. 6A, SECTOR 17, SPECIAL ECONOMIC ZONE, MIHAN, NAGPUR 441108, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	05/10/2021
4265	NDA/MAL/HDP/9 785	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	VAROXA-10	RIVAROXABAN	10MG	MICRO LABS LIMITED .,92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	05/10/2021

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4266	NDA/MAL/HDP/9786	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	VAROXA-20	RIVAROXABAN	20MG	MICRO LABS LIMITED .,92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	05/10/2021
4267	NDA/MAL/HDP/9790	PANACEA BIOTEC PHARMA LTD	VITACARE LIMITED	WILLGO CR	ACECLOFENAC	200MG	PANACEA BIOTEC PHARMA LIMITED MALPURI BADDI, DISTRICT SOLAN, HIMACHAL PRADESH-173205 - INDIA	INDIA	ORAL SOLID RETARD FILM-COATED TABLETS	1.0X5.0X2.0X10.0 TABLET BLISTER	05/10/2021

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4268	NDA/MAL/HDP/9791	IMPACT RH360	UNITED HEALTHCARE DISTRIBUTORS LTD	AVIBELA	LEVONORGESTREL	52 MG/ SYSTEM	ODYSSEA PHARMA SPRLRUE DU TRAVAIL 16, 4460 GRACE-HOLLOGNE	BELGIUM	VAGINAL INTRA UTERINE DEVICES	1.0X1.0X52.0 MG DEVICE	05/10/2021
4269	NDA/MAL/HDP/9792	ACINO AG	LABOREX UGANDA LIMITED	NBAXO 500 G IV	MEROPENEM TRIHYDRATE	500MG/VIAL	DEMO SA21ST KM NATIONAL ROAD, ATHENS, LAMIA 14568 KRYONERI, ATHENS	GREECE	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X500.0 MG VIAL	05/10/2021

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4270	NDA/MAL/HDP/9 793	ACINO AG	LABOREX UGANDA LIMITED	NBAXO 1000 G IV	MEROPENEM TRIHYDRATE	1000MG/VIAL	DEMO SA21ST KM NATIONAL ROAD, ATHENS, LAMIA 14568 KRYONERI, ATHENS	GREECE	PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES	1.0X1.0X1000.0 MG VIAL	05/10/2021
4271	NDA/MAL/HDP/9 794	VERVE HUMAN CARE LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	VERMOR-10	MORPHINE SULPHATE	10MG/ML	VERVE HUMAN CARE LABORATORIESPLOT 15A, PHARMACY, SELAQUI DEHRADUN- 248011, UTTARAKHAND	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X1.0 ML AMPOULE	05/10/2021



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4272	NDA/MAL/HDP/9 796	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	APDROPS	MOXIFLOXACIN HYDROCHLORIDE	0.5%W/V	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119, N-113 MIDC TARAPUR BOISAR DIST. THANE 401506 MAHARASHTRA	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	05/10/2021
4273	NDA/MAL/HDP/9 797	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	TRAMASURE-100	TRAMADOL HYDROCHLORIDE	100 MG/2ML	MANKIND PHARMA LTD.VILLAGE KISHANPURA, POAMTA SAHI DISTRICT SIRMOUR HIMACHAL PRADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1X1X4X2 ML AMPOULE	12/10/2021

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4274	NDA/MAL/HDP/9 801	CIPLA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LENOSIDE 10	LENALIDOMIDE	10MG	CIPLA LTDUNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X7.0 CAPSULE BLISTER	05/10/2021
4275	NDA/MAL/HDP/9 802	CIPLA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LENOSIDE 15	LENALIDOMIDE	15MG	CIPLA LTDUNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X7.0 CAPSULE BLISTER	05/10/2021

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4276	NDA/MAL/HDP/9 803	CIPLA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LENOSIDE 25	LENALIDOMIDE	25MG	CIPLA LTDUNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X7.0 CAPSULE BLISTER	05/10/2021
4277	NDA/MAL/HDP/9 804	LABORATOIRE AGUETTANT	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	ATROPINE SULFATE AGUETTANT	ATROPINE SULFATE	0.5MG/5ML	LABORATOIRE AGUETTANT1 RUE ALEXANDER FLEMING 69007, LYON - FRANCE	FRANCE	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X10.0X5.0 ML PRE- FILLED SYRINGE	05/10/2021

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4278	NDA/MAL/HDP/9 807	LABORATOIRE AGUETTANT	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	EPHEDRINE AGUETTANT	EPHEDRINE HYDROCHLORIDE	30MG/10ML	LABORATOIRE AGUETTANT1 RUE ALEXANDER FLEMING 69007, LYON - FRANCE	FRANCE	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X10.0X10.0 ML PRE- FILLED SYRINGE	05/10/2021
4279	NDA/MAL/HDP/9 809	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	REVENTA	ALENDRONATE SODIUM	70MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	29/09/2021

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4280	NDA/MAL/HDP/9 810	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	MONTIGET	MONTELUKAST SODIUM	4MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X1.0X7.0X2.0 TABLET BLISTER	29/09/2021
4281	NDA/MAL/HDP/9 815	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	ADVANT	CANDESARTAN	8MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1X2X10 TABLET BLISTER	29/09/2021

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4282	NDA/MAL/HDP/9 816	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	LOPICARD 5MG	AMLODIPINE	5MG	GETZ PHARMA (PVT) LIMITED 29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	29/09/2021
4283	NDA/MAL/HDP/9 817	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	LARINEX	DESLORATIDINE	5MG	GETZ PHARMA (PVT) LIMITED 29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1X1X10 TABLET BLISTER	29/09/2021

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

4284	NDA/MAL/HDP/9 818	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	CYTOPAN	DICLOFENAC / MISOPROSTOL	75MG/200MCG	GETZ PHARMA (PVT) LIMITED 29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	29/09/2021
4285	NDA/MAL/HDP/9 819	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	CYTOPAN	DICLOFENAC SODIUM + MISOPROSTOL	50MG + 200MCG	GETZ PHARMA (PVT) LIMITED 29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	29/09/2021

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

4286	NDA/MAL/HDP/9 820	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	PHENYTOIN INJECTION BP 50 MG/ML, 5 ML	PHENYTOIN SODIUM	50 MG/ML	SWISS PARENTERALS PVT LTD 809 KERALA INDUSTRIAL ESTATE GIDC NR. BAVLA DIST. AHMEDABAD- 380220 GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X5.0 ML AMPOULE	05/10/2021
4287	NDA/MAL/HDP/9 821	JERUSALEM PHARMACEUTICAL S CO. LIMITED	GAMA PHARMACEUTICAL S (U) LIMITED	FRINASE NASAL SPRAY	FLUTICASONE PROPIONATE	50 MCG/0.1 ML (ONE ACTUATION)	JERUSALEM PHARMACEUTICALS CO. LTDAL-BIREH RAMALLAH INDUSTRIAL ZONE, AL-BIREH NABLUS ROAD, P.O. BOX: 3570 PALESTINE	PALESTINE	NASAL TOPICAL SPRAYS WITHOUT GAS	1.0X1.0X120.0 DOSE CONTAINER	05/10/2021



## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

4288	NDA/MAL/HDP/9 827	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	CAPEMAX 500	CAPECITABINE	500MG	INTAS PHARMACEUTICALS LTD.PLOT NO. 457, 458, & 191/218P,VILLAGE: MATODA, TAL. SANAND, AHMEDABAD, GUJARAT, 382210 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	11/10/2021
4289	NDA/MAL/HDP/9 828	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	OXYTOCIN INJECTION BP 10 IU/ML	OXYTOCIN	10 IU/ML	SWISS PARENTERALS PVT LTD ..809, KERALA INDUSTRIAL ESTAE, GIDC NEAR BAVLA, AHMEDABAD 382220, GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0X1.0 ML AMPOULE	05/10/2021

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

4290	NDA/MAL/HDP/9 829	RENATA LIMITED	MARIE STOPES UGANDA LIMITED	WELL-PLAN	LEVONORGESTRE L + ETHINYLESTRADI OL	0.15MG + 0.03 MG	RAJENDRAPUR POTENT PRODUCT FACILITY (RPPF), RENATA LIMITEDNOYAPARA, BHAWAL MIRZAPUR, RAJENDRAPUR, GAZIPUR 1700 - BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY COATED TABLETS	1.0X1.0X28.0 TABLET BLISTER	05/10/2021
4291	NDA/MAL/HDP/9 831	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ABACAVIR (AS SULFATE) AND LAMIVUDINE DISPERSIBLE TABLETS 120/60 MG	ABACAVIR SULFATE + LAMIVUDINE	120 MG + 60 MG	CIPLA LTD ,.PLOT NO. A-33, A-2 (UNIT 1), A42 (UNIT II), MIDC PATALGANGA, DISTRICT-RAIGAD MAHARASHTRA, 410220 INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X30.0 TABLET BOTTLE	05/10/2021

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

4292	NDA/MAL/HDP/9 834	ABACUS PARENTERAL DRUGS LTD (APDL)	ABACUS PARENTERAL DRUGS LIMITED	TFEN	KETOTIFEN FUMARATE	0.025%W/V	ABACUS PARENTERAL DRUGS LTD (APDL)PLOT 114, BLOCK 191, KINGA - MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML VIAL	08/12/2021
4293	NDA/MAL/HDP/9 835	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	METAPROMIDE	METOCLOPRAMI DE HYDROCHLORIDE	10 MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/12/2021

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

4294	NDA/MAL/HDP/9 836	WALLACE PHARMACEUTICAL S PVT. LTD	STAR PHARMACEUTICAL S LTD	DIOVOL FORTE SUSPENSION	ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE	300MG + 250MG + 40MG	WALLACE PHARMACEUTICALS PVT LTDBHATIAN, NALAGARH, DIST. SOLAN HP 174101	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X170.0 ML BOTTLE	19/01/2022
4295	NDA/MAL/HDP/9 839	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	DOLUTEGRAVIR AND LAMIVUDINE TABLETS 50 MG / 300 MG	DOLUTEGRAVIR SODIUM + LAMIVUDINE	50 MG + 300 MG	CIPLA LTDUNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER,1.0X90. 0 TABLET CONTAINER	16/12/2021

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4296	NDA/MAL/HDP/9 842	LABORATOIRE AGUETTANT	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ADRENALINE AGUETTANT	ADRENALINE TARTRATE	1MG/10ML	LABORATOIRE AGUETTANT1 RUE ALEXANDER FLEMING 69007, LYON - FRANCE	FRANCE	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X10.0X10.0 ML SYRINGE	16/12/2021
4297	NDA/MAL/HDP/9 843	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	HACTOSEC	LEVODROPROPIZINE	30MG/5ML	BILIM ILAC SAN.VE TIC.A.SGEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY	TURKEY	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X150.0 ML BOTTLE	08/12/2021

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

4298	NDA/MAL/HDP/9 845	ALTHEA PHARMA PVT LTD.	JOINT MEDICAL STORE (UPMB - UCMB)	ALTLEVO	LEVOFLOXACIN HEMIHYDRATE	500MG/100ML	ALTHEA PHARMA PRIVATE LIMITEDWORKS: PLOT NO. 374, SHED NO. 'E', ALPHA INDL. PARK, ATHIAWAD, DABHEL, NANI DAMAN - 396210 (U.T.), INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	08/12/2021
4299	NDA/MAL/HDP/9 846	GLOBELA PHARMA PVT. LTD.	TATA UGANDA LIMITED	SQUAM	DIHYDROARTEMI SININ + PIPERAQUINE PHOSPHATE	400MG + 320MG	GLOBELA PHARMA PVT.LTD.357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X1X9 TABLET BLISTER,	16/12/2021

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

4300	NDA/MAL/HDP/9 848	ALTHEA PHARMA PVT LTD.	JOINT MEDICAL STORE (UPMB - UCMB)	STERILIZED WATER FOR INJECTION	WATER FOR INJECTION	N/A	ALTHEA PHARMA PRIVATE LIMITEDWORKS: PLOT NO. 374, SHED NO. 'E', ALPHA INDL. PARK, ATHIAWAD, DABHEL, NANI DAMAN - 396210 (U.T.), INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X10.0 ML AMPOULE	08/12/2021
4301	NDA/MAL/HDP/9 849	HETERO BIOPHARMA LIMITED,	AIVEEN (U) LIMITED	PAMERA 40	ADALIMUMAB (R- DNA ORIGIN)	40MG/ SYRINGE	HETERO BIOPHARMA LIMITEDSY. NO. 458 (PART), TSIC- FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL MAHABOBNAGAR DISTRICT – 509 301, TELANGANA STATE, INDIA.	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0X0.8 ML SYRINGE	08/12/2021

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4302	NDA/MAL/HDP/9 850	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	ZEDGRA 50	SILDENAFIL CITRATE	50 MG	ZOTA HEALTHCARE LIMITEDPLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY SATTION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X1X4 TABLET BLISTER	16/12/2021
4303	NDA/MAL/HDP/9 853	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	MYCOREN V	NYSTATIN	100,000 IU	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	PESSARIES	1.0X1.0X15.0 PESSARY BLISTER	08/12/2021



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4304	NDA/MAL/HDP/9 854	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	FLUZOLE	FLUCONAZOLE	200MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X4.0 CAPSULE STRIP	08/12/2021
4305	NDA/MAL/HDP/9 856	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	LARTEM DISPERSIBLE	ARTEMETHER + LUMEFANTRINE	20MG +120MG	S KANT HEALTHCARE LIMITED 1802 – 1805, G.I.D.C., PHASE III, VAPI -396195 GUJARAT, INDIA.	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X6.0 TABLET BLISTER	16/12/2021

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4306	NDA/MAL/HDP/9 858	VIIV HEALTHCARE UK LTD-	UNITED HEALTHCARE DISTRIBUTORS LTD	TIVICAY 25MG	DOLUTEGRAVIR SODIUM	25MG	GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS)PRIORY STREET, WARE, SG12 ODJ	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	08/12/2021
4307	NDA/MAL/HDP/9 859	VIIV HEALTHCARE UK LTD-	UNITED HEALTHCARE DISTRIBUTORS LTD	TIVICAY 10MG	DOLUTEGRAVIR SODIUM	10MG	GLAXO WELLCOME S.AAVENIDA EXTREMADURA 3, 09400 ARANDA DE DUERO - SPAIN GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS)PRIORY STREET, WARE, SG12 ODJ	SPAIN UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	08/12/2021

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4308	NDA/MAL/HDP/9860	THE UNITED PHARMACEUTICALS MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CLINDACIN 300 MG	CLINDAMYCIN HYDROCHLORIDE	300 MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X8.0 CAPSULE BLISTER	08/12/2021
4309	NDA/MAL/HDP/9864	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	EFAVIRENZ, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS, 400 MG / 300 MG / 300 MG	EFAVIRENZ, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE	400MG+300MG+300MG	MACLEODS PHARMACEUTICALS LTD BLOCK N2, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X90.0 TABLET BOTTLE, 1.0X30.0 TABLET BOTTLE	21/12/2021

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4310	NDA/MAL/HDP/9 865	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	PINFOL	FOLIC ACID	5MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1X10X10 TABLET BLISTER	21/12/2021
4311	NDA/MAL/HDP/9 866	VIIV HEALTHCARE UK LTD-	UNITED HEALTHCARE DISTRIBUTORS LTD	JULUCA 50MG/25MG	DOLUTEGRAVIR SODIUM + RILPIVIRINE HYDROCHLORIDE	50MG + 25MG	GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS)PRIORY STREET, WARE, SG12 ODJ	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	08/12/2021

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4312	NDA/MAL/HDP/9 867	ASTRA PHARMA UGANDA LTD	ASTRA PHARMA (U) LIMITED	CEFTRIAZONE	CEFTRIAZONE SODIUM	1G	INJECT CARE PARENTERALS PVT LTD PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195 CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHANG) CO. LTD NO. 88 YANGZI ROAD, SHIJIAZHANG CITY, HEBEI PROVINCE, (WORKSHOP 402)CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL,1.0X10.0X1.0 G VIAL	21/12/2021
4313	NDA/MAL/HDP/9 872	SAGA LIFESCIENCES LTD	ABACUS PHARMA (AFRICA) LIMITED	COL-COL	PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + CHLORPHENIRAM INE MALEATE USP + CAFFEINE ANHYDROUS	500MG + 5MG + 2MG + 15MG	SAGA LIFESCIENCES LIMITED SURVEY NO. 198/2 & 198/3, CHACHRAWADI VASNA, TA-SANAND, DIST. AHMEDABAD - 382210, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X4.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	08/12/2021

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4314	NDA/MAL/HDP/9 874	OCTAPHARMA AG	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	OCTANATE 500 IU	HUMAN COAGULATION FACTOR VIII	500IU PER VIAL	OCTAPHARMA DESSAU GMBHOTTO- REUTER-STR.3 06847 DESSAU, ROSSLAU	GERMANY	PARENTERAL ORDINARY DRY VIALS	1X500 I.U VIAL	21/12/2021
4315	NDA/MAL/HDP/9 875	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	TALIMUS 0.1%	TACROLIMUS	0.1% W/W	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X10.0 G TUBE	08/12/2021

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4316	NDA/MAL/HDP/9 876	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	LENIOL	PARACETAMOL	1000MG/100 ML	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED SURVEY NO. 199 TO 201 & 208 TO 210, MF01 AND MF02 VILLAGE- VASNA CHACHARWADI, TAL. SANAND DISTRICT. AHMEDABAD-382 213	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BAG, 1.0X100.0 ML BOTTLE (GLASS BOTTLE), 1.0X100.0 ML BOTTLE (NIPPLE HEAD PLASTIC BOTTLE), 1.0X100.0 ML BOTTLE (EURO HEAD PLASTIC BOTTLE)	08/12/2021
4317	NDA/MAL/HDP/9 877	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	LACOMA-T	LATANOPROST + TIMOLOL MALEATE	(50MCG + 5MG)/ML	CIRON DRUGS AND PHARMACEUTICALS PVT LTD .N-118, 118/1, 119, 119/1, 119/2, 113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, MAHARASHTRA STATE	INDIA	OPHTHALMIC DROPS	1.0X1.0X2.5 ML BOTTLE	08/12/2021

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

4318	NDA/MAL/HDP/9 878	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	LACOMA	LATANOPROST	0.005%W/V	CIRON DRUGS AND PHARMACEUTICALS PVT LTD .N-118, 118/1, 119, 119/1, 119/2, 113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, MAHARASHTRA STATE	INDIA	OPHTHALMIC DROPS	1.0X1.0X2.5 ML BOTTLE	08/12/2021
4319	NDA/MAL/HDP/9 879	LABORATE PHARMACEUTICAL S INDIA LIMITED	HEALTHCARE LTD.	AMILAB-500	AMIKACIN SULFATE	500MG/2 ML	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X2.0 ML VIAL	08/12/2021



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4320	NDA/MAL/HDP/9880	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	LEFLOXIN 750	LEVOFLOXACIN HEMIHYDRATE	750MG	FREDUN PHARMACEUTICALS LIMITED <sup>14,15,16</sup> , ZORABIAN INDUSTRIAL COMPLEX, VEOOR, PALGHAR (E), DIST: PALGHAR-401 404	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BOTTLE	08/12/2021
4321	NDA/MAL/HDP/9881	HETERO LABS LTD	AIVEEN (U) LIMITED	DOLUTEGRAVIR, EMTRICITABINE AND TENOFOVIR ALAFENAMIDE TABLETS 50MG/200MG/25 MG	DOLUTEGRAVIR SODIUM + EMTRICITABINE + TENOFOVIR ALAFENAMIDE HEMIFUMARATE	50MG+200MG+25 MG	HETERO LABS LIMITED (UNIT III)...22-110, I.D.A, JEEDIMETLA, HYDERABAD-500 055, ANDHRA PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE	08/12/2021

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4322	NDA/MAL/HDP/9 882	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	KAMAGRA CT 50	SILDENAFIL CITRATE	50MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	08/12/2021
4323	NDA/MAL/HDP/9 884	LABORATE PHARMACEUTICAL S INDIA LIMITED	HEALTHCARE LTD.	FOLILAB	FOLIC ACID,	5MG	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/12/2021

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4324	NDA/MAL/HDP/9885	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BELOCORT	BECLOMETHASONE DIPROPIONATE	50MCG/METERED DOSE	AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	JORDAN	NASAL TOPICAL METERED-DOSE LIQUIDS	1.0X1.0X30.0 ML BOTTLE	08/12/2021
4325	NDA/MAL/HDP/9888	GLOBELA PHARMA PVT. LTD.	SHREEJI CARE LIMITED	GLOMET 200	METRONIDAZOLE	200MG	GLOBELA PHARMA PVT.LTD.357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	08/12/2021

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4326	NDA/MAL/HDP/9 889	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	MOMADERM	MOMETASONE FUROATE	0.1%W/W	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	08/12/2021
4327	NDA/MAL/HDP/9 897	MEDOPHARM	PLANET PHARMACEUTICAL S UGANDA LTD	CO-TRIMOXAZOLE TABLETS BP	TRIMETHOPRIM + SULPHAMETHOX AZOLE	400MG + 80MG	MEDOPHARM PVT LTD. 50, KAYARAMBEDU VILLAGE, GUDUVANCHERY VILLAGE, 603 203	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	11/12/2021

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4328	NDA/MAL/HDP/9 899	MEDICAL UNION PHARMACEUTICAL S.	KARURI PHARMACEUTICAL S LTD.	MUCOSOL ADULT SYRUP	CARBOCYSTEINE	250MG/5ML	MEDICAL UNION PHARMACEUTICAL CO.PLANT: ABU- SULTAN, ISMAILIA, EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X120.0 ML BOTTLE	08/12/2021
4329	NDA/MAL/HDP/9 902	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	SEVLAREN 800	SEVELAMER CARBONATE	800MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRIA L AREA,MEHATPUR- 174 315, HIMACHAL PRADESH.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/12/2021

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4330	NDA/MAL/HDP/9 903	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA U LIMITED	MEDICLOAMP 500MG	AMPICILLIN TRIHYDRATE + CLOXACILLIN SODIUM	250MG + 250MG	REGAL PHARMACEUTICALS LTD PLOT NO. 7879/18, OFF BABA DOGO ROAD, RUARAKA - NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	08/12/2021
4331	NDA/MAL/HDP/9 904	MEDOPHARM PRIVATE LIMITED	VITACARE LIMITED	CLEDOMOX 228.5 DT	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	200 MG + 28.5 MG	MEDOPHARM PVT LTD. 50, KAYARAMBEDU VILLAGE, GUDUVANCHERY VILLAGE, 603 203	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X2.0X10.0 TABLET STRIP	11/12/2021

## NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JULY 2024

4332	NDA/MAL/HDP/9 906	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	NEBTAS-5	NEBIVOLOL HYDROCHLORIDE	5MG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI- 248197, DEHRADUN (UTTARAKHAND)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/12/2021
4333	NDA/MAL/HDP/9 907	LEGIT MEDEQ 2007 LIMITED	LEGIT MEDEQ 2007 LIMITED	ONDAZEN	ONDANSETRON HYDROCHLORIDE DIHYDRATE	8MG/4ML	ZEN PHARMA PVT LTD75/1, GIDC. VAPI- 396 195 GUJARAT,	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X4.0 ML AMPOULE	11/12/2021

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4334	NDA/MAL/HDP/9 911	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BISOPROL® 5	BISOPROLOL FUMARATE	5MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/12/2021
4335	NDA/MAL/HDP/9 912	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	IBUREN SUSPENSION	IBUPROFEN	100MG/5ML	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X60.0 ML BOTTLE	08/12/2021



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4336	NDA/MAL/HDP/9 913	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	BRUTAFLAM-120	ETORICOXIB	120MG	MANKIND PHARMA LTD, UNIT II ,VILLAGE- KISHANPURA, PAONTA SAHIB, DIST. SIRMOUR, HP	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/12/2021
4337	NDA/MAL/HDP/9 920	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	CIS-CURON	CIS- ATRACURIUMBES YLATE	10MG/5ML	BROOKES PHARMA (PRIVATE) LIMITED58 59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X5.0X5.0 ML AMPOULE	08/12/2021

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4338	NDA/MAL/HDP/9 921	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA U LIMITED	SONATEC MOUTHWASH MENTHOL BREEZE	CETYLPIRIDINIU M CHLORIDE	0.05%W/V	REGAL PHARMACEUTICALS LTD PLOT NO. 7879/18, OFF BABA DOGO ROAD, RUARAKA - NAIROBI	KENYA	ORAL TOPICAL LIQUIDS	1.0X250.0 ML BOTTLE	08/12/2021
4339	NDA/MAL/HDP/9 922	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	PALONOSETRON HYDROCHLORIDE INJECTION	PALONOSETRON HYDROCHLORIDE	0.25MG/5ML	CIPLA LIMITED.PLOT NO. L-139, S-103 & M-62, VERNA INDUSTRIAL ESTATE, VERNA SALCETTE, GOA, PIN 403722	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X5.0 ML VIAL	08/12/2021

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4340	NDA/MAL/HDP/9 924	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	OPTIZOLINE EYE DROPS	TETRAHYDROZOLI NE HYDROCHLORIDE	0.5%W/V	XEPA-SOUL PATTINSON (MALAYSIA) SDN.BHD.1-5 CHENG INDUSTRIAL ESTATE, 75250, MELAKA	MALAYSIA	OPHTHALMIC DROPS	1.0X5.0 ML VIAL	17/01/2022
4341	NDA/MAL/HDP/9 925	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	TUSSIDEX LINCTUS	DEXTROMETHOR PHAN	10MG	XEPA-SOUL PATTINSON (MALAYSIA) SDN.BHD.1-5 CHENG INDUSTRIAL ESTATE, 75250, MELAKA	MALAYSIA	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	17/01/2022

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4342	NDA/MAL/HDP/9 931	MERIDIAN ENTERPRISES PRIVATE LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	CLOSUPP 100	CLOTRIMAZOLE	100MG	MERIDIAN ENTERPRISES PVT. LTD-PLOT NO. 418, G.I.D.C., KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	VAGINAL TABLETS	1.0X1.0X6.0 PESSARY STRIP	08/12/2021
4343	NDA/MAL/HDP/9 932	INFUGEN PHARMA PVT. LTD.	TATA UGANDA LIMITED	INFUDEXA	DEXAMETHASON E	0.5MG	FREDUN PHARMACEUTICALS LIMITED14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PA LGHAR (E), DIST: PALGHAR-401 404	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	31/03/2022

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4344	NDA/MAL/HDP/9 933	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BISOPROL® 10	BISOPROLOL FUMARATE	10MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANYJORDAN - NUZHAT SAHAB	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/03/2022
4345	NDA/MAL/HDP/9 935	APEX LABORATORIES PRIVATE LIMITED	NORVIK ENTERPRISES LIMITED	ZINCOFER CAPSULES	FERROUS FUMARATE + FOLIC ACID BP + CYANOCOBALAMI N + ASCORBIC ACID + PYRIDOXINE HYDROCHLORIDE + ZINC SULPHATE MONOHYDRATE	350MG + 1MG + 5MCG +75MG + 1.5 MG +55MG	APEX LABORATORIES PRIVATE LIMITED- PLANT 1-B-23, SIDCO PHARMACEUTICAL COMPLEX ALATHUR, KANCHEEPURAM DISTRICT 603 110	INDIA	ORAL SOLID ORDINARY CAPSULES	1X3X10 CAPSULE BLISTER,	31/03/2022

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4346	NDA/MAL/HDP/9 936	GUFIC BIOSCIENCES LTD	EUROPA HEALTHCARE (U) LTD	VAMOCIN 1GM	VANCOMYCINHY DROCHLORIDE	1G/VIAL	GUFIC BIOSCIENCES LIMITED (UNIT 2)SURVEY NO. 171, NATIONAL HIGHWAY NO. 8, NEAR GRID, AT & PO: KABILPORE, NAVSARI - 396424, GUJARAT - INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL	31/03/2022
4347	NDA/MAL/HDP/9 941	ALTHEA PHARMA PVT LTD.	JOINT MEDICAL STORE (UPMB - UCMB)	STERILIZED WATER FOR INJECTION	WATER FOR INJECTION	WATER FOR INJECTION	ALTHEA PHARMA PRIVATE LIMITEDWORKS: PLOT NO. 374, SHED NO. 'E', ALPHA INDL. PARK, ATHIAWAD, DABHEL, NANI DAMAN - 396210 (U.T.), INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X20.0X5.0X5.0 ML AMPOULE	24/03/2022

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4348	NDA/MAL/HDP/9 942	FOSUN PHARMACEUTICAL DISTRIBUTION JIANGSU CO. LTD	TRIDEM PHARMA UGANDA LIMITED	GLUMAC DISPERSIBLE TABLETS	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	GUILIN PHARMACEUTICAL CO LTD .NO. 43, QULIDIAN ROAD, GUILIN 541004	CHINA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1X1X6 TABLET BLISTER	31/03/2022
4349	NDA/MAL/HDP/9 943	FOSUN PHARMACEUTICAL DISTRIBUTION JIANGSU CO. LTD	TRIDEM PHARMA UGANDA LIMITED	GLUMAC DISPERSIBLE TABLETS	ARTEMETHER + LUMEFANTRINE	40MG + 240MG	GUILIN PHARMACEUTICAL CO LTD .NO. 43, QULIDIAN ROAD, GUILIN 541004	CHINA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1X1X6 TABLET BLISTER	31/03/2022

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4350	NDA/MAL/HDP/9 944	FOSUN PHARMACEUTICAL DISTRIBUTION JIANGSU CO. LTD	TRIDEM PHARMA UGANDA LIMITED	GLUMAC DISPERSIBLE TABLETS	ARTEMETHER + LUMEFANTRINE	60MG + 360MG	GUILIN PHARMACEUTICAL CO LTD .NO. 43, QULIDIAN ROAD, GUILIN 541004	CHINA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1X1X6 TABLET BLISTER	31/03/2022
4351	NDA/MAL/HDP/9 948	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	SANTRIAX-1000	CEFTRIAXONE SODIUM	1000MG/VIAL	INJECT CARE PARENTERALS PVT LTD PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X25.0X1000.0 MG VIAL, 1.0X10.0 ML VIAL	24/03/2022



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4352	NDA/MAL/HDP/9 949	LABORATE PHARMACEUTICAL S INDIA LIMITED	HEALTHCARE LTD.	GENTAM	GENTAMICIN SULPHATE	80MG/2ML	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	24/03/2022
4353	NDA/MAL/HDP/9 950	XL LABORATORIES PRIVATE LIMITED	ROYAL PHARMA 2011 LIMITED	RETOVIT	VITAMIN A	200000 IU	XL LABORATORIES PRIVATE LIMITEDA- 141, EPIP INDUSTRIAL AREA, NEEMRANA, DIST. ALWAR, RAJASTHAN - 301705 (INDIA)	INDIA	ORAL SOLID ORDINARY CAPSULES	1X3X10 CAPSULE BLISTER	31/03/2022

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4354	NDA/MAL/HDP/9 951	ARCELIA LIFE SCIENCES LTD.	NOVOMED HEALTHCARE LIMITED	ARCELIA ARTESUNATE FOR INJECTION	ARTESUNATE	60MG/VIAL	SANJAR PHARMA LLPSURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA INDASI LIFESCIENCE PRIVATE LIMITEDPLOT NO. 73 TO 77, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN - 396210, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X60.0 MG VIAL + 1 CLEAR GLASS AMPOULE OF SODIUM BICARBONATE + 1 CLEAR GLASS AMPOULE OF SODIUM CHLORIDE	31/03/2022
4355	NDA/MAL/HDP/9 952	ARCELIA LIFE SCIENCES LTD.	NOVOMED HEALTHCARE LIMITED	ARCELIA DEXAMETHASONE SODIUM PHOSPHATE	DEXAMETHASON E SODIUM PHOSPHATE	8MG/2ML	SANJAR PHARMA LLPSURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X100.0X2.0 ML VIAL	31/03/2022

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4356	NDA/MAL/HDP/9 954	MARVIN PHARMA LTD (BURUNDI)	MARVIN PHARMA LIMITED	MARISUNATE 30MG	ARTESUNATE	30MG/VIAL	SANJAR PHARMA LLPSURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X30.0 MG VIAL + 1 CLEAR GLASS AMPOULE OF SODIUM BICARBONATE + 1 CLEAR GLASS AMPOULE OF SODIUM CHLORIDE	31/03/2022
4357	NDA/MAL/HDP/9 955	VEERAM HEALTHCARE (U) LIMITED	VEERAM HEALTHCARE (U) LIMITED	DICLONI	DICLOFENAC DIETHYLAMINE + METHYL SALICYLATE + LINSEED OIL + MENTHOL	1.16%W/W+ 1.0% W/W+3.0%W/W+ 10%W/W+2.0% W/W	KESAR PHARMA PVT LTD PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X1.0X15.0 G TUBE, 1.0X1.0X30.0 G TUBE	31/03/2022

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4358	NDA/MAL/HDP/9 956	ARCELIA LIFE SCIENCES LTD.	NOVOMED HEALTHCARE LIMITED	ARCELIA OMEPRAZOLE FOR INJECTION	OMEPRAZOLE SODIUM	40 MG/VIAL	SANJAR PHARMA LLPSURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X40.0 MG VIAL +10ML GLASS AMPOULE OF WATER FOR INJECTION	31/03/2022
4359	NDA/MAL/HDP/9 957	INDCHEMIE HEALTH SPECIALITIES PVT. LTD.	NUMED STORES SMC LIMITED	TERBICON CREAM	TERBINAFINE HYDROCHLORIDE	1.0%W/W	INDCHEMIE HEALTH SPECIALITIES PVT. LTDVILLAGE-THANA, BADDI, DIST. SOLAN, HIMACHAL PRADESH- 173 205.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X10.0 G TUBE	24/03/2022

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4360	NDA/MAL/HDP/9 958	INDCHEMIE HEALTH SPECIALITIES PVT. LTD.	NUMED STORES SMC LIMITED	MUPRICON	MUPIROCIN	2.0%W/W	INDCHEMIE HEALTH SPECIALITIES PVT. LTDVILLAGE-THANA, BADDI, DIST. SOLAN, HIMACHAL PRADESH- 173 205.	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X5.0 G TUBE	24/03/2022
4361	NDA/MAL/HDP/9 959	MARVIN PHARMA LTD (BURUNDI)	MARVIN PHARMA LIMITED	MARISUNATE 60MG	ARTESUNATE	60MG/VIAL	SANJAR PHARMA LLPSURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1, CLEAR GLASS AMPOULE OF SODIUM BICARBONATE + 1 CLEAR GLASS AMPOULE SODIUM CHLORIDE	31/03/2022

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4362	NDA/MAL/HDP/9 960	MARVIN PHARMA LTD (BURUNDI)	MARVIN PHARMA LIMITED	MARISUNATE 120MG	ARTESUNATE	120MG/VIAL	SANJAR PHARMA LLPSURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1, CLEAR GLASS AMPOULE OF SODIUM BICARBONATE + 1 CLEAR GLASS AMPOULE SODIUM CHLORIDE	31/03/2022
4363	NDA/MAL/HDP/9 961	FDC LIMITED -	AIVEEN (U) LIMITED	ALLERCROM EYE DROPS	SODIUM CROMOGLICATE	2%W/V	FDC LIMITED, WALUJ .PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD	INDIA	OPHTHALMIC LIQUIDS	1.0X1.0X10.0 ML BOTTLE	31/03/2022

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4364	NDA/MAL/HDP/9 962	ARCELIA LIFE SCIENCES LTD.	NOVOMED HEALTHCARE LIMITED	ARCELIA ARTEMETHER	ARTEMETHER	80MG/ML	SANJAR PHARMA LLPSURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X2.0X3.0X1.0 ML AMPOULE	31/03/2022
4365	NDA/MAL/HDP/9 963	SEARLE PAKISTAN LIMITED	SURGIPHARM (U) LIMITED	SEA-MOX	MOXIFLOXACIN HYDROCHLORIDE	400MG	SEARLE PAKISTAN LTD..F-319, S.I.T.E., OPP. KESC POWER STATION, KARACHI	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X5.0 TABLET BLISTER	31/03/2022

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4366	NDA/MAL/HDP/9 964	VIIV HEALTHCARE UK LTD-	UNITED HEALTHCARE DISTRIBUTORS LTD	TIVICAY 5 MG	DOLUTEGRAVIR SODIUM	5MG	GLAXO WELLCOME S.AAVENIDA EXTREMADURA 3, 09400 ARANDA DE DUERO - SPAIN GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS)PRIORY STREET, WARE, SG12 ODJ	SPAIN	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X60.0 TABLET CONTAINER	31/03/2022
4367	NDA/MAL/HDP/9 966	PHARMATEC PAKISTAN PVT LTD	HEALTHCARE LTD.	FLU-GONE	MULTI- INGREDIENT	MULTI- INGREDIENT	ATCO LABS LTD,-B- 18, S.I.T.E, KARACHI	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	24/02/2022



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4368	NDA/MAL/HDP/9 967	MACLEODS PDHARMACEUTICA LS LT	VITACARE LIMITED	VENTOMAC 100	SALBUTAMOL SULFATE	100MCG PER ACTUATION	OXALIS LABS LIMITEDVILLAGE THEDA, P.O LODHIMAJRA, TEHSIL,BADDI, DIST.SOLAN, INDIA	INDIA	LUNG ADMINISTRATION METERED-DOSE LIQUIDS	1.0X1.0X200.0 METERED DOSE CANNISTER	24/03/2022
4369	NDA/MAL/HDP/9 968	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	MAXICEF	CEFEPIME HYDROCHLORIDE	1G	ARISTO PHARMACEUTICALS PVT LTD .PLOT 208, NEW INDUSTRIAL AREA, NO. II, MANDIDEEP 462046 DIST-RAISEN, RAISEN, MADHYA PRADESH	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL	24/03/2022

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4370	NDA/MAL/HDP/9 972	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	OLMESAR 20	OLMESARTAN MEDOXOMIL	20MG	MACLEODS PHARMACEUTICALS LTD BLOCK N2, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	31/03/2022
4371	NDA/MAL/HDP/9 973	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	ARBITEL 80 H	TELMISARTAN + HYDROCHLOROT HIAZIDE	80MG + 12.5MG	MICRO LABS LIMITED .,92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/03/2022

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4372	NDA/MAL/HDP/9 974	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	NEBTAS-H	NEBIVOLOL HYDROCHLORIDE + HYDROCHLOROT HIAZIDE	5MG + 12.5 MG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI- 248197, DEHRADUN (UTTARAKHAND)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/03/2022
4373	NDA/MAL/HDP/9 975	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	RENERVE-P	PREGABALIN + MECOBALAMIN	75MG + 750MG	CORONA REMEDIES PVT. LTDVILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	ORAL SOLID ORDINARY CAPSULES	1X3X10 CAPSULE BLISTER	31/03/2022

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4374	NDA/MAL/HDP/9 976	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EZIFLO	TAMSULOSIN HYDROCHLORIDE	0.4 MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/03/2022
4375	NDA/MAL/HDP/9 977	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	EMTRICITABINE + TENOFVIR DISOPROXIL FUMARATE TABLETS 200 MG/ 300 MG	EMTRICITABINE + TENOFVIR DISOPROXIL FUMARATE	200MG + 300MG	LAURUS LABS LTD (UNIT 2)PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER,1.0X90. 0 TABLET CONTAINER	24/03/2022

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4376	NDA/MAL/HDP/9 978	ASPIRO PHARMA LIMITED	AIVEEN (U) LIMITED	PALOX	PALONOSETRON HYDROCHLORIDE	0.25MG/5ML	ASPIRO PHARMA LIMITEDSY. NO. 321, BIOTECH PARK, PHASE-III, KARKAPATLA, MARKOOK MANDAL, SIDDIPET DISTRICT- 502 281, TELANGANA, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X0.25 MG VIAL	31/03/2022
4377	NDA/MAL/HDP/9 983	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE EXTENDED RELEASE TABLETS 25 MG/1000 MG	EMPAGLIFLOZIN + METFORMIN HYDROCHLORIDE	25MG + 1000MG	CIPLA LIMITED.PLOT NO. L-139, S-103 & M-62, VERNA INDUSTRIAL ESTATE, VERNA SALCETTE, GOA, PIN 403722	INDIA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X60.0 TABLET BOTTLE	24/03/2022

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4378	NDA/MAL/HDP/9 984	CIPLA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE EXTENDED RELEASE TABLETS 12.5 MG/1000 MG	EMPAGLIFLOZIN + METFORMIN HYDROCHLORIDE	12.5MG + 1000MG	CIPLA LTD, GOA UNIT V & UNIT XL-139, S- 103&M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA	INDIA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X60.0 TABLET BOTTLE	24/03/2022
4379	NDA/MAL/HDP/9 985	CIPLA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE EXTENDED RELEASE TABLETS 5 MG/1000 MG	EMPAGLIFLOZIN + METFORMIN HYDROCHLORIDE	5MG + 1000MG	CIPLA LTD, GOA UNIT V & UNIT XL-139, S- 103&M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA	INDIA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X60.0 TABLET BOTTLE	24/03/2022

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4380	NDA/MAL/HDP/9 986	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE EXTENDED RELEASE TABLETS 10 MG/1000 MG	EMPAGLIFLOZIN + METFORMIN HYDROCHLORIDE	10MG + 1000MG	CIPLA LTD, GOA UNIT V & UNIT XL-139, S- 103&M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA	INDIA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X60.0 TABLET BOTTLE	24/03/2022
4381	NDA/MAL/HDP/9 987	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SACROFER	IRON SUCROSE	100MG/5ML	AMOUN PHARMACEUTICAL COMPANY...-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, CAIRO	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X5.0X5.0 ML AMPOULE	24/03/2022

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4382	NDA/MAL/HDP/991	CACHET PHARMACEUTICALS PVT LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EASCOF-LS	LEVOSALBUTAMOL SULPHATE + AMBROXOL HYDROCHLORIDE + GUAIPHENESIN	1MG + 30MG + 50 MG	CACHET PHARMACEUTICALS PVT LTD .VILLAGE THANA, BADDI, TEHSIL-NALAGARH DIST. SOLAN, HIMACHAL PRADESH-173205	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	24/03/2022
4383	NDA/MAL/HDP/992	REGAL PHARMACEUTICALS LTD	REGAL PHARMA U LIMITED	ASPEC EXTRA	ASPIRIN + PARACETAMOL + CAFFEINE ANHYDROUS	300MG + 250MG + 30MG	REGAL PHARMACEUTICALS LTD PLOT NO. 7879/18, OFF BABA DOGO ROAD, RUARAKA - NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X2.0 TABLET STRIP	24/03/2022



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4384	NDA/MAL/HDP/995	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	LYDIA FINE TABLET	LEVONORGESTREL + ETHINYLESTRADIOL	0.15 MG + 0.03MG	RAJENDRAPUR POTENT PRODUCT FACILITY (RPPF), RENATA LIMITED NOYAPARA, BHAWAL MIRZAPUR, RAJENDRAPUR, GAZIPUR 1700 - BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X1.0X28.0 TABLET BLISTER	24/03/2022
4385	NDA/MAL/HDP/996	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	MONTEMAC 4	MONTELUKAST SODIUM	4MG	MACLEODS PHARMACEUTICALS LTD BLOCK N2, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	31/03/2022

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4386	NDA/MAL/HDP/997	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	RIVATAS 10	RIVAROXABAN	10MG	INTAS PHARMACEUTICALS LTD.PLOT NO. 457, 458, & 191/218P,VILLAGE: MATODA, TAL. SANAND, AHMEDABAD, GUJARAT, 382210 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/03/2022
4387	NDA/MAL/HDP/998	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	DERMOCIN	MUPIROCIN	2.0%W/W	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X15.0 G TUBE	24/03/2022

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