

NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - MAY 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/0002	ABACUS PARENTERAL DRUGS LIMITED.	ABACUS PARENTERAL DRUGS LIMITED	X-SONE-N	DEXAMETHASONE +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
2	NDA/MAL/HDP/0003	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

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3	NDA/MAL/HDP/0006	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
4	NDA/MAL/HDP/0007	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/0012	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. ORGANONKLOOSTERSTRAAT 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
8	NDA/MAL/HDP/0017	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS LIMITED	S-HYDRO	HYDROCORTISONE	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

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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, GUJRAT, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X2.0 ML AMPOULE, 1.0X2.0 X5.0X2.0 ML AMPOULE	01/07/2013
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/0030	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/0031	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
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

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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
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. THANE 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: ABU-SULTAN, 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
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

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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
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
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

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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
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	A-B ARTEETHER INJECTION	75MG/ML	SAKAR HEALTHCARE PVT LTD -406, SILVER OAKS COMMERCIAL COMPLEX,	INDIA	PARENTERAL ORDINARY AMPOULES	1X3.2 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
32	NDA/MAL/HDP/0077	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	X-SONE	DEXAMETHASONE 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

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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, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM TAL-	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	01/07/2014
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, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM TAL-	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	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 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 COMBINATION PACK POWDERS/GRANULES	4.0X500.0 ML SACHET + 1*10 BLISTERS,10.0X200.0 ML SACHET + 1*10 BLISTERS,2.0X100.0 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
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. THANE 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, 1.0X1000.0X10.0 CAPSULE BLISTER	01/07/1998

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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
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. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER, 1.0X500.0 TABLET CONTAINER, 1.0X100.0 TABLET CONTAINER, 1.0X1000.0 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
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

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45	NDA/MAL/HDP/01 12	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
46	NDA/MAL/HDP/01 14	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	BREATHEZY 4	MONTELUKAST SODIUM	4MG	MSN LABORATORIES LTD PLOT NO. 42 INDUSTRIAL ESTARE BOLLARAM MEDAK DISTRIC 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
47	NDA/MAL/HDP/01 16	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/0118	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. ALKEM LABORATORIES LTDVILLAGE – THANA, BADDI TEHSIL – NALAGARH, DIST-SOLAN (HP), INDIA – 173205	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X750.0 MG VIAL + 1 AMPOULE WFI	01/07/2013
49	NDA/MAL/HDP/0119	DAWA LIMITED	SUPER MEDIC LTD	DACOLD	CAFFEINE ANHYDROUS+CHL ORPHENIRAMINE MALEATE+PARAC ETAMOL+PSEUDO EPHEDRINE	30MG+4MG+400 MG+30MG	DAWA LIMITED BABA DOGO RWARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013
50	NDA/MAL/HDP/0121	SHELYS PHARMACEUTICALS 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

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51	NDA/MAL/HDP/01 24	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/SYRU PS/DROPS	1.0X100.0 ML BOTTLE	01/07/2015
52	NDA/MAL/HDP/01 25	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/01 35	SHELYS PHARMACEUTICALS 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/0139	DAWA LIMITED-	SUPER MEDIC LTD	MOXAFORTE	FLUCLOXACILLIN SODIUM + AMOXICILLIN TRIHYDRATE	250MG + 250MG	DAWA PHARMACEUTICALS LIMITED PLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2014
55	NDA/MAL/HDP/0141	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
56	NDA/MAL/HDP/0157	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RECODIN	CODEINE PHOSPHATE + CHLORPHENIRAMINE MALEATE	10MG + 4MG /5ML	RENE INDUSTRIES LIMITED PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2015

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57	NDA/MAL/HDP/0158	MEGA LIFESCIENCES (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
58	NDA/MAL/HDP/0160	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	TIZIGESIC	TIZANIDINE HYDROCHLORIDE	2MG	UNICHEM LABORATORIES LIMITED DC-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/0161	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	TRAMAREN	TRAMADOL HYDROCHLORIDE	50MG	RENE INDUSTRIES LIMITED PLOT 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/01 62	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	COSYP-D LINCTUS	DEXTROMETHORP HAN 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/01 63	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
62	NDA/MAL/HDP/01 64	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	RENPRESS	PROPRANOLOL	40MG	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014

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63	NDA/MAL/HDP/0165	TORRENT PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS 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
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/01 68	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS 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/01 75	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
68	NDA/MAL/HDP/01 78	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	COLD CAP DAYTIME AND NIGHT TIME CAPSULE	DAY TIME(PARACETAMOL +CAFFEINE ANHYDROUS+PSEUDO EPHEDRINE HCL) AND NIGHT TIME(PARACETAMOL +CHLORPHENIRAMINE 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

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69	NDA/MAL/HDP/01 82	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS 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
70	NDA/MAL/HDP/01 86	WIDE SPECTRUM ENTERPRISES (U) LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BBC SPRAY	BENZOCAINE+BEN ZYDAMINE+CATAL KONIUM 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/01 87	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 PHARMACEUTICALS LTD	BOOTS PHARMACEUTICALS 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 PHARMACEUTICALS 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
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

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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
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 WELLCOMEPRODUCTION 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/0204	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/0205	MACLEODS PHARMACEUTICALS 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
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

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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
82	NDA/MAL/HDP/0212	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS 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/0221	DAWA LIMITED	SUPER MEDIC LTD	AMPICLO-DAWA	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	DAWA PHARMACEUTICALS LIMITED PLOT 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/0222	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 LTD PLOT SURVEY NO	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
85	NDA/MAL/HDP/0226	AMOUM PHARMACEUTICALS LTD	BOOTS PHARMACEUTICALS LIMITED	ULTRASOLV SYRUP	OXOMEMAZINE HCL & CARBOCYSTEINE & GUAIFENESIN	2MG+125MG+100MG/5ML	AMOUN PHARMACEUTICALS CO. S.A.E1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2014
86	NDA/MAL/HDP/0230	STRIDES SHASUN LIMITED	DELMAR 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 SURAGAJKANAHALLI, INDLAWADI CROSS, ANKAL TALUK, BANGALORE SOUTH -	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 1.0X30.0	01/07/2013

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87	NDA/MAL/HDP/02 32	TORRENT PHARAMACEUTICALS 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
88	NDA/MAL/HDP/02 33	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	CEFIMED 400	CEFIXIME TRIHYDRATE	400MG	MEDOCHEMIE 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/02 34	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	CEFIMED 200	CEFIXIME TRIHYDRATE	200MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X8.0 TABLET BLISTER,1.0X2.0X 5.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2014

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90	NDA/MAL/HDP/02 35	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/02 39	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,1.0X2.0X 6.0 TABLET BLISTER	01/07/2014
92	NDA/MAL/HDP/02 44	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

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93	NDA/MAL/HDP/02 48	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
94	NDA/MAL/HDP/02 50	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/02 52	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS 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/02 54	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CONCOR 5	BISOPROLOL HEMIFUMARATE	5MG	WINTHROP PHARMACEUTICALS(PTY) LTD,315 WATLOO ROAD,WATLOO,PRETORI A,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/02 55	BYANSI SERVICES LIMITED	AIVEEN (U) LIMITED	CAPETERO 150	CAPECITABINE	150MG	HETERO LABS (UNIT VI), INDIAAPIIC, 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
98	NDA/MAL/HDP/02 56	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

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99	NDA/MAL/HDP/02 66	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(WORKSHOP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0 VIAL CARTON	01/07/2001
100	NDA/MAL/HDP/02 69	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICALS 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/02 70	HETERO LABS LTD	AIVEEN (U) LIMITED	LEVIN 500MG	LEVOFLOXACIN HEMIHYDRATE	500MG	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,1.0X10.0 TABLET BLISTER	01/07/2013

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102	NDA/MAL/HDP/0271	BIOLOGICAL E. LTD	GITTOES PHARMACEUTICALS LIMITED	BETT	TETANUS VACCNE ADSORBED	40 I.U	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 AMPOULES	1.0X20.0X10.0 ML AMPOULE, 1.0X24.0X10.0 ML AMPOULE, 1.0X5.0 ML VIAL (10 DOSES)	01/07/2015
103	NDA/MAL/HDP/0272	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
104	NDA/MAL/HDP/0275	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	ZENTEL	ALBENDAZOLE	400MG	GLAXOSMITHKLINE CONSUMER HEALTHCARE S.A (PTY) LIMITED 39 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

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105	NDA/MAL/HDP/0276	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
106	NDA/MAL/HDP/0278	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CHLORPROMAZINE TABLETS B.P 100MG	CHLORPROMAZINE 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,1.0X100.0 TABLET CONTAINER,10.0X10.0 TABLET BLISTER	01/07/1998
107	NDA/MAL/HDP/0283	DAWA LIMITED	SUPER MEDIC LTD	AMPICLO-DAWA	AMPICILLIN + CLOXACILLIN	125 MG + 125 MG	DAWA PHARMACEUTICALS LIMITED PLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2013

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108	NDA/MAL/HDP/02 90	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,1.0X1 0.0X10.0 TABLET BLISTER	01/07/1997
109	NDA/MAL/HDP/02 96	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,1.0X10.0 X10.0 TABLET BLISTER	01/07/1998
110	NDA/MAL/HDP/02 98	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/SYRU PS/DROPS	1.0X1.0X60.0 ML BOTTLE	01/07/2013

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111	NDA/MAL/HDP/0301	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
112	NDA/MAL/HDP/0303	HETERO LABS LTD	AIVEEN (U) LIMITED	ABACAVIR SULPHATE	ABACAVIR SULPHATE	300MG	HETERO DRUGS LTD, UNIT III 22-110, IDA, JEEDIMETLA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2014
113	NDA/MAL/HDP/0305	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,1.0X1.0X100.0 ML BOTTLE	01/07/2013

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114	NDA/MAL/HDP/0307	HETERO DRUGS LTD	AIVEEN (U) LIMITED	LAMIVUDINE ORAL SOLUTION	LAMIVUDINE	10MG/ML	HETERO DRUGS LTD, UNIT III 22-110, IDA, JEEDIMETLA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X240.0 ML CONTAINER	01/07/2013
115	NDA/MAL/HDP/0308	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
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

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117	NDA/MAL/HDP/03 12	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/SYRU PS/DROPS	1.0X100.0 ML BOTTLE	01/07/2013
118	NDA/MAL/HDP/03 14	MARTINDALE PHARMACEUTICAL S LTD	LABOREX UGANDA LIMITED	SUXAMETHO NIUM CHLORIDE SOLUTION FOR INJECTION	SUXAMETHONI UM CHLORIDE	50MG/ML	MARTINDALE PHARMA BAMPTON ROAD, HAROLD HILL,ROMFORD, RM3844	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2013
119	NDA/MAL/HDP/03 17	YURIA PHARM LTD- UKRAINE	PHARMA VILLE LIMITED	CIPROFLOXA CIN-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/03 18	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/03 20	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
122	NDA/MAL/HDP/03 22	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (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

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123	NDA/MAL/HDP/03 26	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	OSTEBON	CALCIUM + COLECALCIFEROL	250MG + 125 IU	ARISTO PHARMACEUTICALS PVT LIMITED PLOT 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
124	NDA/MAL/HDP/03 33	KOPRAN LIMITED	TATA UGANDA LIMITED	CLAVAMYN- 625	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500MG +125MG	KOPRAN LIMITED VILLAGE- 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/03 35	GOOD DAY PHARMACY LIMITED	PLANET PHARMACEUTICALS 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/03 37	IND-SWIFT	PLANET PHARMACEUTICALS 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, 1.0X10.0X1.0X3.0 X10.0 TABLET BLISTER	01/07/2014
127	NDA/MAL/HDP/03 39	IND-SWIFT	PLANET PHARMACEUTICALS 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
128	NDA/MAL/HDP/03 41	IND SWIFT LTD	PLANET PHARMACEUTICALS UGANDA LTD	TELSWIFT- H 40	TELMISARTAN + HYDROCHLOROTH IAZIDE	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,1.0X3.0X 10.0 TABLET BLISTER	01/07/2014

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129	NDA/MAL/HDP/03 42	IND SWIFT LTD	PLANET PHARMACEUTICALS UGANDA LTD	TELSWIFT- H 80	TELMISARTAN + HYDROCHLOROTH IAZIDE	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
130	NDA/MAL/HDP/03 48	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/03 49	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICALS 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/03 50	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/03 51	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
134	NDA/MAL/HDP/03 54	KOPRAN LIMITED	TATA UGANDA LIMITED	LEVOKOP	LEVOFLOXACIN	500MG	KOPRAN LIMITED VILLAGE- SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2013

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135	NDA/MAL/HDP/03 55	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS 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
136	NDA/MAL/HDP/03 58	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS 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
137	NDA/MAL/HDP/03 60	ASTRA ZENECA AB	MACNAUGHTON LIMITED	NEXIUM 20MG	ESOMEPRAZOLE	20MG	ASTRA ZENECA AB, SODERTALJEGARTUNAYE GEN, 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

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138	NDA/MAL/HDP/03 62	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS 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
139	NDA/MAL/HDP/03 63	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
140	NDA/MAL/HDP/03 66	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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141	NDA/MAL/HDP/0370	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILONG-H	NEBIVOLOL + HYDROCHLOROTHIAZIDE	5MG + 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	01/07/2010
142	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
143	NDA/MAL/HDP/0376	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ASOMEX-D	AMLODIPINE + HYDROCHLOROTHIAZIDE	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

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144	NDA/MAL/HDP/03 86	EMCURE PHARMACEUTICAL S 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
145	NDA/MAL/HDP/03 88	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,1.0X1 000.0 CAPSULE CONTAINER,1.0X5 00.0 CAPSULE CONTAINER,1.0X1 00.0X10.0 CAPSULE BLISTER	01/07/1997
146	NDA/MAL/HDP/03 89	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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147	NDA/MAL/HDP/03 94	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
148	NDA/MAL/HDP/03 97	EMCURE PHARMACEUTICAL S 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
149	NDA/MAL/HDP/04 01	FOURRTS (INDIA) LABORATORIES PVT LTD	DELMAN 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

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150	NDA/MAL/HDP/0403	NEON LABORATORIES 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
151	NDA/MAL/HDP/0404	GLAXOSMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ACTIFED WET COUGH & COLD	TRIPLORIDINE HCL/PSEUDOEPHEDRINE/GUAIPHENESIN	1.25MG/30MG/100MG	GLAXO WELLCOME EGYPT SAE.EL SALAM CITY 11491, CAIRO	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X2.0 L JERRYCAN	01/07/1997
152	NDA/MAL/HDP/0405	NEON LABORATORIES 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

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153	NDA/MAL/HDP/04 06	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
154	NDA/MAL/HDP/04 07	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/04 08	MSN LABORATORIES LTD	METRO PHARMACEUTICALS 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/04 09	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	TYDE-S*	CHLORAMPHENIC OL 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/04 10	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
158	NDA/MAL/HDP/04 11	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	JADELLE SINE	LEVONORGESTREL	150MG	BAYER OYPANSIONATE 47 20210 TURKU FINLAND	FINLAND	PARENTERAL RETARD IMPLANTS	1.0X10.0X1.0X2.0 X75.0 MG IMPLANT	01/07/2003

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159	NDA/MAL/HDP/04 13	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
160	NDA/MAL/HDP/04 15	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/04 18	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/04 19	ASTRAZENECA	MACNAUGHTON LIMITED	KOMBIGLYZE XR 2.5MG/1000 MG	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/04 21	MSN LABORATORIES PRIVATE LIMITED,	METRO PHARMACEUTICALS 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
164	NDA/MAL/HDP/04 22	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.THAN E INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2013

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165	NDA/MAL/HDP/04 23	GITTOES PHARMACEUTICAL S 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.THAN E INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100. 0X10.0 CAPSULE BLISTER	01/07/2013
166	NDA/MAL/HDP/04 24	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CHLORPROM AZINE 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,1.0X1 000.0 TABLET CONTAINER,10.0X 10.0 TABLET BLISTER	01/07/1998
167	NDA/MAL/HDP/04 27	MICRO LABS LTD	LABOREX UGANDA LIMITED	AMLOZAAR - H	LOSARTAN POTASSIUM + AMLODIPINE BESILATE + HYDROCHLOROTH IAZIDE	50MG + 5MG + 12.5MG	MICRO LABS LTD ..57, SIPCOT INDUSTRIAL COMPLEX, HOSUR- 635126, TAMIIL 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/04 28	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/04 29	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	FLEXON MR	IBUPROFEN + PARACETAMOL + CHLORZOXAZONE	400MG + 325MG + 250MG	ARISTO PHARMACEUTICALS PVT. LIMITEDPLOT 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,1.0X10.0 X1.0X10.0 TABLET BLISTER	01/07/2014
170	NDA/MAL/HDP/04 30	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO ACECLO PLUS	ACECLOFENAC+PA RACETAMOL	100MG+500MG	ARISTO PHARMACEUTICALS PVT LIMITEDPLOT 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

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171	NDA/MAL/HDP/04 32	FOURRTS (INDIA) LABORATORIES PVT LTD	DELMAN ENTERPRISES LIMITED	K MAC ORAL SOLUTION	POTASSIUM CITRATE + MAGNESIUM CITRATE	22MG + 7.5MG	FOURRTS INDIA LABORATORIES PVT. LIMITEDVANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X200.0 ML BOTTLE	01/07/2013
172	NDA/MAL/HDP/04 33	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/04 34	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,1.0X10.0 X10.0 CAPSULE STRIP	01/07/2010

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174	NDA/MAL/HDP/04 41	AGIO PHARMACEUTICAL S 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/04 47	PT SANBE FARMA	MEDVIN PHARMA LIMITED	SANEXON®12 5	METHYLPREDNISO LONE 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
176	NDA/MAL/HDP/04 49	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AMINO GUAR D GRANULES	CYANOCOBALAMI N	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

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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
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 INDUSTRI NO.8 KOMPLEKS INDUSTRI CIMAREME PADALARANG BANDUNG	INDONESIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2014

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180	NDA/MAL/HDP/04 56	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/04 60	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	AMBRODIL	AMBROXOL HYDROCHLORIDE	7.5MG/ML	ARISTO PHARMACEUTICALS PVT. LIMITEDPLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X15.0 ML BOTTLE	01/07/2009
182	NDA/MAL/HDP/04 63	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS 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,1.0X1 00.0X10.0 CAPSULE BLISTER	01/07/2011

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183	NDA/MAL/HDP/04 67	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
184	NDA/MAL/HDP/04 70	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	DENMARK BRAZIL FRANCE	PARENTERAL ORDINARY DRY PRE- FILLED PENS	1.0X5.0X3.0 ML PREFILLED PEN	01/07/2014
185	NDA/MAL/HDP/04 71	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	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
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

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189	NDA/MAL/HDP/04 82	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
190	NDA/MAL/HDP/04 89	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/04 91	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/04 93	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/04 96	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, 1.0X3.0X 10.0 CAPSULE BLISTER	01/07/2014
194	NDA/MAL/HDP/04 97	LABORATORY & ALLI ED 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/SYRU PS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

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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
196	NDA/MAL/HDP/0507	FOURRTS (INDIA) LABORATORIES PVT LTD	DELMAN ENTERPRISES LIMITED	FILDILOL 12.5	CARVEDILOL	12.5 MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITED VANDALUR ROAD, KELAMBAKKAM-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	DELMAN ENTERPRISES LIMITED	FILDILOL 25	CARVEDILOL	25MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITED VANDALUR ROAD, KELAMBAKKAM-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/05 10	GLENMARK PHARMACEUTICAL 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/05 12	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	FILSTAT 10	ATORVASTATIN CALCIUM	10MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITED VANDALUR ROAD, KELAMBAKKAM- 603 103, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014
200	NDA/MAL/HDP/05 15	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	FILSTAT 20	ATORVASTATIN	20MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITED VANDALUR ROAD, KELAMBAKKAM- 603 103, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014

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201	NDA/MAL/HDP/05 18	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
202	NDA/MAL/HDP/05 20	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	FILSTAT 40	ATORVASTATIN CALCIUM	40MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITED VANDALUR ROAD, KELAMBAKKAM- 603 103, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2014
203	NDA/MAL/HDP/05 21	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PAN 40	PANTOPRAZOLE SODIUM	40MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA ALKEM LABORATORIES LTD . VILLAGE THANA BADDI TEHSIL NALAGARH DIST SOLAN HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY ENTERIC- COATED TABLETS	1.0X10.0 TABLET BLISTER, 1.0X3.0X 10.0 TABLET BLISTER	01/07/2014

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204	NDA/MAL/HDP/05 26	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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2014
205	NDA/MAL/HDP/05 31	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
206	NDA/MAL/HDP/05 38	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,1.0X1.0X 10.0 TABLET BLISTER	01/07/2013

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207	NDA/MAL/HDP/05 41	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
208	NDA/MAL/HDP/05 42	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/05 43	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/05 44	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/05 47	NAARI LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	MISO-KARE	MISOPROSTOL	200MCG	NAARI PHARMA PRIVATE LIMITED PLOT NO. 14-16 &55-57, SECTOR-5, IIE, PANTNAGAR, RUHRAPUR- 263153, DIST. U.S. NAGAR, UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0 TABLET BLISTER (COMBIPACK),1.0 X3.0X4.0 TABLET BLISTER	01/07/2013
212	NDA/MAL/HDP/05 48	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

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213	NDA/MAL/HDP/05 50	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
214	NDA/MAL/HDP/05 53	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
215	NDA/MAL/HDP/05 55	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	CARZEPIN	CARBAMAZEPINE	200MG	HOVID BHDLOT 56442,71/2 MILES JALAN IPOH,PERAK,MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013

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216	NDA/MAL/HDP/05 58	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABGENTA EYE DROPS	GENTAMICIN SULPHATE	0.3% W/V	ABACUS PARENTERAL DRUGS LIMITED BLOCK 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
217	NDA/MAL/HDP/05 59	HOVID BHD	MEDICAL ACCESS (UGANDA) LIMITED	DIABETMIN RETARD	METFORMIN HYDROCHLORIDE	850MG	HOVID BHD LOT 56442,71/2 MILES JALAN IPOH,PERAK,MALAYSIA	MALAYSIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
218	NDA/MAL/HDP/05 63	IND SWIFT LTD	PLANET PHARMACEUTICALS 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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219	NDA/MAL/HDP/0566	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, GUJJURAT, INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X1.0X50.0 ML BOTTLE	01/07/2013
220	NDA/MAL/HDP/0568	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
221	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

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222	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
223	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
224	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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225	NDA/MAL/HDP/0576	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	DUODART	DUTASTERIDE + TAMSULOSIN	0.5MG + 0.4MG	CATALENT GERMANY SCHONDORF GMBH STEINBEISSSTRASSE 1-2, 73614 SCHORNDORF, GERMANY	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X30.0 CAPSULE CONTAINER	01/07/2015
226	NDA/MAL/HDP/0580	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
227	NDA/MAL/HDP/0582	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ACECLO SERA	ACECLOFENAC+PARACETAMOL+SERINORBITALPHOSPHATASE	100MG + 500MG + 15MG	ARISTO PHARMACEUTICALS PVT LTDVILLAGE: MAKHNUMAJRA P.O. BHUD BADDI DISTRIC: SOLAN (H.P) 173205	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2015

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228	NDA/MAL/HDP/05 84	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	TRIGLIMIPRE X 1	GLIMEPIRIDE+PIO GLITAZONE+METF ORMIN HYDROCHLORIDE	1MG+15MG+500 MG	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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2014
229	NDA/MAL/HDP/05 87	CADILA PHARMACEUTICAL S LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	CADIGREL	CLOPIDOGREL	75MG	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
230	NDA/MAL/HDP/05 88	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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231	NDA/MAL/HDP/0589	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	TRIGLIMIPRE X 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
232	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
233	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

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234	NDA/MAL/HDP/05 95	ARISTO PHARMACEUTICAL S 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,1.0X3.0X 10.0 TABLET BLISTER	01/07/2015
235	NDA/MAL/HDP/05 96	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ARBITEL-H	TELMISARTAN/HY DROCHLOROTHIA ZIDE	40MG/12.5MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2011
236	NDA/MAL/HDP/05 98	INTAS PHARMACEUTICAL S 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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237	NDA/MAL/HDP/0599	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
238	NDA/MAL/HDP/0600	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
239	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

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240	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
241	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
242	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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243	NDA/MAL/HDP/0611	GALPHAR LABORATORIES LTD	DAWASANA PHARMACEUTICALS LTD	GALCIPRO 500	CIPROFLOXACIN HYDROCHLORIDE	500MG	GALPHA LABORATORIES LIMITED VILLAGE "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
244	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, CLAR ENDON 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
245	NDA/MAL/HDP/0617	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

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246	NDA/MAL/HDP/0619	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
247	NDA/MAL/HDP/0623	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, 1.0X10.0X5.0X5.0 ML AMPOULE IN BLISTER PACK, 1.0X5.0 ML AMPOULE IN BLISTER PACK	01/07/2015
248	NDA/MAL/HDP/0626	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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249	NDA/MAL/HDP/0627	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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2015
250	NDA/MAL/HDP/0633	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	CIPROCIN	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
251	NDA/MAL/HDP/0634	MEDLEY PHARMACEUTICALS	EUROPA HEALTHCARE (U) LTD	TRISOLIV	ANDROGRAPHOLIDES/TRICHOLINE CITRATE	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

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252	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. THAN E 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
253	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, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM TAL-	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0 TABLET BLISTER	01/07/2014
254	NDA/MAL/HDP/0637	NABIQASIM INDUSTRIES (PVT) LIMITED	JEET PHARMACEUTICALS LIMITED	ZUDICORT	FUSIDIC ACID + BETAMETHASONE VALERATE	20MG + 1MG/G	NABIQASIM INDUSTRIES (PVT) LIMITED 17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2014

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255	NDA/MAL/HDP/0638	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABL0L-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
256	NDA/MAL/HDP/0639	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
257	NDA/MAL/HDP/0665	HETERO LABS LTD	AIVEEN (U) LIMITED	IRBIS 150	IRBESARTAN	150MG	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 TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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258	NDA/MAL/HDP/0666	HETERO LABS LTD	AIVEEN (U) LIMITED	IRBIS-H 300	IRBESARTAN	300MG	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 TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER	01/07/2013
259	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
260	NDA/MAL/HDP/0670	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	FLUNAZ-200	FLUCONAZOLE	200MG	AGOG PHARMA LTDPLOT 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

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261	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.THANE INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER	01/07/2013
262	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.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER	01/07/2013
263	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, MALAYSIKESAR PHARMA PVT LTD PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL - -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2015

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264	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
265	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.THAN E INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0X10.0 CAPSULE BLISTER	01/07/2013
266	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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267	NDA/MAL/HDP/0685	FERRER INTERNACIONAL S.A	PHILLIPS PHARMACEUTICALS (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
268	NDA/MAL/HDP/0687	FERRER INTERNACIONAL S.A	PHILLIPS PHARMACEUTICALS (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
269	NDA/MAL/HDP/0688	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014

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270	NDA/MAL/HDP/0689	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
271	NDA/MAL/HDP/0690	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	HEALTHEASE CREAM	BECLOMETHASONE DIPROPIONATE + PHENYLEPHRINE HCL + LIGNOCAINE HCL + CHLOROCRESOL	0.025%W/W + 0.1%W/W + 2.5%W/W + 0.1%W/W	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	01/07/2014
272	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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273	NDA/MAL/HDP/0692	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
274	NDA/MAL/HDP/0693	DAWA LIMITED	SUPER MEDIC LTD	MOXACIL - 250	AMOXYCILLIN TRIHYDRATE	250MG	DAWA PHARMACEUTICALS LIMITED PLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/2014
275	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,1.0X10.0 X10.0 TABLET CARTON	01/07/2013

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276	NDA/MAL/HDP/0696	BYANSI SERVICES LIMITED	AIVEEN (U) LIMITED	RITONAVIR	RITONAVIR	100MG	HETERO LABS LTD22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2014
277	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
278	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

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279	NDA/MAL/HDP/0704	HETERO LABS LTD UNIT IX	AIVEEN (U) LIMITED	M-FLOX	MOXIFLOXACIN HYDROCHLORIDE	400MG	HETERO LABS LTD UNIT 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,10.0X1.0 X5.0 TABLET BLISTER	01/07/2013
280	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
281	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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282	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
283	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
284	NDA/MAL/HDP/0712	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	ZENTEL	ALBENDAZOLE	100MG/5ML	ASPEN BAD OLDESLOE GMBH, INDUSTRIESTRASSEINDUSTRIESTRASSE 32-36, 23843 BAD OLDESLOE	FRANCE	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X20.0 ML BOTTLE	01/07/1997

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285	NDA/MAL/HDP/07 13	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	PANTO-DENK 20	PANTOPRAZOLE SODIUM SESQUIHYDRATE	20MG	ALLPHAMED PHARMBIL ARZNEIMITTEL GMBHHILDERBRAND, STR 12-37081, GOTTINGEN	GERMANY	ORAL SOLID ORDINARY ENTERIC- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2015
286	NDA/MAL/HDP/07 15	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
287	NDA/MAL/HDP/07 18	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICALS LIMITED	GLYMET-2	GLIMEPIRIDE+ME TFORMIN HYDROCHLORIDE	2MG + 500MG	LINCOLN PHARMACEUTICALS L.T.DTRIMUL ESTATE KHATRAJ 382721 GHANDINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X5.0X 10.0 TABLET BLISTER	01/07/2014

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288	NDA/MAL/HDP/07 19	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
289	NDA/MAL/HDP/07 20	STEDMAN PHARMACEUTICAL S 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
290	NDA/MAL/HDP/07 22	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

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291	NDA/MAL/HDP/07 26	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
292	NDA/MAL/HDP/07 27	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	STOMACH FIT SYRUP	BISMUTH AMMONIUM CITRATE+BELLADO NA DRY EXTRACT+THYMO L+MENTHOL	140MG+9MG+0.1 5MG+0.2/5ML	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X225.0 ML BOTTLE	01/07/2013
293	NDA/MAL/HDP/07 28	IPCA LABORATOIES LTD	MEDVIN PHARMA LIMITED	ARTESUNATE AND AMODIAQUINE 25/67.5	ARTESUNATE+AM ODIAQUINE	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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294	NDA/MAL/HDP/0731	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
295	NDA/MAL/HDP/0732	AIVEEN (U) LIMITED	AIVEEN (U) LIMITED	VOLTAMED-100	DICLOFENAC	100 MG	MEDICO REMEDIES PVT LIMITED 8 & 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
296	NDA/MAL/HDP/0734	AIVEEN (U) LIMITED	AIVEEN (U) LIMITED	OMMED -20	OMEPRAZOLE	20MG	MEDICO REMEDIES PVT LIMITED 8 & 9 DEWAN & SONS, UDYOG NAGAR PALGAR, DISTRICT THANE MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	01/07/2015

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297	NDA/MAL/HDP/07 36	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
298	NDA/MAL/HDP/07 40	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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2013
299	NDA/MAL/HDP/07 41	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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2013

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300	NDA/MAL/HDP/07 42	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
301	NDA/MAL/HDP/07 46	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
302	NDA/MAL/HDP/07 48	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

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303	NDA/MAL/HDP/07 49	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (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
304	NDA/MAL/HDP/07 50	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
305	NDA/MAL/HDP/07 51	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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306	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
307	NDA/MAL/HDP/0759	MICRO LABS LTD	PHARMA VILLE 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
308	NDA/MAL/HDP/0764	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	CORVADIL 5	AMLODIPINE	5MG	UNICHEM LABORATORIES LIMITED UNIT II VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2011

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309	NDA/MAL/HDP/07 65	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
310	NDA/MAL/HDP/07 68	FDC LTD	AIVEEN (U) LIMITED	PYRIMON EYE DROP	DEXAMETHASONE /CHLORAMPHENI COL	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
311	NDA/MAL/HDP/07 70	BEIJING HOLLEY COTEC PHARMA CHINA	SUPER PHARMACEUTICALS LIMITED	AMPIL-500	AMPICILLIN	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	1.0X50.0X500.0 MG VIAL	01/07/2013

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312	NDA/MAL/HDP/07 72	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
313	NDA/MAL/HDP/07 75	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
314	NDA/MAL/HDP/07 84	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

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315	NDA/MAL/HDP/0792	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
316	NDA/MAL/HDP/0794	REMINGTON PHARMACEUTICAL INDUSTRIES PVT LTD	HEALTHCARE LTD.	AMYGYDEX	TOBRAMYCIN/DEXAMETHASONE	3MG+1MG/ML	REMINGTON PHARMACEUTICALS (PVT) LTD 18KM, MULTAN ROAD, LAHORE 53800, PAKISTAN	PAKISTAN	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2014
317	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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318	NDA/MAL/HDP/0802	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	EXFORGE HCT 5MG/160MG/12.5MG	AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE	5MG+ 160MG+ 12.5MG	NOVARTIS PHARMA STEIN AGSCHAFFHARVSERTRASSE CH-4332 STEIN SWITZERLAND.	SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER	01/07/2015
319	NDA/MAL/HDP/0811	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
320	NDA/MAL/HDP/0816	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

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321	NDA/MAL/HDP/08 21	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
322	NDA/MAL/HDP/08 22	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
323	NDA/MAL/HDP/08 24	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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324	NDA/MAL/HDP/08 26	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
325	NDA/MAL/HDP/08 27	GALPHA LABORATORIES LTD	DAWASANA PHARMACEUTICALS LTD	CLANOXY 1.2	AMOXYCILLIN + 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
326	NDA/MAL/HDP/08 30	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,1.0X4.0X 25.0 TABLET BLISTER	01/07/2015

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327	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
328	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
329	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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330	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
331	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
332	NDA/MAL/HDP/0842	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS 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

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333	NDA/MAL/HDP/08 43	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
334	NDA/MAL/HDP/08 45	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICALS 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,1.0X5.0X 1.0X10.0 TABLET BLISTER	01/07/2013
335	NDA/MAL/HDP/08 46	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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336	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
337	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
338	NDA/MAL/HDP/0853	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICALS 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

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339	NDA/MAL/HDP/0855	HETERO LABS LTD	AIVEEN (U) LIMITED	LAZINE	LEVOCETIRIZINE DIHYDROCHLORIDE	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
340	NDA/MAL/HDP/0857	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS 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
341	NDA/MAL/HDP/0858	ASTRA ZENECA	MACNAUGHTON LIMITED	PLENDIL	FELODIPINE	5MG	ASTRAZENECA SWEDEN OPERATIONSASTRAZENECA 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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342	NDA/MAL/HDP/0861	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	PROZINE	PROMETHAZINE	25MG/ML	SAKAR HEALTHCARE PVT. LTD PLOT 10/13 SAKHEJ-BAVLA ROAD, AHMEDABAD, GUJRAT, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	2.0X5.0X2.0 ML AMPOULE	01/07/2013
343	NDA/MAL/HDP/0864	HETERO LABS LTD UNIT IX	AIVEEN (U) LIMITED	PANTIN-40	PANTOPRAZOLE SODIUM	40 MG	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 ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	01/07/2013
344	NDA/MAL/HDP/0866	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	LIZOLID	LINEZOLID	2MG/ML	AMANTA HEALTHCARE LIMITED PLOT NO. 876 N.H. NO. 8 VILLAGE-HIRIYALA TALUKA, MATAR, DIST KHEDA-387411, GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X300.0 ML BOTTLE, 1.0X100.0 ML BOTTLE	01/07/2013

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345	NDA/MAL/HDP/0868	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
346	NDA/MAL/HDP/0870	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TROY-K	PHYTOMENADIONE	10MG/ML	TROIKAA PHARMACEUTICALS LIMITEDTHOL, DIST. MEHSANA-382728, GUJARAT,INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2010
347	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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348	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 AHEMABAD 382213 GUJARATI	CHINA INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2009
349	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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2014
350	NDA/MAL/HDP/0877	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

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351	NDA/MAL/HDP/0879	COSMOS LTD.	ASTRA PHARMA (U) LIMITED	TRIBEEES FORTE FILM COATED TABLETS	THIAMINE + PYRIDOXINE + CYANOCOBALAMIN	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
352	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
353	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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354	NDA/MAL/HDP/0889	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	DNS	SODIUM CHLORIDE + GLUCOSE	0.9%W/V + 5% W/V	ABACUS PARENTERAL DRUGS LIMITED BLOCK 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
355	NDA/MAL/HDP/0895	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
356	NDA/MAL/HDP/0897	VIRCHOW HEALTHCARE PVT LTD	LEGIT MEDEQ 2007 LIMITED	DEBRIDACE	PAPAIN + UREA	521700UNITS+100MG/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

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357	NDA/MAL/HDP/0899	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	VIRIAXONE	CEFTRIAZONE	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
358	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
359	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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360	NDA/MAL/HDP/0911	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
361	NDA/MAL/HDP/0914	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
362	NDA/MAL/HDP/0920	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BUPIROY 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

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363	NDA/MAL/HDP/09 26	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
364	NDA/MAL/HDP/09 28	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.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013
365	NDA/MAL/HDP/09 29	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	DUOQUIN	DIHYDROARTEMIS ININ + 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,10.0X1.0 X8.0 TABLET BLISTER	01/07/2012

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366	NDA/MAL/HDP/09 38	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
367	NDA/MAL/HDP/09 40	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
368	NDA/MAL/HDP/09 41	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

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369	NDA/MAL/HDP/09 48	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
370	NDA/MAL/HDP/09 51	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
371	NDA/MAL/HDP/09 52	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	EFECTAL	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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372	NDA/MAL/HDP/09 53	NEON LABORATORIES 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
373	NDA/MAL/HDP/09 54	NEON LABORATORIES 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
374	NDA/MAL/HDP/09 57	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

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375	NDA/MAL/HDP/0959	AJANTA PHARMA LTD 31-0	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN DISPERSIBLE 20/120	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	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 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, 1.0X30.0X12.0 TABLET BLISTER	01/07/2013
376	NDA/MAL/HDP/0969	EMCURE PHARMACEUTICALS 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
377	NDA/MAL/HDP/0974	SQUARE CEPHALOSPORINS LTD	GAMA PHARMACEUTICALS (U) LIMITED	CEF-3	CEFIXIME	100MG/5ML	SQUARE CEPHALOSPORINS LTD KALIAKOIR, GAZIPUR - 1750, BANGLADESH	BANGLADESH	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X50.0 ML BOTTLE	01/07/2015

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378	NDA/MAL/HDP/0978	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	AMBROX 75 SR CAPSULE	AMBROXOL	75MG	SQUARE PHARMACEUTICALS LIMITEDKALIAKOIR GAZIPUR – 1750, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2012
379	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
380	NDA/MAL/HDP/0986	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

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381	NDA/MAL/HDP/0988	CADILA PHARMACEUTICALS LIMITED	PLANET PHARMACEUTICALS 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
382	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
383	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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384	NDA/MAL/HDP/0997	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	GENUPHIL	GLUCOSAMINE SULPHATE SODIUM CHLORIDE+METHYLSULPHONYLMETHANE+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
385	NDA/MAL/HDP/0999	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	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
386	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

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387	NDA/MAL/HDP/1001	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	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
388	NDA/MAL/HDP/10018	RATNAMANI HEALTHCARE PVT. LTD	VIDA AFRICA LTD	BRUMAX PLUS TABLETS	IBUPROFEN + PARACETAMOL	400MG + 325MG	RATNAMANI HEALTHCARE PRIVATE LIMITEDSURVEY NO. 750/1, AHMEDABAD - MEHSANA HIGHWAY, VILLAGE-INDRAD, NR. CHHATRAL G.I.D.C., TALUKA-KADI, DIST-MEHSANA, PIN-382721 (NG), GUJARAT - INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1X1X20 TABLET BLISTER	28/02/2022
389	NDA/MAL/HDP/1002	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	CIPROKEN 750	CIPROFLOXACIN	750MG	SQUARE PHARMACEUTICALS LIMITEDKALIAKOIR GAZIPUR – 1750, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2013

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390	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
391	NDA/MAL/HDP/10033	MEDOPHARM	PLANET PHARMACEUTICALS 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,1.0X50.0X10.0 TABLET BLISTER,1.0X100.0X1.0X10.0 TABLET BLISTER	14/07/2022
392	NDA/MAL/HDP/10034	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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393	NDA/MAL/HDP/10 036	MEDOPHARM	PLANET PHARMACEUTICALS UGANDA LTD	MEDOMOL	PARACETAMOL	500 MG	MEDOPHARMNO. 34B, INDUSTRIAL AREA, MALUR-563160, KARNATAKA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X1 0.0X10.0 TABLET BLISTER,1.0X50.0 X10.0 TABLET BLISTER,1.0X100. 0X1.0X10.0 TABLET BLISTER	14/07/2022
394	NDA/MAL/HDP/10 037	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
395	NDA/MAL/HDP/10 038	MEDOPHARM PRIVATE LIMITED	VITACARE LIMITED	CLEDOMOX 312.5 MG/5 ML	AMOXILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	312.5 MG/5 ML	MEDOPHARM PVT LIMITEDNO. 50 KAYARAMBEDU VILLAGE, GUDUVANCHERY-603202	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRU PS/DROPS	1.0X1.0X100.0 ML CONTAINER	14/07/2022

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396	NDA/MAL/HDP/10039	LEGIT MEDEQ 2007 LIMITED	LEGIT MEDEQ 2007 LIMITED	ZENMIC	TRANEXAMIC ACID	500MG/5 ML	ZEN PHARMA PVT LTD75/1, 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
397	NDA/MAL/HDP/10041	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
398	NDA/MAL/HDP/10042	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

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399	NDA/MAL/HDP/10 043	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
400	NDA/MAL/HDP/10 044	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
401	NDA/MAL/HDP/10 045	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

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402	NDA/MAL/HDP/10 046	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
403	NDA/MAL/HDP/10 048	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
404	NDA/MAL/HDP/10 049	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ERYTHROMY CIN 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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405	NDA/MAL/HDP/10050	SERUM INSTITUTE OF INDIA PVT LTD	NORVIK ENTERPRISES LIMITED	ROTAVIRUS VACCINE, LIVE ATTENUATED (ORAL) ROTASIIIL LIQUID	LIVE ATTENUATED BOVINE - HUMAN ROTAVIRUS REASSORTANT [G1, G2, G3, G4 AND G9]	≥105.6 FFU / SEROTYPE PER DOSE (2 ML)	SERUM INSTITUTE OF INDIA PVT LTD .212/2, HADAPSAR, PUNE-411028, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X2.0 ML VIAL,1.0X50.0X2.0 ML VIAL	06/07/2022
406	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
407	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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408	NDA/MAL/HDP/10055	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
409	NDA/MAL/HDP/10056	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	AVARIN	SIMETHICONE+ ALVERINE CITRATE	300 MG + 60 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	1X5X1X10 CAPSULE BLISTER	19/07/2022
410	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

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411	NDA/MAL/HDP/1006	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TRIPRIIDE-2	GLIMEPIRIDE + PIOGLITAZONE+ METFORMIN	2MG+15MG+500 MG	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
412	NDA/MAL/HDP/10061	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
413	NDA/MAL/HDP/10062	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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414	NDA/MAL/HDP/10 063	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	CARDIONE 25	SPIRONOLACTONE	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
415	NDA/MAL/HDP/10 065	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
416	NDA/MAL/HDP/10 066	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

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417	NDA/MAL/HDP/10067	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	TRITINI	TINIDAZOLE	500MG	TRIVENI FORMULATIONS LTD PLOT NO. 52,53,54,63,62,64 ALEAP INDUSTRIAL ESTATE SARAMPALLI VIJAYWADA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X25.0X4.0 TABLET BLISTER	19/07/2022
418	NDA/MAL/HDP/10068	LEGIT MEDEQ 2007 LIMITED	LEGIT MEDEQ 2007 LIMITED	Z- ENOX	ENOXAPARIN SODIUM	10 MG/0.1 ML	ZEN PHARMA PVT LTD 75/1, 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
419	NDA/MAL/HDP/10069	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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420	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
421	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,1.0X1.0X200.0 ML BOTTLE	14/07/2022
422	NDA/MAL/HDP/10075	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

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423	NDA/MAL/HDP/10076	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
424	NDA/MAL/HDP/10080	COMED CHEMICALS LTD.	LEGIT MEDEQ 2007 LIMITED	LYSER-D	DICLOFENAC SODIUM + SERRATIOPEPTIDA SE	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
425	NDA/MAL/HDP/10083	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

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426	NDA/MAL/HDP/10084	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
427	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
428	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/SYRUPS/DROPS	1X1X30 ML BOTTLE	14/07/2022

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429	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
430	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
431	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 SATTION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY CAPSULES	1X3X10 CAPSULE BLISTER,	14/07/2022

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432	NDA/MAL/HDP/10092	SYNOKEM PHARMACEUTICALS 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
433	NDA/MAL/HDP/10093	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
434	NDA/MAL/HDP/10095	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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435	NDA/MAL/HDP/10 096	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
436	NDA/MAL/HDP/10 097	ALKEM LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	NULOC 20	ESOMEPRAZOLE MAGNESIUM	20 MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC- COATED TABLETS	1X3X10 TABLET BLISTER	18/07/2022
437	NDA/MAL/HDP/10 098	ALKEM LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	NULOC 40	ESOMEPRAZOLE MANESIUM	40 MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC- COATED TABLETS	1X3X10 TABLET BLISTER	18/07/2022

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438	NDA/MAL/HDP/10099	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
439	NDA/MAL/HDP/10100	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
440	NDA/MAL/HDP/10101	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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441	NDA/MAL/HDP/10102	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	VILDARIL 100	VILDAGLIPTIN	100 MG	AJANTA PHARMA LIMITED 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	18/07/2022
442	NDA/MAL/HDP/10103	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	COLDPIL	PARACETAMOL +PHENYLEPHRINE HYDROCHLORIDE + CHLORPEHNAMINE MALEATE	650 MG + 5 MG + 2 MG	PINNACLE LIFE SCIENCE PVT LTD KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1X10X10 TABLET BLISTER	18/07/2022
443	NDA/MAL/HDP/10104	IND-SWIFT LIMITED	PLANET PHARMACEUTICALS 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

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444	NDA/MAL/HDP/10105	IND-SWIFT LIMITED	PLANET PHARMACEUTICALS 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
445	NDA/MAL/HDP/10106	VEERAM HEALTHCARE (U) LIMITED	VEERAM HEALTHCARE (U) LIMITED	SERAFEN	DICLOFENAC POTASSIUM + SERRATIOPEPTIDASE	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
446	NDA/MAL/HDP/10107	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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447	NDA/MAL/HDP/10108	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
448	NDA/MAL/HDP/10109	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
449	NDA/MAL/HDP/10110	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

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450	NDA/MAL/HDP/10112	KESAR PHARMA	ABACUS PHARMA (AFRICA) LIMITED	KESKETO	KETOCONAZOLE	2 % W/W	KESAR PHARMA PVT LTD PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL - -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	14/07/2022
451	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
452	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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453	NDA/MAL/HDP/10 117	FAES FARMA S.A	PHILLIPS PHARMACEUTICALS (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
454	NDA/MAL/HDP/10 12	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
455	NDA/MAL/HDP/10 129	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 IISURVEY 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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456	NDA/MAL/HDP/1013	NEON LABORATORIES 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
457	NDA/MAL/HDP/10134	MACLEODS PHARMACEUTICALS 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
458	NDA/MAL/HDP/10135	RAPTAKOS, BRETT & CO. LTD.	EUROPA HEALTHCARE (U) LTD	ZEVAC SYRUP	ZINC ACETATE (AS DIHYDRATE)	20MG/5ML	RAPTAKOS BRETT & CO.LTD 1ST POKHRAN ROAD,THANE 400 606	INDIA	ORAL LIQUID ORDINARY SYRUPS	1X1X60 ML BOTTLE	18/07/2022

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459	NDA/MAL/HDP/10 138	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
460	NDA/MAL/HDP/10 14	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
461	NDA/MAL/HDP/10 140	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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462	NDA/MAL/HDP/10141	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
463	NDA/MAL/HDP/10144	VIRCHOW BIOTECH PVT LTD,	SURGIPHARM (U) LIMITED	CLASIPRO	BACILLUS CLAUSII SPORES	2 X 10 ⁹ 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
464	NDA/MAL/HDP/10145	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	I-PILL	LEVONORGESTREL	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 INDUSTRIAL ESTATE, VERNA SALCETTE-GOIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X1.0 TABLET BLISTER	12/13/2023

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465	NDA/MAL/HDP/10 146	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
466	NDA/MAL/HDP/10 148	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
467	NDA/MAL/HDP/10 149	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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468	NDA/MAL/HDP/1015	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
469	NDA/MAL/HDP/10150	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
470	NDA/MAL/HDP/10151	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

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471	NDA/MAL/HDP/10 152	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
472	NDA/MAL/HDP/10 155	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
473	NDA/MAL/HDP/10 156	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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474	NDA/MAL/HDP/10 164	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ASPIRIN TABLETS	ACETYLSALICYCLIC 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
475	NDA/MAL/HDP/10 168	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
476	NDA/MAL/HDP/10 169	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,1.0X10.0 X10.0 TABLET BLISTER,1.0X1000 .0 TABLET CONTAINER	02/09/2022

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477	NDA/MAL/HDP/1017	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYCLOX	AMPICILLIN/CLOXACILLIN	125MG/125MG	ELYS CHEMICAL INDUSTRIES LIMITED ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2015
478	NDA/MAL/HDP/10170	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
479	NDA/MAL/HDP/10172	SURGE LABORATORIES (PVT.) LTD.	HEALTHCARE LTD.	SURGICOMB INJECTION 2G	CEFOPRAZONE SODIUM + SULBACTAM SODIUM	(1G + 1G)/VIAL	SURGE LABORATORIES (PVT) LTD., 10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEKHUPURA-PAKISTAN.	PAKISTAN	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X2.0 G VIAL + 10ML WFI CLEAR GLASS AMPOULE	09/09/2022

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480	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
481	NDA/MAL/HDP/1018	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM CHLOR	CHLORAMPHENICOL	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
482	NDA/MAL/HDP/10183	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	TEXAKIND	TRANEXAMIC ACID	500MG/5ML	MANKIND PHARMA LIMITED UNIT - 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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483	NDA/MAL/HDP/10185	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
484	NDA/MAL/HDP/10186	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICALS LIMITED	AARLOFLOX OZ	OFLOXACIN + ORNIDAZOLE	200 MG + 500 MG	PINNACLE LIFE SCIENCE PVT LTD KHASRA 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
485	NDA/MAL/HDP/10187	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICALS LIMITED	AARCET 5	CETIRIZINE HYDROCHLORIDE	5 MG	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	09/09/2022

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486	NDA/MAL/HDP/10 188	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICALS 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
487	NDA/MAL/HDP/10 189	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICALS 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
488	NDA/MAL/HDP/10 192	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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489	NDA/MAL/HDP/10193	UNITED PHARMACEUTICALS MANUFACTURING LIMITED COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VIVAZAC PLUS	IRBESARTAN + HYDROCHLOROTHIAZIDE	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
490	NDA/MAL/HDP/10194	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BETOLINA	BUPIVACAINE HYDROCHLORIDE	0.5%W/V	MS PHARMA - JORDAN PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH-WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY VIALS	1X5X20 ML VIAL	03/10/2022
491	NDA/MAL/HDP/10196	CONCEPT PHARMACEUTICAL LTD	JEET PHARMACEUTICALS LIMITED	PANTEC-DSR	PANTOPRAZOLE SODIUM SESQUIHYDRATE + DOMPERIDONE	40 MG + 30 MG	CONCEPT PHARMACEUTICALS LIMITED KISHANPUR 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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492	NDA/MAL/HDP/10197	CENTURION LABORATORIES PVT. LTD.	SHREEJI PHARMACEUTICALS LIMITED	LEVOZINE	LEVOCETIRIZINE DIHYDROCHLORIDE	5 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
493	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	1.0X6.0X1.0X1.0X10.0 CAPSULE BLISTER	09/09/2022
494	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

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495	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
496	NDA/MAL/HDP/10201	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICALS LIMITED	ETRICOX 60	ETORICOXIB	60 MG	PINNACLE LIFE SCIENCE PVT LTD KHASRA 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
497	NDA/MAL/HDP/10207	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	TACROTAS-1	TACROLIMUS MONOHYDRATE	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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498	NDA/MAL/HDP/10 208	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	KENZOPRAZO L	ESOMEPRAZOLE SODIUM	40MG PER VIAL	MS PHARMA - JORDANPLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL- HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY DRY VIALS	1X10X40 MG VIAL	03/10/2022
499	NDA/MAL/HDP/10 209	FERRER INTERNATIONAL, S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TRAMAPA FORT 75MG/650M G	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
500	NDA/MAL/HDP/10 210	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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501	NDA/MAL/HDP/10 211	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICALS 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
502	NDA/MAL/HDP/10 212	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICALS 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
503	NDA/MAL/HDP/10 213	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	PANTAKIND- 40	PANTOPRAZOLE SODIUM	40 MG	MANKIND PHARMA LIMITEDUNIT - 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

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504	NDA/MAL/HDP/10214	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
505	NDA/MAL/HDP/10215	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	PARACETAMOL INTRAVENOUS INFUSION	PARACETAMOL	10 MG/ML	ABARIS HEALTHCARE PVT. LTD SURVEY 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
506	NDA/MAL/HDP/10216	KLM LABORATORIES PVT. LTD.	REDDYS PHARMA LIMITED	LULIZOL CREAM	LULICONAZOLE	1%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	29/09/2022

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507	NDA/MAL/HDP/10218	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	COMIT-100	SILDENAFIL CITRATE	100 MG	BLISS GVS PHARMA LIMITED10,11 & 12,DEWAN UDYOG NAGAR,ALIYALI,PALGHAR, MAHARASHTRA 401404,INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	09/09/2022
508	NDA/MAL/HDP/10219	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	COMIT-50	SILDENAFIL CITRATE	50 MG	BLISS GVS PHARMA LIMITED10,11 & 12,DEWAN UDYOG NAGAR,ALIYALI,PALGHAR, MAHARASHTRA 401404,INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	09/09/2022
509	NDA/MAL/HDP/1022	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES -	WIDE SPECTRUM ENTERPRISES (U) LIMITED	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

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510	NDA/MAL/HDP/10 225	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
511	NDA/MAL/HDP/10 226	LUKAS LAB LTD	PLUTO PHARMACEUTICALS 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
512	NDA/MAL/HDP/10 228	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 - 382 220	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	09/09/2022

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513	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, 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 – 382 220	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	09/09/2022
514	NDA/MAL/HDP/1023	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ZINNIA P	LEVONORGESTREL + ETHINYLESTRADIOL ²	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. 1606-1609, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM TAL-	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X28.0 TABLET BLISTER,3.0X28.0 TABLET BLISTER	01/07/2013
515	NDA/MAL/HDP/10230	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 – 382 220	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X30.0 ML BOTTLE	09/09/2022

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516	NDA/MAL/HDP/10 231	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 - 382 220	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X20.0X6.0 TABLET BLISTER	09/09/2022
517	NDA/MAL/HDP/10 232	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
518	NDA/MAL/HDP/10 233	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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519	NDA/MAL/HDP/10 234	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	TERBINAFOR CE 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
520	NDA/MAL/HDP/10 235	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
521	NDA/MAL/HDP/10 239	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

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522	NDA/MAL/HDP/10240	MACLEODS PHARMACEUTICALS 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
523	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
524	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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525	NDA/MAL/HDP/10 246	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICALS LTD	GLENDES	DES Loratadine	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
526	NDA/MAL/HDP/10 247	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/SYRU PS/DROPS	1.0X1.0X100.0 ML BOTTLE	09/09/2022
527	NDA/MAL/HDP/10 249	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

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528	NDA/MAL/HDP/10250	JOHNSON & JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SINUTAB SINUS PAIN EXTRA STRENGTH	CODEINE PHOSPHATE +CHLORPHENIRAMINE MALEATE +PSEUDOEPHEDRINE 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
529	NDA/MAL/HDP/10251	THE UNITED PHARMACEUTICALS 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
530	NDA/MAL/HDP/10254	CENTURION LABORATORIES PVT. LTD.	SHREEJI PHARMACEUTICALS 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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531	NDA/MAL/HDP/10 257	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FENTEX®	PHENYTOIN	250MG/5ML	MS PHARMA - JORDANPLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL- HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY VIALS	1X10X5 ML VIAL	19/09/2022
532	NDA/MAL/HDP/10 258	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SENERGY PLUS 5/160 25 MG	AMLODIPINE BESYLATE + VALSARTAN + HYDROCHLOROTH IAZIDE	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
533	NDA/MAL/HDP/10 259	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SENERGY PLUS 10/160 12.5 MG	AMLODIPINE BESYLATE + VALSARTAN + HYDROCHLOROTH IAZIDE	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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534	NDA/MAL/HDP/10 261	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 = 382 220	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	09/09/2022
535	NDA/MAL/HDP/10 262	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
536	NDA/MAL/HDP/10 263	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 = 382 220	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X10.0 ML BOTTLE	09/09/2022

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537	NDA/MAL/HDP/10 267	SAGA LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	PROTOZOX- 500	NITAZOXANIDE	500MG	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	09/09/2022
538	NDA/MAL/HDP/10 268	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 – 382 220	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X1.0 TABLET BLISTER	09/09/2022
539	NDA/MAL/HDP/10 269	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

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540	NDA/MAL/HDP/10 280	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
541	NDA/MAL/HDP/10 282	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
542	NDA/MAL/HDP/10 283	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

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543	NDA/MAL/HDP/10 284	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
544	NDA/MAL/HDP/10 285	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
545	NDA/MAL/HDP/10 286	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	PERLEX 250	CEFALEXIN MONOHYDRATE	250 MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	09/09/2022

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546	NDA/MAL/HDP/10 287	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
547	NDA/MAL/HDP/10 292	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
548	NDA/MAL/HDP/10 294	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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549	NDA/MAL/HDP/10296	LUPIN LIMITED-	AIVEEN (U) LIMITED	RIFAMPIN, ISONIAZID, PYRAZINAMIDE, ETHAMBUTOL HYDROCHLORIDE TABLETS USP150/75/400/275MG	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
550	NDA/MAL/HDP/10297	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
551	NDA/MAL/HDP/10298	ZOTA HEALTHCARE LTD	HARLEYS UGANDA LIMITED	COXZOTA 90	ETORICOXIB	90 MG	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	1.0X3.0X10.0 TABLET BLISTER	09/09/2022

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552	NDA/MAL/HDP/10 299	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
553	NDA/MAL/HDP/10 30	LABORATORIOS SALVAT SA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MALACUR	DIHYDROARTEMIS ININ + 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,1.0X1.0X 9.0 TABLET BLISTER	01/07/2014
554	NDA/MAL/HDP/10 300	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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555	NDA/MAL/HDP/10303	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (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
556	NDA/MAL/HDP/10304	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (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
557	NDA/MAL/HDP/10305	SAGA LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	SPASCOLIC	DICYCLOMINE HYDROCHLORIDE + MEFENAMIC ACID	10 MG + 250 MG	SAGA LIFESCIENCES LIMITED SURVEY 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

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558	NDA/MAL/HDP/10307	ZOTA HEALTHCARE LTD	HARLEYS UGANDA LIMITED	DESLOZED-5	DESLOZATADINE	5 MG	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	1.0X10.0X10.0 TABLET BLISTER	09/09/2022
559	NDA/MAL/HDP/1031	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
560	NDA/MAL/HDP/10310	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ZINRO INFUSION	ORNIDAZOLE	500MG/100ML	ABACUS PARENTERAL DRUGS LIMITED PLOT 114, BLOCK 191, KINGA	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	09/09/2022

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561	NDA/MAL/HDP/10311	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
562	NDA/MAL/HDP/10313	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
563	NDA/MAL/HDP/10315	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

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564	NDA/MAL/HDP/10317	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
565	NDA/MAL/HDP/1032	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
566	NDA/MAL/HDP/10320	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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567	NDA/MAL/HDP/10323	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	XELTIN	TOFACITINIB CITRATE	5MG	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	09/09/2022
568	NDA/MAL/HDP/10325	MEDLEY PHARMACEUTICALS LTD	EUROPA HEALTHCARE (U) LTD	ONCET	CETIRIZINE DIHYDROCHLORIDE	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
569	NDA/MAL/HDP/10326	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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570	NDA/MAL/HDP/1033	FAES FARMA S.A	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DYNAMOGEN	GLUTODINE (CYPROHEPTADINE 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
571	NDA/MAL/HDP/10338	NEOMI PHARMACEUTICALS 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
572	NDA/MAL/HDP/1034	VOGEN LABORATORIES LTD	BUFFALO HEALTH CARE LTD	DURAMOX	AMOXICILLIN	250MG/5ML	VOGEN LABORATORIES LTD 70, M.HERACLEOUS STR. AYIOS ATHANASIOS INDUSTRIAL AREA, LIMASSOL, CYPRUS	CYPRUS	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2007

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573	NDA/MAL/HDP/10 343	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
574	NDA/MAL/HDP/10 346	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
575	NDA/MAL/HDP/10 349	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

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576	NDA/MAL/HDP/10353	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
577	NDA/MAL/HDP/10355	INTAS PHARMACEUTICALS 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
578	NDA/MAL/HDP/10356	INTAS PHARMACEUTICALS 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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579	NDA/MAL/HDP/10 358	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
580	NDA/MAL/HDP/10 361	AFRICURE PHARMACEUTICAL S (INDIA) PVT. LTD	AFRICURE PHARMACEUTICALS 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
581	NDA/MAL/HDP/10 363	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

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582	NDA/MAL/HDP/10365	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
583	NDA/MAL/HDP/10369	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SITAPRIL 50	SITAGLIPTIN PHOSPHATE MONOHYDRATE	50MG	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	09/09/2022
584	NDA/MAL/HDP/10370	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SITAPRIL 100	SITAGLIPTIN PHOSPHATE MONOHYDRATE	100MG	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	09/09/2022

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585	NDA/MAL/HDP/10371	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
586	NDA/MAL/HDP/10374	B&O PHARM	TRIDEM PHARMA UGANDA LIMITED	FERLIX *FOLIX	FERROUS SULFATE + FOLIC ACID	200 MG + 0.4 MG	BIO NOVA PHARMACEUTICALS PVT.LTDC-66/1, OKHLA INDUSTRIAL AREA, PHASE -II, NEW DELHI INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022
587	NDA/MAL/HDP/10376	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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588	NDA/MAL/HDP/10378	CENTURION LABORATORIES PVT. LTD.	SHREEJI PHARMACEUTICALS 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
589	NDA/MAL/HDP/10379	ACINO PHARMA (PTY) LTD	LABOREX UGANDA LIMITED	ORATANEÂ® 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
590	NDA/MAL/HDP/1038	SQUARE CEPHALOSPORINS LTD	GAMA PHARMACEUTICALS (U) LIMITED	CEF-3	CEFIXIME TRIHYDRATE	200MG	SQUARE CEPHALOSPORINS LTD KALIAKOIR, GAZIPUR - 1750, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X6.0 CAPSULE BLISTER	01/07/2014

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591	NDA/MAL/HDP/10380	ACINO PHARMA (PTY) LTD	LABOREX UGANDA LIMITED	ORATANEÂ® 20 MG	ISOTRETINOIN	20MG	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	NEW ZEALAND SWITZERLAND	ORAL SOLID ORDINARY OTHER CAPSULES	1X4X15 CAPSULE BLISTER	19/09/2022
592	NDA/MAL/HDP/10381	ACINO PHARMA (PTY) LTD	LABOREX UGANDA LIMITED	ORATANEÂ® 40 MG	ISOTRETINOIN	40MG	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	NEW ZEALAND	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X15.0 CAPSULE BLISTER	19/09/2022
593	NDA/MAL/HDP/10382	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICALS LIMITED	PINN-TRYPTILLIN	AMITRIPTYLINE HYDROCHLORIDE	25MG	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	09/09/2022

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594	NDA/MAL/HDP/10385	XL LABORATORIES PRIVATE LIMITED-	ROYAL PHARMA 2011 LIMITED	SOFKOF	DEXTROMETHORPHAN HYDROBROMIDE + PHENYLEPHRINE HYDROCHLORIDE + CHORPHENIRAMINE 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
595	NDA/MAL/HDP/10386	MACLEODS PHARMACEUTICALS 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
596	NDA/MAL/HDP/10387	MACLEODS PHARMACEUTICALS 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

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597	NDA/MAL/HDP/10389	EAST AFRICAN (INDIA) OVERSEAS	ROYAL PHARMA 2011 LIMITED	VIREXIM INJECTION	CEFTRIAZONE SODIUM	1G	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 1*10ML AMPOULE OF WFI	09/09/2022
598	NDA/MAL/HDP/10390	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN DT 40/240	ARTEMETHER + LUMEFANTRINE	40MG + 240MG	AJANTA PHARMA LIMITED MIRZA-PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X6.0 TABLET BLISTER	09/09/2022
599	NDA/MAL/HDP/10391	SANDOZ GMBH .	SURGIPHARM (U) LIMITED	HYDROXYUREA 100MG	HYDROXYCARBAMIDE	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, 1.0X1.0X120.0 TABLET BOTTLE, 1.0X200.0 TABLET BOTTLE	09/09/2022

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600	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
601	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
602	NDA/MAL/HDP/10418	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

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603	NDA/MAL/HDP/10419	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
604	NDA/MAL/HDP/1042	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO TELVAS-H 80/12.5	TELMISARTAN +HYDROCHLOROT HIAZIDE	80MG +12.5 MG	ARISTO PHARMACEUTICALS PVT. LIMITEDPLOT 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
605	NDA/MAL/HDP/10420	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	SITAPRIL M 50/500	SITAGLIPTIN PHOSPHATE MONOHYDRATE + METFORMIN HYDROCHLORIDE	50 MG + 500 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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606	NDA/MAL/HDP/10 421	MEGA LIFESCIENCES 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
607	NDA/MAL/HDP/10 422	MEGA LIFESCIENCES 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
608	NDA/MAL/HDP/10 423	S KANT HEALTHCARE LTD -	ABACUS PHARMA (AFRICA) LIMITED	MALAKANT DISPERSIBLE JUNIOR	SULFADOXINE + PYRIMETHAMINE	250MG + 12.5MG	S KANT HEALTHCARE LIMITED1802 – 1805, G.I.D.C., PHASE III, VAPI - 396195 GUJARAT, INDIA.	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X25.0X3.0 TABLET BLISTER	08/02/2023

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609	NDA/MAL/HDP/10 424	S KANT HEALTHCARE LTD -	ABACUS PHARMA (AFRICA) LIMITED	MALAKANT DISPERSIBLE	SULFADOXINE + PYRIMETHAMINE	500MG + 25MG	S KANT HEALTHCARE LIMITED1802 – 1805, G.I.D.C., PHASE III, VAPI - 396195 GUJARAT, INDIA.	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X25.0X3.0 TABLET BLISTER	08/02/2023
610	NDA/MAL/HDP/10 425	SUPREME PHARMA HEALTHCARE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	FLOXYPREME- 500	LEVOFLOXACIN HEMIHYDRATE	500 MG	SAI MIRRA INNOPHARM PVT. LIMITED288 & 299 SIDCO ESTATE, AMBATTUR, CHENNAI- 600098. INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	08/02/2023
611	NDA/MAL/HDP/10 427	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

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612	NDA/MAL/HDP/10428	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	AMOXI-DENK 1000	AMOXICILLIN TRIHYDRATE	1000 MG	PENCEF PHARMA GMBHBREITENBACHSTRASSE 13-14, 13509 BERLIN - GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	08/02/2023
613	NDA/MAL/HDP/10429	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	AMOXI-DENK 500	AMOXICILLIN TRIHYDRATE	500 MG	PENCEF PHARMA GMBHBREITENBACHSTRASSE 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
614	NDA/MAL/HDP/10430	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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615	NDA/MAL/HDP/10432	GUFIC BIOSCIENCES LTD	EUROPA HEALTHCARE (U) LTD	VAMOCIN 500	VANCOMYCIN HYDROCHLORIDE	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 INFUSION DRY VIALS/BOTTLES	1.0X500.0 MG VIAL	08/02/2023
616	NDA/MAL/HDP/10433	BIOLOGICAL E. LIMITED	GITTOES PHARMACEUTICALS LIMITED	TETANUS ANTITOXIN 1500 IU/ML BP	TETANUS ANTITOXIN	1500 IU/ML	BIOLOGICAL E. LIMITED18/1 & 3, AZAMABAD, HYDERABAD, TELANGANA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X20.0 ML VIAL	08/02/2023
617	NDA/MAL/HDP/10434	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	AZIBRU	AZITHROMYCIN DIHYDRATE	200 MG/5 ML	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X1.0X30.0 ML BOTTLE	08/02/2023

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618	NDA/MAL/HDP/10435	PROFARMA SH.A	JOINT MEDICAL STORE (UPMB - UCMB)	AFEBRIL 5 MG/2.5ML	DIAZEPAM	5MG/2.5ML	PROFARMA SH.AMYSLYM KETA,TIRANA	ALBANIA	RECTAL SYSTEMIC OTHER SUPPOSITORIES	1.0X5.0X1.0 ML AMPOULE,1.0X2.5 ML AMPOULE,1.0X5.0 X1.0X2.5 ML VIAL	08/02/2023
619	NDA/MAL/HDP/10436	YICHANGHUMANWELL PHARMACEUTICAL CO., LTD.	KAIYUANTANG (U) LIMITED	PETHIDINE HYDROCHLORIDE INJECTION	PETHIDINE HYDROCHLORIDE	50 MG/ML	YICHANG HUMANWELL PHARMACEUTICAL COMPANY LIMITEDNO. 19, DALIAN ROAD, YICHANG DEVELOPING ZONE, YICHANG, HUBEI, CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	08/02/2023
620	NDA/MAL/HDP/10438	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	ZABDENO	ADENOVIRUS TYPE 26 ENCODING THE ZAIRE EBOLAVIRUS (EBOV) MAYINGA VARIANT GLYCOPROTEIN (GP),	NOT LESS THAN 8.75 LOG 10 INFECTIOUS UNITS (INF.U),/DOSE (0.5 ML)	IDT BIOLOGIKA GMBHAM PHARMAPARK, DESSAU-ROSSLAU, SACHSEN-ANHALT, 06861, GERMANY	GERMANY	PARENTERAL ORDINARY VIALS	1.0X20.0X0.5 ML VIAL	08/02/2023

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621	NDA/MAL/HDP/10439	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	MVABEA	ONE DOSE (0.5 ML) CONTAINS:MODIFIED VACCINIA ANKARA BAVARIAN NORDIC VIRUS* ENCODING THE: ZAIRE EBOLAVIRUS (EBOV) MAYINGA VARIANT GLYCOPROTEIN	NOT LESS THAN 0.7 X 108 INFECTIOUS UNITS (INF.U), /DOSE (0.5 ML)	IDT BIOLOGIKA GMBHAM PHARMAPARK, DESSAU-ROSSLAU, SACHSEN-ANHALT, 06861, GERMANY	GERMANY	PARENTERAL ORDINARY VIALS	1.0X20.0X0.5 ML VIAL	08/02/2023
622	NDA/MAL/HDP/1044	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ANGINET 80MG	VALSARTAN	80MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD.P.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
623	NDA/MAL/HDP/10440	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	PHENIREX	CHLORPHENAMINE MALEATE	4 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/02/2023

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624	NDA/MAL/HDP/10 441	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
625	NDA/MAL/HDP/10 442	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	ACECARB	CARBAMAZEPINE	200MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/02/2023
626	NDA/MAL/HDP/10 443	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	FUNGIDERM	CLOTRIMAZOLE	1 % W/W	NANZ MED SCIENCE PHARMA PVT. LTDRAMPUR GHAT, PAONTA SAHIB, DISTRICT SIRMOUR-173025, HIMACHAL PRADESH, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	08/02/2023

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627	NDA/MAL/HDP/10 444	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	STERODERM OINTMENT	BETAMETHASONE VALERATE	0.1 % W/W	NANZ MED SCIENCE PHARMA PVT. LTDRAMPUR GHAT, PAONTA SAHIB, DISTRICT SIRMOUR-173025, HIMACHAL PRADESH, INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X15.0 G TUBE	08/02/2023
628	NDA/MAL/HDP/10 445	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	STERODERM CREAM	BETAMETHASONE VALERATE	0.1 % W/W	NANZ MED SCIENCE PHARMA PVT. LTDRAMPUR GHAT, PAONTA SAHIB, DISTRICT SIRMOUR-173025, HIMACHAL PRADESH, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	08/02/2023
629	NDA/MAL/HDP/10 446	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	ZITHROPLUS 500	AZITHROMYCIN DIHYDRATE	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	1.0X20.0X1.0X3.0 TABLET BLISTER	08/02/2023

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630	NDA/MAL/HDP/10447	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
631	NDA/MAL/HDP/10448	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
632	NDA/MAL/HDP/1045	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (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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633	NDA/MAL/HDP/10450	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
634	NDA/MAL/HDP/10451	GUANGZHOU WONDFO BIOTECH CO. LTD	METRO PHARMACEUTICALS 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
635	NDA/MAL/HDP/10452	JAMJOOM PHARMACEUTICALS COMPANY	MU PHARMA CO - SMC LIMITED	OPTIPRED	PREDNISOLONE ACETATE	1.0% W/V	CIPLA LTD, GOA UNIT V & UNIT XL-139, S-103&M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA	SAUDI ARABIA	OPHTHALMIC SUSPENSIONS	1.0X1.0X5.0 ML BOTTLE	08/02/2023

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636	NDA/MAL/HDP/10453	SANJAR PHARMA LLP.	NILKANTH PHARMACY LIMITED	ARTICURE 60MG	ARTESUNATE	60MG	SANJAR PHARMA LLPSURVEY 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 AMPOULE	08/02/2023
637	NDA/MAL/HDP/10454	PAMAJITA INTERNATIONAL LPP	NILKANTH PHARMACY LIMITED	OMEZOLE	OMEPRAZOLE SODIUM	40MG PER VIAL	SANJAR PHARMA LLPSURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X40.0 MG VIAL + 10ML OF WATER FOR INJECTION, GLASS AMPOULE	08/02/2023
638	NDA/MAL/HDP/10455	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 LABORATORIES P.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

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639	NDA/MAL/HDP/10456	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 LABORATORIES P.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
640	NDA/MAL/HDP/10457	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 LABORATORIES P.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
641	NDA/MAL/HDP/10458	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 LABORATORIES P.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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642	NDA/MAL/HDP/10 459	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
643	NDA/MAL/HDP/10 460	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	AERIALLERG 5MG	DES Loratidine	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
644	NDA/MAL/HDP/10 461	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	AERIALLERG 0.5MG/ML	DES Loratidine	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

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645	NDA/MAL/HDP/10 462	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TOR - LOOP 10	ANHYDROUS TORSEMIDE	10 MG	AUROBINDO PHARMA LIMITED, UNIT IISURVEY 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
646	NDA/MAL/HDP/10 463	FAES FARMA S.A	PHILLIPS PHARMACEUTICALS (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
647	NDA/MAL/HDP/10 464	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN 4 FLU TABLETS	DIPHENHYDRAMINE + PARACETAMOL + PSEUDOEPHEDRINE	12.5MG + 500MG + 22.5MG	SPEGX 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/10 465	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ZESBINA 200	PROGESTERONE	200 MG	EUGIA PHARMA SPECIALITIES LIMITEDSURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	08/02/2023
649	NDA/MAL/HDP/10 466	ARCELIA LIFE SCIENCES LTD.	PLUTO PHARMACEUTICALS LIMITED	ARCELIA CEFIXIME	CEFIXIME TRIHYDRATE	400 MG	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	08/02/2023
650	NDA/MAL/HDP/10 467	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	RABIRIV-DSR	RABEPRAZOLE SODIUM + DOMPERIDONE	20 MG + 30 MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	08/02/2023

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651	NDA/MAL/HDP/10 468	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CORTIRIV- 100	HYDROCORTISON E SODIUM SUCCINATE	100 MG/VIAL	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY 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
652	NDA/MAL/HDP/10 469	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	VG KIT	FLUCONAZOLE + AZITHROMYCIN DIHYDRATE + SECNIDAZOLE	150 MG + 1 G + 1G	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	08/02/2023
653	NDA/MAL/HDP/10 47	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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654	NDA/MAL/HDP/10470	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROYODOL	TRAMADOL HYDROCHLORIDE	50MG	PSYCHOTROPICS INDIA LTD PLOT NO. 12 & 12A, INDUSTRIAL PARK-II, PHASE-1, VILLAGE SALEMPUR, MEHDOOD-2 HARIDWAR-249403, UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	08/02/2023
655	NDA/MAL/HDP/10471	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CIPROSCOT-500	CIPROFLOXACIN HYDROCHLORIDE	500 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	08/02/2023
656	NDA/MAL/HDP/10472	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

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657	NDA/MAL/HDP/10 473	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
658	NDA/MAL/HDP/10 474	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
659	NDA/MAL/HDP/10 475	MARCYRL PHARMACEUTICAL INDUSTRIES	SHREEJI PHARMACEUTICALS LIMITED	EVASTINE	EBASTINE	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 FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	08/02/2023

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660	NDA/MAL/HDP/10476	CENTURION LABORATORIES PVT. LTD.	SHREEJI PHARMACEUTICALS LIMITED	DEXCEN 10	RAMIPRIL	10 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/02/2023
661	NDA/MAL/HDP/10477	CENTURION LABORATORIES PVT. LTD.	SHREEJI PHARMACEUTICALS 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
662	NDA/MAL/HDP/10478	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	FENTANYL SANDOZ 12 µG/H	FENTANYL	12µG/HOUR	HEXAL AG INDUSTRIESTRASSE 25 D-83607 HOLZKIRCHEN	GERMANY	TRANSDERMAL PATCHES	1.0X5.0 SACHET CARTON	08/02/2023

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663	NDA/MAL/HDP/10479	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	FENTANYL SANDOZ 25 µG/H	FENTANYL	25µG/HOUR	HEXAL AG INDUSTRIESTRASSE 25 D- 83607 HOLZKIRCHEN	GERMANY	TRANSDERMAL PATCHES	1.0X1.0X5.0 G TUBE	08/02/2023
664	NDA/MAL/HDP/10480	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	FENTANYL SANDOZ 75 µG/H	FENTANYL	75µG/HOUR	HEXAL AG INDUSTRIESTRASSE 25 D- 83607 HOLZKIRCHEN	GERMANY	TRANSDERMAL PATCHES	1.0X5.0 SACHET CARTON	08/02/2023
665	NDA/MAL/HDP/10481	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	FENTANYL SANDOZ 50 µG/H	FENTANYL	50µG/HOUR	HEXAL AG INDUSTRIESTRASSE 25 D- 83607 HOLZKIRCHEN	GERMANY	TRANSDERMAL PATCHES	1.0X5.0 SACHET CARTON	08/02/2023

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666	NDA/MAL/HDP/10482	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	FENTANYL SANDOZ 100 µG/H	FENTANYL	100µG/HOUR	HEXAL AG INDUSTRIESTRASSE 25 D- 83607 HOLZKIRCHEN	GERMANY	TRANSDERMAL PATCHES	1.0X5.0 SACHET CARTON	08/02/2023
667	NDA/MAL/HDP/10483	NVS KENYA LTD	SURGIPHARM (U) LIMITED	PATIZRA	RANIBIZUMAB	10 MG/ML	NOVARTIS PHARMA STEIN AG STERILE OPERATIONS SOLID OPERATIONSNOVARTIS PHARMA STEIN AG SCHAFFHAUSERSTRASSE, 4332 STEIN - SWITZERLAND	SWITZERLAND	PARENTERAL ORDINARY VIALS	1.0X1.0X0.23 ML VIAL	08/02/2023
668	NDA/MAL/HDP/10484	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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669	NDA/MAL/HDP/10489	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	SWASTIK PHARMACEUTICAL LTD	TERBIN	TERBINAFINE HYDROCHLORIDE	250 MG	GLOBAL NAPI PHARMACEUTICALS-2ND INDUSTRIAL ZONE, ST 18, 6TH OCTOBER CITY	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	08/02/2023
670	NDA/MAL/HDP/1049	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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
671	NDA/MAL/HDP/10490	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	SWASTIK PHARMACEUTICAL LTD	BISOCARD PLUS 5MG/12.5MG	BISOPROLOL FUMARATE + HYDROCHLOROTHIAZIDE	5MG + 12.5MG	GLOBAL NAPI PHARMACEUTICALS-2ND INDUSTRIAL ZONE, ST 18, 6TH OCTOBER CITY	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023

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672	NDA/MAL/HDP/10491	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	APRETUDE 30 MG	CABOTEGRAVIR	30 MG	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	UNITED KINGDOM	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	08/02/2023
673	NDA/MAL/HDP/10492	MACLEODS PHARMACEUTICALS 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
674	NDA/MAL/HDP/10493	CENTURION LABORATORIES PVT. LTD.	SHREEJI PHARMACEUTICALS 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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675	NDA/MAL/HDP/10494	CENTURION LABORATORIES PVT. LTD.	SHREEJI PHARMACEUTICALS LIMITED	FORMET 1000	METFORMIN HYDROCHLORIDE	1000 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023
676	NDA/MAL/HDP/10495	EGYPHAR	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HELI-CURE	CLARITHROMYCIN + OMEPRAZOLE + TINIDAZOLE	250 MG + 20 MG + 500 MG	EGYPHAR FACTORY OUBOUR CITY- INDUSTRIAL ZONE (A), BLOCK NO 13026. PIECE NO 9&0- EGYPT	EGYPT	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	08/02/2023
677	NDA/MAL/HDP/10496	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

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678	NDA/MAL/HDP/10497	EGYPHAR	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ZISROCIN	AZITHROMYCIN	500MG	EGYPHAR FACTORYOUBOUR CITY- INDUSTRIAL ZONE (A), BLOCK NO 13026. PIECE NO 9&0- EGYPT	EGYPT	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X1.0X3.0 CAPSULE BLISTER	08/02/2023
679	NDA/MAL/HDP/10499	AL ANDALOUS FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TIRATAM 500 MG XR	LEVETIRACETAM	500 MG	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	08/02/2023
680	NDA/MAL/HDP/1050	INTAS PHARMACEUTICALS 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	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER,10.0X10.0 TABLET BLISTER	01/07/2013

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681	NDA/MAL/HDP/10 502	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	VORIOLE 200	VORICONAZOLE	200MG	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	08/02/2023
682	NDA/MAL/HDP/10 503	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
683	NDA/MAL/HDP/10 504	INFUGEN PHARMA PVT. LTD.	TATA UGANDA LIMITED	INFUROXIM 1.5 G	CEFUROXIME SODIUM	1.5G	ZEISS PHARMACEUTICALS PRIVATE LIMITEDPLOT NO. 72 EPIP-PHASE-1 JHARMAJRI BADDI DISTRICT SOLAN (H.P.)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.5 G VIAL (CLEAR GLASS VIAL)	08/02/2023

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684	NDA/MAL/HDP/10505	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
685	NDA/MAL/HDP/10506	PHARMATHEN S.A	GOODMAN INTERNATIONAL LTD	A-CNOTREN® 10MG	ISOTRETINOIN	10MG	PHARMATHEN S.A6, DERVENAKION STR. 15351 PALLINI ATHENS PHARMATHEN INTERNATIONAL S.A INDUSTRIAL PARK SAPE, RODOPI PREFECTURE, BLOCK NO. 5, RODOPI 69300 - GREECE GAP S.A.46 AGISSILAOU STR. 17341 AGIOS DIMITRIOS	GREECE	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	08/02/2023
686	NDA/MAL/HDP/10507	AUROLAB	SWASTIK PHARMACEUTICAL LTD	TOB - DEX	TOBRAMYCIN SULFATE + DEXAMETHASONE 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

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687	NDA/MAL/HDP/10508	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/SYRUPS/DROPS	1.0X1.0X60.0 ML BOTTLE	08/02/2023
688	NDA/MAL/HDP/10509	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	PANTRO INJECTION	PANTOPRAZOLE SODIUM	40MG	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X40.0 MG VIAL + (1*1*10ML OF SODIUM CHLORIDE SOLUTION IN CLEAR GLASS AMPOULE)	08/02/2023
689	NDA/MAL/HDP/10510	ZIM LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	NEUROZIM 75	PREGABALIN	75MG	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	08/02/2023

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690	NDA/MAL/HDP/10511	VRUSHIK INVESTMENT (U) LTD.	SHREEJI PHARMACEUTICALS LIMITED	METO	METOCLOPRAMIDE HYDROCHLORIDE	10MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/02/2023
691	NDA/MAL/HDP/10512	CENTURION LABORATORIES PVT. LTD.	SHREEJI PHARMACEUTICALS LIMITED	FINADOL ULTRA	PARACETAMOL + CAFFEINE	500 MG + 30 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/02/2023
692	NDA/MAL/HDP/10513	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EXITINE 0.5MG/5ML	FLUMAZENIL	0.5MG/5ML	MS PHARMA - JORDAN PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH-WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY VIALS	1X5X5 ML VIAL	10/02/2023

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693	NDA/MAL/HDP/10515	TAKEDA PHARMA A/S	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NINLARO 2.3 MG	IXAZOMIB CITRATE	2.3MG	HAUPT PHARMA AMAREG GMBHDONAUSTAUFER STRASSE 378, 93055 REGENSBURG	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X1.0X1.0 CAPSULE BLISTER	08/02/2023
694	NDA/MAL/HDP/10516	TAKEDA PHARMA A/S	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NINLARO 3.0 MG	IXAZOMIB CITRATE	3MG	HAUPT PHARMA AMAREG GMBHDONAUSTAUFER STRASSE 378, 93055 REGENSBURG	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X1.0X1.0 CAPSULE BLISTER	08/02/2023
695	NDA/MAL/HDP/10517	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BRULEXIN-250	CEFALEXIN MONOHYDRATE	250MG	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	08/02/2023

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696	NDA/MAL/HDP/10519	PT SANBE FARMA	MEDVIN PHARMA 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
697	NDA/MAL/HDP/1052	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS LIMITED	MICLOGEN	MICONAZOLE NITRATE+CLOBET ASOLE PROPIONATE+GEN TAMICIN 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.THAN E INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2013
698	NDA/MAL/HDP/10520	ENCORE HEALTHCARE PVT. LTD.	REDDYS PHARMA LIMITED	ENCOBLOC	PROPRANOLOL HYDROCHLORIDE	40MG	ENCORE HEALTHCARE PVT LTDD-5, MIDC AREA, PAITHAN- 431148, DIST. AURANGABAD, MAHARASHTRA - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	08/02/2023

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699	NDA/MAL/HDP/10521	SCOTT-EDIL ADVANCE RESEARCH LABORATORIES & EDUCATION LTD.,	ROYAL PHARMA 2011 LIMITED	SCOTXONE PLUS	CEFTRIAXONE SODIUM + SULBACTAM SODIUM	1000 MG + 500 MG	M/S SCOTT-EDIL ADVANCE RESEARCH LABORATORIES AND EDUCATION LIMITEDHILL- TOP, INDUSTRIAL AREA, BHATOLI KALAN, BADDI, DISTT. SOLAN (HP) - 173205, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1500.0 MG VIAL	08/02/2023
700	NDA/MAL/HDP/10522	ZIM LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	CEFRIM 500	CEFUROXIME AXETIL	500MG	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	08/02/2023
701	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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702	NDA/MAL/HDP/10524	AGIO PHARMACEUTICALS LIMITED	ROYAL PHARMA 2011 LIMITED	DICLOGEN RETARD 100	DICLOFENAC SODIUM	100MG	AGIO PHARMACEUTICALS LIMITED.T- 81, 82, MIDC, BHOSARI, PUNE - 411 026 INDIA	INDIA	ORAL SOLID RETARD FILM-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	08/02/2023
703	NDA/MAL/HDP/10528	THE SEARLE COMPANY LIMITED	SURGIPHARM (U) LIMITED	EZIUM 20 MG	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	20MG	SEARLE PAKISTAN LTD..F-319, S.I.T.E., OPP. KESC POWER STATION, KARACHI	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER	08/02/2023
704	NDA/MAL/HDP/10529	THE SEARLE COMPANY LIMITED	SURGIPHARM (U) LIMITED	EZIUM 40 MG	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40MG	SEARLE PAKISTAN LTD..F-319, S.I.T.E., OPP. KESC POWER STATION, KARACHI	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER	08/02/2023

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705	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
706	NDA/MAL/HDP/10530	ZOTA HEALTHCARE LTD	HARLEYS UGANDA LIMITED	COXZOTA 120	ETORICOXIB	120MG	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	08/02/2023
707	NDA/MAL/HDP/10531	GLAXOSMITHKLINE LIMITED-	UNITED HEALTHCARE DISTRIBUTORS LTD	ENO CALCIUM ANTACID TABLETS	CALCIUM CARBONATE	500MG	GLAXOSMITHKLINE LIMITED LIKONI ROAD, INDUSTRIAL AREA, P.O. BOX 78392-00507, VIWANDANI, NAIROBI GLAXOSMITHKLINE CONSUMER HEALTHCARE HOLDINGS (US) LLC 320 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

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708	NDA/MAL/HDP/10 532	ALKEM LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	TAXIM-O	CEFIXIME TRIHYDRATE	400MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X5.0 CAPSULE BLISTER	08/02/2023
709	NDA/MAL/HDP/10 533	CELON LABORATORIES PRIVATE LIMITED.	GOOD DAY PHARMACY LIMITED	HYPRO 200	PROPOFOL	200 MG/20 ML	CELON LABORATORIES PRIVATE LIMITED PLOT NO. 2, ALEAP INDUSTRIAL ESTATE, GAJULARAMARAM, MEDCHAL - MALKAJGIRI DIST-500090, TELEGANA - INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X20.0 ML VIAL	08/02/2023
710	NDA/MAL/HDP/10 534	PSYCHOTROPICS INDIA LTD-	ABACUS PHARMA (AFRICA) LIMITED	KETAMINE HYDROCHLO RIDE INJECTION USP 50MG/ML	KETAMINE HYDROCHLORIDE	50MG/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	1.0X1.0X10.0 ML VIAL	08/02/2023

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711	NDA/MAL/HDP/10535	FERRER INTERNATIONAL, S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ANGINOVAG	DEQUALINIUM CHLORIDE + TYROTHRIN + B - GLYCRRHETINIC 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
712	NDA/MAL/HDP/10536	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
713	NDA/MAL/HDP/10537	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

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714	NDA/MAL/HDP/10538	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
715	NDA/MAL/HDP/10539	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	ZOTAMET-850	METFORMIN HYDROCHLORIDE	850MG	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	08/02/2023
716	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.THAN E INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X6.0 CAPSULE BLISTER	01/07/2011

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717	NDA/MAL/HDP/10 540	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICALS 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
718	NDA/MAL/HDP/10 541	GALENICUM HEALTH S.L.	GOODMAN INTERNATIONAL LTD	ROSUVASTAT IN	ROSUVASTATIN	20MG	BIOFARM SP. Z.O.OUL. WALBRZYSKA 13, 60-198 POZNAN - POLAND	POLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X7.0 TABLET BLISTER	08/02/2023
719	NDA/MAL/HDP/10 543	ADWIA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ADWIFLAM	DICLOFENAC POTASSIUM	75MG	SOUTH EGYPT DRUG INDUSTRIES COMPANY (SEDICO)-FIRST INDUSTRIAL ZONE, 6TH OF OCTOBER CITY - EGYPT	EGYPT	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY STRIP	08/02/2023

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720	NDA/MAL/HDP/10544	AUROLAB	SWASTIK PHARMACEUTICAL LTD	ATROP	ATROPINE SULFATE	1%W/V	AUROLAB LIMITED NO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU INDIA	BRAZIL	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	08/02/2023
721	NDA/MAL/HDP/10545	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	BRAMOL	PARACETAMOL	10MG/ML	BROOKES PHARMA (PRIVATE) LIMITED 58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML VIAL	08/02/2023
722	NDA/MAL/HDP/10546	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	OXOFERIN	TETRACHLORODE CAOXIDE	138.0 X 10 ⁶ PMOL/100ML	BROOKES PHARMA (PRIVATE) LIMITED 58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	TOPICAL EXTERNAL LIQUIDS	1.0X1.0X50.0 ML BOTTLE	08/02/2023

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723	NDA/MAL/HDP/10547	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
724	NDA/MAL/HDP/10551	SANJAR PHARMA LLP.	MOTI PHARMA (UGANDA) LIMITED	ADRENALIN	ADRENALINE ACID TARTRATE	1MG	SANJAR PHARMA LLP SURVEY 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
725	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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726	NDA/MAL/HDP/10553	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
727	NDA/MAL/HDP/10554	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
728	NDA/MAL/HDP/10556	KESAR PHARMA	SWASTIK PHARMACEUTICAL LTD	PIADIN	POVIDONE IODINE	5.0 W/W	KESAR PHARMA PVT LTD PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL - -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X10.0 G TUBE	08/02/2023

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729	NDA/MAL/HDP/10 557	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	LOFNAC-50	DICLOFENAC SODIUM	50MG	BLISS GVS PHARMA LIMITED 10,11 & 12, DEWAN UDYOG NAGAR, ALIYALI, PALGHAR, MAHARASHTRA 401404, INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	08/02/2023
730	NDA/MAL/HDP/10 558	KLM LABORATORIES PVT. LTD.	REDDYS PHARMA LIMITED	NEOCLEAN GEL	CLINDAMYCIN PHOSPHATE + NICOTINAMIDE	1.0 %W/W + 4.0%W/W	CURETECH SKINCARE PLOT 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
731	NDA/MAL/HDP/10 559	KLM LABORATORIES PVT. LTD.	REDDYS PHARMA LIMITED	NIOSALIC OINTMENT	CLOBETASOL PROPIONATE + SALICYLIC ACID	0.05%W/W + 3.00W/W	CURETECH SKINCARE PLOT 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

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732	NDA/MAL/HDP/1056	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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
733	NDA/MAL/HDP/10560	LEBEN LABORATORIES PVT.LTD	MALIX PHARMA (U) LIMITED	WHITFIELD'S OINTMENT	BENZOIC ACID + SALICYLIC ACID	6%W/W + 3%W/W	LEBEN LABORATORIES PVT LTD .L-14 PHASE III MIDC AKOLA 444 104	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X20.0 G TUBE	08/02/2023
734	NDA/MAL/HDP/10561	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	WORIV	ALBENDAZOLE	400MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X1.0 TABLET BLISTER	08/02/2023

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735	NDA/MAL/HDP/10562	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
736	NDA/MAL/HDP/10563	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	08/02/2023
737	NDA/MAL/HDP/10564	MYLAN LABORATORIES LIMITED-	KIMSY MEDS LTD	ISONIAZID/PYRIDOXINE HYDROCHLORIDE/SULFAMETHOXAZOLE + TRIMETHOPRIM TABLETS	ISONIAZID + PYRIDOXINE HYDROCHLORIDE + SULFAMETHOXAZOLE + TRIMETHOPRIM	300 MG + 25 MG + 800 MG + 160 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	1.0X1.0X10.0 TABLET BLISTER, 1.0X1.0X30.0 TABLET BOTTLE	08/02/2023

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738	NDA/MAL/HDP/10565	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
739	NDA/MAL/HDP/10566	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
740	NDA/MAL/HDP/10567	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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741	NDA/MAL/HDP/10568	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
742	NDA/MAL/HDP/10569	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
743	NDA/MAL/HDP/1057	NECTAR LIFESCIENCES 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

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744	NDA/MAL/HDP/10570	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
745	NDA/MAL/HDP/10571	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
746	NDA/MAL/HDP/10572	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	NAT-B FORTE	THIAMINE MONONITRATE (VITAMIN B1) + PYRIDOXINE HYDROCHLORIDE (VITAMIN B6) + METHYLCOBALAM IN (VITAMIN B12) + FOLIC ACID + D-ALPHA-TOCOPHEROL ACETATE + VITAMIN A +	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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747	NDA/MAL/HDP/10575	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BINOVEN 75	VENLAFAXINE HYDROCHLORIDE	75MG	AUROBINDO PHARMA LIMITED, UNIT IISURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELENGANA (STATE)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	08/02/2023
748	NDA/MAL/HDP/10576	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	QUITIDE 100	QUETIAPINE FUMARATE	100MG	AUROBINDO PHARMA LIMITED, UNIT IISURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELENGANA (STATE)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023
749	NDA/MAL/HDP/10578	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	OCORTIN	HYDROCORTISONE	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

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750	NDA/MAL/HDP/10 579	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
751	NDA/MAL/HDP/10 589	PSYCHOTROPICS INDIA LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	PILECA-EZ	ATORVASTATIN + EZETIMIBE	10 MG + 10 MG	PSYCHOTROPICS INDIA LTD PLOT NO. 46 & 49, SECTOR-6A, IIE, SIDCUL, HARIDWAR - 249403(UTTARAKHARD)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
752	NDA/MAL/HDP/10 590	MYLAN LABORATORIES LIMITED-	KIMSY MEDS LTD	ULCEREST 20	ESOMEPRAZOLE MAGNESIUM	20MG	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 BOTTLE	15/02/2023

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753	NDA/MAL/HDP/10 591	MYLAN LABORATORIES LIMITED-	KIMSY MEDS LTD	ULCEREST 40	ESOMEPRAZOLE MAGNESIUM	40MG	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 BOTTLE	15/02/2023
754	NDA/MAL/HDP/10 592	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	ASCARD-75	ASPIRIN	75MG	ATCO LABORATORIES LIMITEDB-18, S.I.T.E, KARACHI - 74700	PAKISTAN	ORAL SOLID ORDINARY ENTERIC- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
755	NDA/MAL/HDP/10 593	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	MOMRIV	MOMETASONE FUROATE	0.1%W/W	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	15/02/2023

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756	NDA/MAL/HDP/10597	MEDISEL(K) LTD	SUPER MEDIC LTD	GABANERVE	GABAPENTIN + METHYLCOBALAMIN	300MG + 500MCG	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
757	NDA/MAL/HDP/10598	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	MIXIF	CEFIXIME TRIHYDRATE	400MG	DAR AL DAWANA'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	15/02/2023
758	NDA/MAL/HDP/10599	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	BETAMET CREAM	BETAMETHASONE VALERATE	0.1%W/W	ATCO LABORATORIES LIMITED B-18, S.I.T.E, KARACHI - 74700	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	15/02/2023

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759	NDA/MAL/HDP/10600	MEDISEL(K) LTD	AIVEEN (U) LIMITED	OSTEOCERIN	GLUCOSAMINE SULPHATE POTASSIUM CHLORIDE + METHL 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
760	NDA/MAL/HDP/10601	MSN LABORATORIES PRIVATE LIMITED,	ABACUS PHARMA (AFRICA) LIMITED	VORIOLE 50	VORICONAZOLE	50 MG	MSN LABS LTD (FORMULATION DIVISION) PLOT 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT ZIP CODE 502325, ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	15/02/2023
761	NDA/MAL/HDP/10602	WORLD MEDICINE İLAÇ SAN. VE TIC. A.Ş.	GOODMAN INTERNATIONAL LTD	ZIROMIN 200 MG/5 ML	AZITHROMYCIN DIHYDRATE	200 MG/5 ML	WORLD MEDICINE İLAC SAN VE TIC A.S.15 TEMMUZ MAHALLESİ, CAMI YOLU CADDESİ, NO: 50 K:4 WM PLAZA, GUNESIL-BAGCILAR/INSTANBUL, TURKEY	TURKEY	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X1.0X30.0 ML BOTTLE	15/02/2023

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762	NDA/MAL/HDP/10 604	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	PIPERATAZ 4.5	PIPERACILIN + 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
763	NDA/MAL/HDP/10 605	PSYCHOTROPICS INDIA LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	HALOPAC	HALOPERIDOL	5MG	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	15/02/2023
764	NDA/MAL/HDP/10 606	MEDISEL(K) LTD	AIVEEN (U) LIMITED	EMADON SYRUP	ONDANSETRON HYDROCHLORIDE	2MG/5ML	CORONA REMEDIES PVT. LTD VILLAGE 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

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765	NDA/MAL/HDP/10607	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS 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
766	NDA/MAL/HDP/10609	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
767	NDA/MAL/HDP/1061	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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768	NDA/MAL/HDP/10610	WORLD MEDICINE İLAÇ SAN. VE TIC. A.Ş.	GOODMAN INTERNATIONAL LTD	ESLOTIN	DES Loratadine	2.5 MG/5ML	WORLD MEDICINE İLAC SAN VE TIC A.S.15 TEMMUZ MAHALLESİ, CAMI YOLU CADDESİ, NO: 50 K:4 WM PLAZA, GUNESİL-BAGCILAR/İSTANBUL, TURKEY	TURKEY	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	15/02/2023
769	NDA/MAL/HDP/10611	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	NEWSTAR 160/10 MG	VALSARTAN + AMLODIPINE BESYLATE	160 MG + 10 MG	PHARMA INTERNATIONAL CO. LTD AL QASTAL AIRPORT ROAD, P.O. BOX 334 AL JUBAIHA 11941, AMAAN	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER	15/02/2023
770	NDA/MAL/HDP/10612	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	NEWSTAR 160/5 MG	VALSARTAN + AMLODIPINE BESYLATE	160 MG + 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	1.0X4.0X7.0 TABLET BLISTER	15/02/2023

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771	NDA/MAL/HDP/10613	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	SYNER-CEF 500	CEFUROXIME AXETIL	500MG	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 FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	15/02/2023
772	NDA/MAL/HDP/10614	S KANT HEALTHCARE LTD -	ABACUS PHARMA (AFRICA) LIMITED	AVIRAX	ACICLOVIR	5% W/W	S KANT HEALTHCARE LIMITED1802 – 1805, G.I.D.C., PHASE III, VAPI - 396195 GUJARAT, INDIA.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	15/02/2023
773	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

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774	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
775	NDA/MAL/HDP/10617	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
776	NDA/MAL/HDP/10618	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 LIMITED PLOT 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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777	NDA/MAL/HDP/10619	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	DEXIREN	DEXKETOPROFEN TROMETAMOL	50MG/2ML	IDOL LLAC DOLUM A.S.DAVUTPASA CADDESİ. CEBE ALI BEY SOK. NO. 20 34010/ DAVUTPASA - TOPKAPI / ISTANBUL	TURKEY	PARENTERAL ORDINARY AMPOULES	1.0X1.0X6.0X2.0 ML AMPOULE	15/02/2023
778	NDA/MAL/HDP/1062	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
779	NDA/MAL/HDP/10620	RENE INDUSTRIES LIMITED	RENE PHARMACY LTD	BUSCOREN	HYOSCINE BUTYLBROMIDE	10 MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	15/02/2023

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780	NDA/MAL/HDP/10 621	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
781	NDA/MAL/HDP/10 622	CENTURION LABORATORIES PVT. LTD.	SHREEJI PHARMACEUTICALS 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
782	NDA/MAL/HDP/10 623	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

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783	NDA/MAL/HDP/10 624	MSN LABORATORIES PRIVATE LIMITED,	ABACUS PHARMA (AFRICA) LIMITED	MIBZO	BORTEZOMIB	3.5 MG/VIAL	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325-TELENGANA,	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X3.5 MG VIAL	15/02/2023
784	NDA/MAL/HDP/10 625	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
785	NDA/MAL/HDP/10 628	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	SITAGLU MET 50/500	SITAGLIPTIN PHOSPHATE + METFORMIN HYDROCHLORIDE	50 MG + 500 MG	HILTON PHARMACEUTICALS (PVT) LIMITEDPLOT NO. 13-14, SECTOR 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	15/02/2023

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786	NDA/MAL/HDP/10629	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	SITAGLU MET 50/1000	SITAGLIPTIN PHOSPHATE + METFORMIN HYDROCHLORIDE	50 MG + 1000 MG	HILTON PHARMACEUTICALS (PVT) LIMITED PLOT NO. 13-14, SECTOR 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	15/02/2023
787	NDA/MAL/HDP/10630	INNOVA CAPTAB LTD.	TATA UGANDA LIMITED	INFIXIME 400	CEFIXIME TRIHYDRATE	400MG	INNOVA CAPTAB PVT. LTD 1281/1, 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	15/02/2023
788	NDA/MAL/HDP/10631	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	RYALTRIS	OLOPATADINE HYDROCHLORIDE + MOMETASONE FUROATE	665 MCG/25 MCG	GLENMARK PHARMACEUTICALS LIMITED-UNIT III VILLAGE 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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789	NDA/MAL/HDP/10 632	PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS AND PHARMACEUTICALS PVT. LTD)	ROYAL PHARMA 2011 LIMITED	ROSUVAT 10	ROSUVASTATIN CALCIUM	10 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	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
790	NDA/MAL/HDP/10 633	MYLAN PHARMACEUTICAL PRIVATE LIMITED - PLOT NO. 1-A/2	KIMSY MEDS LTD	FULPHILA	PEGFILGRASTIM	6 MG/0.6 ML	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 I V PRE- FILLED SYRINGES	1.0X1.0X1.0X0.6 ML PRE- FILLED SYRINGE	15/02/2023
791	NDA/MAL/HDP/10 634	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROFLU-CARE	PARACETAMOL + CAFFEINE + CHLORPHENIRAMI NE 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

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792	NDA/MAL/HDP/10636	UNICHEM LABORATORIES LIMITEDv	EUROPA HEALTHCARE (U) LTD	UNIPROEX ER 250	DIVALPROEX SODIUM	250MG	UNICHEM LABORATORIES LTD PLOT NO. 15,16,17,17A & 18, PILERNE INDUSTRIAL ESTATE, PILERNE, BARDEZ, GOA- 403511	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
793	NDA/MAL/HDP/10637	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
794	NDA/MAL/HDP/10638	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CLOTRIMAZOLE, BETAMETHASONE DIPROPIONATE, GENTAMICIN SULPHATE CREAM	CLOTRIMAZOLE + BETAMETHASONE DIPROPIONATE + GENTAMICIN SULPHATE	(10 MG + 0.5 MG + 1 MG)/G	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	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	15/02/2023

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795	NDA/MAL/HDP/10 639	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CIROVIR	ACICLOVIR	5%W/W	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	TOPICAL EXTERNAL CREAMS	1.0X1.0X5.0 G TUBE	15/02/2023
796	NDA/MAL/HDP/10 640	FAES FARMA S.A	PHILLIPS PHARMACEUTICALS (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
797	NDA/MAL/HDP/10 642	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	PACSITA 150	CAPECITABINE	150MG	EUGIA PHARMA SPECIALITIES LIMITEDSURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	15/02/2023

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798	NDA/MAL/HDP/10 643	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	PACSITA 500	CAPECITABINE	500MG	EUGIA PHARMA SPECIALITIES LIMITEDSURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	15/02/2023
799	NDA/MAL/HDP/10 645	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VINKAMINE	VANCOMYCIN HYDROCHLORIDE	500MG	MS PHARMA - JORDANPLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL- HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES	1X1X500 MG VIAL	06/03/2023
800	NDA/MAL/HDP/10 646	TORRENT PHARAMACEUTICA LS LTD	KARURI PHARMACEUTICALS LTD.	ENZYSTAL P	PANCREAS POWDER	EQUIVALENT TO AMYLASE ACTIVITY 4200 PH. EUR UNITS, LIPASE ACTIVITY 3500 PH. EUR UNITS AND PROTEASE ACTIVITY 250 PH. EUR UNITS	TORRENT PHARMACEUTICALS LTD VILLAGE: BHUD & MAKHNU MAJRA, TEHSIL: BADDI – 173205, DIST: SOLAN, HIMACHAL PRADESH,	INDIA	ORAL SOLID ORDINARY ENTERIC- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	15/02/2023

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801	NDA/MAL/HDP/10647	LITHA PHARMA (PTY) LTD.	LABOREX UGANDA LIMITED	METHYLPHENIDATE HCL-DOUGLAS	METHYLPHENIDATE HYDROCHLORIDE	10MG	DOUGLAS MANUFACTURING LIMITED CORNER TE PAI PLACE AND CENTRAL PARK DRIVE, LINCOLN, AUCKLAND 0610 - NEW ZEALAND	NEW ZEALAND	ORAL SOLID ORDINARY TABLETS	1.0X2.0X15.0 TABLET BLISTER	15/02/2023
802	NDA/MAL/HDP/10648	CIPLA LTD	QUALITY CHEMICALS LTD	TENVIR-AF	TENOFOVIR ALAFENAMIDE FUMARATE	25MG	CIPLA LIMITED PLOT NO. A-33, A-2 & A-37/2/2 (UNIT-I), A-42 (UNIT-II), MIDC PATALGANGA, 410220 DISTRICT RAIGAD, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE	15/02/2023
803	NDA/MAL/HDP/10649	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	ESOCID 40	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40MG	PINNACLE LIFE SCIENCE PVT LTD KHASRA 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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804	NDA/MAL/HDP/10 65	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
805	NDA/MAL/HDP/10 651	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BROZELIN	AMBROXOL HYDROCHLORIDE + SALBUTAMOL + GUAIPHENESIN + MENTHOL	(30 MG + 2 MG + 50 MG + 1 MG)/5 ML	THE MADRAS PHARMACEUTICALS..NO. 137B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI 600096	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	15/02/2023
806	NDA/MAL/HDP/10 652	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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807	NDA/MAL/HDP/10653	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	COXZOTA-60	ETORICOXIB	60MG	ZOTA HEALTHCARE 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	15/02/2023
808	NDA/MAL/HDP/10654	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 LIMITED WORKS: 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
809	NDA/MAL/HDP/10655	HETERO LABS LTD	AIVEEN (U) LIMITED	TENOFOVIR ALAFENAMIDE TABLETS	TENOFOVIR ALAFENAMIDE HEMIFUMARATE	25MG	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 BOTTLE	15/02/2023

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810	NDA/MAL/HDP/10656	AL ANDALOUS FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BIOGLITA PLUS 15/500MG FC TABLETS	PIOGLITAZONE + METFORMIN HYDROCHLORIDE	15MG + 500MG	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,1.0X3.0X10.0 TABLET BLISTER	15/02/2023
811	NDA/MAL/HDP/10657	AL ANDALOUS FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BIOGLITA PLUS 15/850MG FC TABLETS	PIOGLITAZONE + METFORMIN HYDROCHLORIDE	15MG + 850MG	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,1.0X3.0X10.0 TABLET BLISTER	15/02/2023
812	NDA/MAL/HDP/10658	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ATORKEY 40	ATORVASTATIN CALCIUM TRIHYDRATE	40MG	AUROBINDO PHARMA LIMITED, UNIT - XV PLOT NO. 17A, E BONANGI (V), PARAWADA (M), VISAKHAPATNAM DISTRICT, ANDHRA PRADESH. PIN: 531021	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

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813	NDA/MAL/HDP/10659	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	ACENAC-P	ACECLOFENAC + PARACETAMOL	100MG + 500MG	MEDLEY PHARMACEUTICALS LTD LANE 03, PHASE 1, SIDCO INDUSTRIAL COMPLEX, BARI BRAHMANA JAMMU 181133	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
814	NDA/MAL/HDP/10660	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	AZITIZ-250	AZITHROMYCIN DIHYDRATE	250MG	ZOTA HEALTHCARE 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	1.0X1.0X6.0 TABLET BLISTER	15/02/2023
815	NDA/MAL/HDP/10661	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	LIVOTA-750	LEVOFLOXACIN HEMIHYDRATE	750MG	ZOTA HEALTHCARE 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	1.0X1.0X10.0 TABLET BLISTER	15/02/2023

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816	NDA/MAL/HDP/10 662	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	TOMOZA	MOSAPRIDE CITRATE DIHYDRATE	5MG	ZOTA HEALTHCARE 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	15/02/2023
817	NDA/MAL/HDP/10 663	FERRER INTERNATIONAL, S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TRAMAPA 37.5 MG/325 MG	TRAMADOL HYDROCHLORIDE + PARACETAMOL	37.5 MG/325 MG	FERRER INTERNATIONAL, S.A./ JOAN BUSCALLA, 1- 9 08173 SANT CUGAT DEL VALLES,	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	15/02/2023
818	NDA/MAL/HDP/10 664	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

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819	NDA/MAL/HDP/10 665	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CIATUFF 10	TADALAFIL	10 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), TSIIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHRLA MANDAL, MAHABOOB NAGA DISTRICT, PIN CODE: 509302,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X4.0 TABLET BLISTER	15/02/2023
820	NDA/MAL/HDP/10 667	VINS BIOPRODUCTS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	VINRAB 1000 IU	EQUINE ANTIRABIES IMMUNOGLOBULI N FRAGMENTS F (AB') 2	NOT LESS THAN 200 IU PER ML	VINS BIOPRODUCTS LIMITEDSY. NO. 117, THIMMAPUR (V), KOTHUR MANDAL), RANGA REDDY (DIST), TELANDANA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X5.0 ML VIAL	15/02/2023
821	NDA/MAL/HDP/10 668	LUPIN LIMITED	AIVEEN (U) LIMITED	DOLUTEGRAVIR SODIUM/LA MIVUDINE/T ENOFOVIR DISOPROXIL FUMERATE 50MG/300M G/300MG	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFIVIR 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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822	NDA/MAL/HDP/10669	AL ANDALOUS FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CARDIOTIMIDE 20 MG	TORSEMIDE	20 MG	AL ANDALOUS FOR PHARMACEUTICAL INDUSTRIESPART NO. 7/6 6TH INDUSTRIAL AREA - 6TH OCTOBER CITY - GIZA	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	15/02/2023
823	NDA/MAL/HDP/1067	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	IBUPARA	IBUPROFEN+PARACETAMOL	200MG+ 250MG/10ML	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2010
824	NDA/MAL/HDP/10670	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	DOLGINA	DEXLANSOPRAZOLE	30MG	HILTON PHARMACEUTICALS (PVT) LIMITEDPLOT NO. 13-14, SECTOR 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	15/02/2023

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825	NDA/MAL/HDP/10671	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	TRANSAMIN-S	TRANEXAMIC ACID	1000MG/10ML	HILTON PHARMACEUTICALS (PVT) LIMITED PLOT NO. 13-14, SECTOR 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	PARENTERAL ORDINARY I V AMPOULES	1.0X2.0X5.0 ML AMPOULE	15/02/2023
826	NDA/MAL/HDP/10672	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	DNS	SODIUM CHLORIDE + ANHYDROUS GLUCOSE	0.9%W/V & 5%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 BAGS	1.0X1.0X500.0 ML BAG	15/02/2023
827	NDA/MAL/HDP/10673	EAST AFRICAN (INDIA) OVERSEAS	ROYAL PHARMA 2011 LIMITED	CETARIV	CETIRIZINE HYDROCHLORIDE	5MG/5ML	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE	15/02/2023

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828	NDA/MAL/HDP/10 674	VINS BIOPRODUCTS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AFRIVEN-10	NAJA MELANOLEUCA+ NAJA NIGRICOLLIS + NAJA HAJE + DENDROASPIS POLYLEPIS + DENDROASPIS VIRIDIS + DENDROASPIS JAMESONI + BITIS GABONICA + BITIS ARIETANS + ECHIS JELICOGASTER +	NOT LESS THAN 22 LD50 + 22 LD50 + 27.5 LD50 + 27.5 LD50 + 27.5 LD50 + 27.5 LD50 + 27.5 LD50 + 27.5 LD50 + 27.5 LD50 + 27.5 LD50	VINS BIOPRODUCTS LIMITEDSY. NO. 117, THIMMAPUR (V), KOTHUR MANDAL), RANGA REDDY (DIST), TELANDANA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X5.0X10.0 ML VIAL	15/02/2023
829	NDA/MAL/HDP/10 675	THE SEARLE COMPANY LIMITED	SURGIPHARM (U) LIMITED	JENTIN 50	SITAGLIPTIN PHOSPHATE MONOHYDRATE	50 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	15/02/2023
830	NDA/MAL/HDP/10 676	THE SEARLE COMPANY LIMITED	SURGIPHARM (U) LIMITED	JENTIN 100	SITAGLIPTIN PHOSPHATE MONOHYDRATE	100 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	15/02/2023

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831	NDA/MAL/HDP/10 678	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
832	NDA/MAL/HDP/10 679	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	PG-75	PREGABALIN	75 MG	ZOTA HEALTHCARE LIMITED PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY SATTION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER	15/02/2023
833	NDA/MAL/HDP/10 680	RAPTAKOS, BRETT & CO. LTD.	EUROPA HEALTHCARE (U) LTD	NEOPEPTINE PLUS DROPS	ALPHA AMYLASE (BACTERIAL 1:800) + PAPAINE	(20MG + 10MG) PER ML	RAPTAKOS, BRETT & COMPANY LIMITED 1ST POKHRAN ROAD, THANE 400606, MIDC, MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X1.0X15.0 ML BOTTLE	15/02/2023

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834	NDA/MAL/HDP/10 681	BIODEAL LABORATORIES LTD PLOT NO.123	ABACUS PHARMA (AFRICA) LIMITED	PODOSAL OINTMENT	PODOPYLLUM RESIN + SALICYLIC ACID	20%W/W + 25%W/W	BIODEAL LABOARATORIES LTD123, LUNGA LUNGA ROAD, INDUSTRIAL AREA, NAIROBI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X10.0 G TUBE	15/02/2023
835	NDA/MAL/HDP/10 682	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	RALTEGRAVIR TABLETS	RALTEGRAVIR POTASSIUM	400 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	1.0X6.0 TABLET CONTAINER	15/02/2023
836	NDA/MAL/HDP/10 683	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MF-DAY ER 750	METFORMIN HYDROCHLORIDE	750 MG	AUROBINDO PHARMA LIMITED, UNIT IIISURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELENGANA (STATE)	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

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837	NDA/MAL/HDP/10 684	GALENICUM HEALTH S.L.	GOODMAN INTERNATIONAL LTD	DUTASVITAE 0.5MG	DUTASTERIDE	0.5MG	CYNDEA PHARMA, S.L.POLIGONO INDUSTRIAL EMILIANO REVILLA SANZ. AVDA. DE AGREDA, 31 OLVEGA 42110 (SORIA)	SPAIN	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	15/02/2023
838	NDA/MAL/HDP/10 685	AVACARE GLOBAL	GOODMAN INTERNATIONAL LTD	DEMOX	MOXIFLOXACIN HYDROCHLORIDE + DEXAMETHASONE PHOSPHATE	(5MG + 1MG)/ML	WORLD MEDICINE ILAC SAN VE TIC A.S.15 TEMMUZ MAHALLESI, CAMI YOLU CADDESİ, NO: 50 K:4 WM PLAZA, GUNESIL- BAGCILAR/INSTANBUL, TURKEY	TURKEY	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	15/02/2023
839	NDA/MAL/HDP/10 686	HETERO LABS LTD	AIVEEN (U) LIMITED	CELOFEN 200	CELECOXIB	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 ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	15/02/2023

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840	NDA/MAL/HDP/10 687	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	IRNIZET 300	IRINOTECAN HYDROCHLORIDE TRIHYDRATE	300 MG/15ML	EUGIA PHARMA SPECIALITIES LIMITEDSURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X15.0 ML VIAL	15/02/2023
841	NDA/MAL/HDP/10 688	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	UROKA	DUTASTERIDE	0.5 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	15/02/2023
842	NDA/MAL/HDP/10 689	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	LOSARZED- 100	LOSARTAN POTASSIUM	100 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	15/02/2023

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843	NDA/MAL/HDP/1069	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	K-ONE INJECTION	PHYTOMENADIONE	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
844	NDA/MAL/HDP/10690	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
845	NDA/MAL/HDP/10691	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEUROGLOP ENTIN 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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846	NDA/MAL/HDP/10692	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEUROGLOP ENTIN 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
847	NDA/MAL/HDP/10693	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS LIMITED	GEN DEX EYE DROPS	GENTAMICIN SULFATE + DEXAMETHASONE SODIUM PHOSPHATE	0.3% W/V + 0.1% W/V	SWISS PARENTERALS LIMITED (UNIT-1)808, 809, 810, KERALA INDUSTRIAL ESTATE, GIDC, NR. BAVLA, AHMEDABAD - 382220, GUJARAT - INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	15/02/2023
848	NDA/MAL/HDP/10694	MYLAN LABORATORIES LIMITED-	KIMSY MEDS LTD	OTYCULF 500 MG	FLUCYTOSINE	500MG	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	1.0X1.0X100.0 TABLET BOTTLE	15/02/2023

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849	NDA/MAL/HDP/10695	UNIMED TECHNOLOGIES CO., LTD	OMAB UGANDA LIMITED	GLUCOSE 5 % UNIMED	GLUCOSE ANHYDROUS	5%W/V	UNIMED LABORATORIES P.O. BOX 38 - I.Z. KALAA KEBIRA - 4060 KALAA KEBIRA - TUNISIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BAG	15/02/2023
850	NDA/MAL/HDP/10696	MACLEODS PHARMACEUTICALS 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
851	NDA/MAL/HDP/10697	BHARAT SERUMS & VACCINES LTD.	ABACUS PHARMA (AFRICA) LIMITED	ASPORELIX	CETRORELIX ACETATE	0.25MG	BHARAT SERUM AND VACCINES LIMITED PLOT 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

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852	NDA/MAL/HDP/10702	UNIMED LABORATORIES.	OMAB UGANDA LIMITED	VAAMOX 1G/200 MG	SODIUM AMOXICILLIN + POTASSIUM CLAVULANATE.	(1 G + 200 MG)VIAL	UNIMED LABORATORIESP.O. BOX 38 - I.Z. KALAA KEBIRA - 4060 KALAA KEBIRA - TUNISIA	TUNISIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.2 G VIAL	15/02/2023
853	NDA/MAL/HDP/10703	MOTI PHARMA(U) LTD.	MOTI PHARMA (UGANDA) LIMITED	TOPSUNATE	ARTESUNATE	60 MG	SANJAR PHARMA ILLPSURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 5ML OF 0.9%W/V SODIUM CHLORIDE SOLUTION IN A CLEAR GLASS AMPOULE + 1ML OF 5%W/V SODIUM BICARBONATE SOLUTION IN A CLEAR GLASS	15/02/2023
854	NDA/MAL/HDP/10704	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	EMEFILM-4	ONDANSETRON HYDROCHLORIDE	4 MG	SHILPA THERAPEUTICS PVT. LIMITEDPLOT NO. 118, PHASE-III, IDA, CHERLAPALLY, MEDCHAL-MALKAJGIRI DISTRICT, HYDERABAD - 500016, TELANGANA, INDIA	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X5.0 SACHET CARTON	15/02/2023

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855	NDA/MAL/HDP/10705	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	SUPADOL 500	PARACETAMOL	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 TABLETS	1.0X10.0X10.0 TABLET BLISTER	15/02/2023
856	NDA/MAL/HDP/10706	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	NTSUGA 500	METFORMIN 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	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
857	NDA/MAL/HDP/10707	MACLEODS PHARMACEUTICALS 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

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858	NDA/MAL/HDP/10708	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
859	NDA/MAL/HDP/10709	CADILA HEALTHCARE LIMITED "ZYDUS TOWER" -	ABACUS PHARMA (AFRICA) LIMITED	VINGLYN M 50/850	VILDAGLIPTIN + METFORMIN HYDROCHLORIDE	50 MG + 850 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
860	NDA/MAL/HDP/10710	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) OVERSEAS PLOT NO.1, PHARMACY 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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861	NDA/MAL/HDP/10712	RATNAMANI HEALTHCARE PVT. LTD	VIDA AFRICA LTD	ZENEGRA 100	SILDENAFIL CITRATE	100MG	RATNAMANI HEALTHCARE PRIVATE LIMITEDSURVEY NO. 750/1, AHMEDABAD - MEHSANA HIGHWAY, VILLAGE-INDRAD, NR. CHHATRAL G.I.D.C., TALUKA-KADI, DIST-MEHSANA, PIN-382721 (NG), GUJARAT - INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1X1X4 TABLET BLISTER	20/09/2023
862	NDA/MAL/HDP/10713	BIOMATRIX HEALTHCARE PVT LTD.-	MEDIWORLD PHARMA AFRICA LTD	IMMUNCEE 500	ASCORBIC ACID + SODIUM ASCORBATE	100MG + 450MG	BIOMATRIX HEALTHCARE PRIVATE LIMITEDSURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	15/02/2023
863	NDA/MAL/HDP/10714	BIOMATRIX HEALTHCARE PVT LTD.-	MEDIWORLD PHARMA AFRICA LTD	DICLOTRIX PLUS	DICLOFENAC SODIUM + PARACETAMOL	50MG + 500MG	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	15/02/2023

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864	NDA/MAL/HDP/10715	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	VILDARIL M 50/500	VILDAGLIPTIN + METFORMIN HYDROCHLORIDE	50 MG + 500MG	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	15/02/2023
865	NDA/MAL/HDP/10716	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	VILDARIL M 50/850	VILDAGLIPTIN + METFORMIN HYDROCHLORIDE	50 MG + 850 MG	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	15/02/2023
866	NDA/MAL/HDP/10717	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	VILDARIL M 50/1000	VILDAGLIPTIN + METFORMIN HYDROCHLORIDE	50 MG + 1000 MG	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	15/02/2023

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867	NDA/MAL/HDP/10718	ZIM LABORATORIES LTD	REDDYS PHARMA LIMITED	LIPIZAR 10	ATORVASTATIN CALCIUM TRIHYDRATE	10MG	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	15/02/2023
868	NDA/MAL/HDP/10719	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, TELEGANA STATE – 502313, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
869	NDA/MAL/HDP/1072	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CO-ANGINET 80/12.5MG	VALSARTAN + HYDROCHLOROTHIAZIDE	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

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870	NDA/MAL/HDP/10720	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
871	NDA/MAL/HDP/10721	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	FLEXABENZ GEL	DICLOFENAC DIETHYLMAINE + LINSEED OIL + METHYL SALICYLATE + MENTHOL + CYCLOBENZAPRINE 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
872	NDA/MAL/HDP/10722	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MEDWIN	MEDROXYPROGESTERONE ACETATE	150MG/ML	EUGIA PHARMA SPECIALITIES LIMITEDSURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL-MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X1.0 ML VIAL	15/02/2023

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873	NDA/MAL/HDP/10723	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
874	NDA/MAL/HDP/10724	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
875	NDA/MAL/HDP/10725	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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876	NDA/MAL/HDP/10726	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
877	NDA/MAL/HDP/10727	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
878	NDA/MAL/HDP/10728	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS 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

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879	NDA/MAL/HDP/10729	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS 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
880	NDA/MAL/HDP/10730	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	UNICHLOR 25	CHLOROTHALIDONE	25MG	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	15/02/2023
881	NDA/MAL/HDP/10731	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	UNICHLOR 50	CHLOROTHALIDONE	50 MG	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	15/02/2023

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882	NDA/MAL/HDP/10732	B&O PHARM	TRIDEM PHARMA UGANDA LIMITED	BREAZLAX	MONTELUKAST	4MG	BILIM ILAC SAN.VE TIC.A.SGEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY	TURKEY	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X2.0X14.0 TABLET BLISTER	15/02/2023
883	NDA/MAL/HDP/10733	B&O PHARM	TRIDEM PHARMA UGANDA LIMITED	BREAZLAX	MONTELUKAST	5MG	BILIM ILAC SAN.VE TIC.A.SGEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY	TURKEY	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X2.0X14.0 TABLET BLISTER	15/02/2023
884	NDA/MAL/HDP/10734	B&O PHARM	TRIDEM PHARMA UGANDA LIMITED	BREAZLAX	MONTELUKAST	10MG	BILIM ILAC SAN.VE TIC.A.SGEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY	TURKEY	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X2.0X14.0 TABLET BLISTER	15/02/2023

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885	NDA/MAL/HDP/10735	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	CIPLADON PLUS	PARACETAMOL + DOXYLAMINE SUCCINATE + CAFFEINE + CODEINE PHOSPHATE	450MG + 5MG + 30MG + 10MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED (CIPLAQCIL) PLOT 1-7, 1ST RING ROAD, LUZIRA INDUSTRIAL PARK	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER, 1.0X4.0X10.0 TABLET BLISTER	15/02/2023
886	NDA/MAL/HDP/10736	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	UNIPROX ER 500	DIVALPROX SODIUM	500MG	UNICHEM LABORATORIES LTD PLOT NO. 15, 16, 17, 17A & 18, PILERNE INDUSTRIAL ESTATE, PILERNE, BARDEZ, GOA- 403511	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER (ALU-ALU BLISTER), 1.0X3.0X10.0 TABLET BLISTER (ACLAR - PVC BLISTER)	15/02/2023
887	NDA/MAL/HDP/10737	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	ABACAVIR 600 MG AND LAMIVUDINE 300 MG FILM COATED TABLETS	ABACAVIR SULFATE + LAMIVUDINE	600MG + 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 BOTTLE, 1.0X90.0 TABLET BOTTLE, 1.0X180.0 TABLET BOTTLE	15/02/2023

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888	NDA/MAL/HDP/10738	SHANGHAI DESANO BIO-PHARMACEUTICAL CO., LTD	TATA UGANDA LIMITED	DOLUTEGRAVIR, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS	DOLUTEGRAVIR + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE	50 MG + 300 MG + 300 MG	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 BOTTLE,1.0X1.0X90.0 TABLET BOTTLE	15/02/2023
889	NDA/MAL/HDP/1074	NECTAR LIFESCIENCES LTD	SUPER MEDIC LTD	CEFUXIT	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
890	NDA/MAL/HDP/10742	CADILA HEALTHCARE LIMITED "ZYDUS TOWER" -	ABACUS PHARMA (AFRICA) LIMITED	VINGLYN	VILDAGLIPTIN	50 MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

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891	NDA/MAL/HDP/10743	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, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
892	NDA/MAL/HDP/10745	PUNISKA HEALTHCARE PRIVATE LIMITED	NORVIK ENTERPRISES LIMITED	EBROXON	CEFTRIAZONE SODIUM	1 G/VIAL	ZEISS PHARMACEUTICALS PRIVATE LIMITED PLOT NO. 72 EPIP-PHASE-1 JHARMAJRI BADDI DISTRICT SOLAN (H.P.)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL	15/02/2023
893	NDA/MAL/HDP/10746	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	FEBLORIKA-80	FEBUXOSTAT	80 MG	MANKIND PHARMA LIMITED UNIT - II, VILLAGE KISHANPURA, P.O. JAMNIWALA, TEHSIL PAONTA SAHIB, DISTRICT SIRMOUR - 173025, HIMACHAL PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

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894	NDA/MAL/HDP/10747	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	EFAVIRENZ, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS 400 MG/300 MG/300 MG	EFAVIRENZ + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE	400 MG + 300 MG + 300 MG	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,1.0X90.0 TABLET CONTAINER,1.0X180.0 TABLET CONTAINER	15/02/2023
895	NDA/MAL/HDP/10748	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
896	NDA/MAL/HDP/10749	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	TENOFOVIR ALAFENAMIDE TABLETS 25 MG	TENOFOVIR ALAFENAMIDE FUMARATE	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	1.0X30.0 TABLET BOTTLE	15/02/2023

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897	NDA/MAL/HDP/10750	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	RESTOCIN PLUS	PARACETAMOL + DEXTROMETHORPHAN HYDROBROMIDE + PHENYLEPHRINE HYDROCHLORIDE + CHORPHENIRAMINE 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
898	NDA/MAL/HDP/10753	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	HISTALIN 8	BETAHISTINE DIHYDROCHLORIDE	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
899	NDA/MAL/HDP/10754	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	HISTALIN 16	BETAHISTINE DIHYDROCHLORIDE	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

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900	NDA/MAL/HDP/10755	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
901	NDA/MAL/HDP/10756	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
902	NDA/MAL/HDP/10757	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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903	NDA/MAL/HDP/10758	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
904	NDA/MAL/HDP/1076	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
905	NDA/MAL/HDP/10760	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

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906	NDA/MAL/HDP/10761	WORLD MEDICINE İLAÇ SAN. VE TIC. A.Ş.	GOODMAN INTERNATIONAL LTD	ZIROMIN	AZITHROMYCIN DIHYDRATE	500MG	WORLD MEDICINE İLAC SAN VE TIC A.S.15 TEMMUZ MAHALLESİ, CAMI YOLU CADDESİ, NO: 50 K:4 WM PLAZA, GUNESİL-BAGCILAR/İNSTANBUL, TURKEY	TURKEY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	15/02/2023
907	NDA/MAL/HDP/10762	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LINEZOLID TABLETS 600 MG	LINEZOLID	600 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	1.0X1.0X10.0 TABLET BLISTER	15/02/2023
908	NDA/MAL/HDP/10763	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROCORT	TRIAMCINOLONE ACETONIDE	40 MG/ML	AUROLAB LIMITED NO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0X1.0 ML VIAL	15/02/2023

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909	NDA/MAL/HDP/10 764	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	CLOPIVID	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
910	NDA/MAL/HDP/10 765	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
911	NDA/MAL/HDP/10 766	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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912	NDA/MAL/HDP/10767	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ZESBINA 100	PROGESTERONE	100 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	1.0X3.0X10.0 CAPSULE BLISTER	15/02/2023
913	NDA/MAL/HDP/10768	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	NEBUNTA 5	NEBIVOLOL HYDROCHLORIDE	5 MG	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	15/02/2023
914	NDA/MAL/HDP/10769	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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915	NDA/MAL/HDP/10770	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	FITIN	LEVOCETIRIZINE DIHYDROCHLORIDE	2.5MG/5ML	MEDLEY PHARMACEUTICALS LTD PLOT 18 & 19 SURVEY NO. 378/7&8, 379/2&3 ZARI CAUSEWAY ROAD, KACHIGAM DAMAN-396210, INDIA	NULL	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	15/02/2023
916	NDA/MAL/HDP/10771	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD.	HEALTHCARE LTD.	MIZICIN	AZITHROMYCIN DIHYDRATE	250MG	AL FAZAL PHARMA INDUSTRIES (PVT) LTD- PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	15/02/2023
917	NDA/MAL/HDP/10773	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD.	HEALTHCARE LTD.	GESIDOL	TRAMADOL HYDROCHLORIDE	50MG	AL FAZAL PHARMA INDUSTRIES (PVT) LTD- PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	15/02/2023

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918	NDA/MAL/HDP/10774	PSYCHOTROPICS INDIA LTD-	BIOGEN PHARMA LIMITED	QNN 300	QUININE DIHYDROCHLORIDE	300MG/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	15/02/2023
919	NDA/MAL/HDP/10775	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD.	HEALTHCARE LTD.	FICLO SR 100	DICLOFENAC SODIUM	100MG	AL FAZAL PHARMA INDUSTRIES (PVT) LTD- PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN	PAKISTAN	ORAL SOLID RETARD CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	15/02/2023
920	NDA/MAL/HDP/10776	CENTAUR PHARMACEUTICALS PVT. LTD.	GITTOES PHARMACEUTICALS 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

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921	NDA/MAL/HDP/10777	CENTAUR PHARMACEUTICALS PVT. LTD.	GITTOES PHARMACEUTICALS LIMITED	GLUCOTIM 0.5%	TIMOLOL MALEATE	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
922	NDA/MAL/HDP/10778	ZIM LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	ZIMFIL-ODS 20	TADALAFIL	20MG	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY OTHER SPECIAL FORMS	1.0X10.0 STRIP PACK	15/02/2023
923	NDA/MAL/HDP/10779	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	CLAVIX AS 75	CLOPIDOGREL BISULFATE+ ASPIRIN	75MG + 75MG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI-248197, DEHRADUN (UTTARAKHAND)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	15/02/2023

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924	NDA/MAL/HDP/1078	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
925	NDA/MAL/HDP/10783	RUSAN PHARMA LTD	NORVIK ENTERPRISES LIMITED	BIORAN	DICLOFENAC SODIUM	75MG/3ML	RUSAN PHARMA LIMITEDPLOT NO. 59 - 65, SECTOR II, KANDLA SPECIAL ECONOMIC ZONE, GANDHIDHAM KUTCH 370 230 GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X3.0 ML AMPOULE	03/05/2023
926	NDA/MAL/HDP/10785	VINS BIOPRODUCTS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TETAVIN	TETANUS ANTITOXIN	1500 IU/ML	VINS BIOPRODUCTS LIMITEDSY. NO. 117, THIMMAPUR (V), KOTHUR MANDAL), RANGA REDDY (DIST), TELANDANA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X1.0 ML PRE- FILLED SYRINGE,1.0X10.0 X1.0 ML VIAL	03/05/2023

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927	NDA/MAL/HDP/10 786	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	VIATUFF 50	SILDENAFIL CITRATE	50MG	AUROBINDO PHARMA LTD, UNIT VIISY. 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 FILM- COATED TABLETS	1.0X1.0X2.0 TABLET BLISTER	03/05/2023
928	NDA/MAL/HDP/10 787	PSYCHOTROPICS INDIA LIMITED.	BIOGEN PHARMA LIMITED	AZIGEN	AZITHROMYCIN DIHYDRATE	200 MG/5 ML	PSYCHOTROPICS INDIA LTD PLOT NO. 46 & 49, SECTOR-6A, IIE, SIDCUL, HARIDWAR - 249403(UTTARAKHARD)	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X15.0 ML BOTTLE	03/05/2023
929	NDA/MAL/HDP/10 788	THE SEARLE COMPANY LIMITED	SURGIPHARM (U) LIMITED	DIULACTONE 25 MG	SPIRONOLACTONE	25MG	SEARLE PAKISTAN LTD..F- 319, S.I.T.E., OPP. KESC POWER STATION, KARACHI	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	03/05/2023

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930	NDA/MAL/HDP/10789	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	FEBLORIKA-40	FEBUXOSTAT	40MG	MANKIND PHARMA LIMITED UNIT - II, VILLAGE KISHANPURA, P.O. JAMNIWALA, TEHSIL PAONTA SAHIB, DISTRICT SIRMOUR - 173025, HIMACHAL PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	03/05/2023
931	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
932	NDA/MAL/HDP/10790	THE SEARLE COMPANY LIMITED	SURGIPHARM (U) LIMITED	DIULACTONE 100 MG	SPIRONOLACTONE	100MG	SEARLE PAKISTAN LTD..F-319, S.I.T.E., OPP. KESC POWER STATION, KARACHI	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	03/05/2023

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933	NDA/MAL/HDP/10791	THE SEARLE COMPANY LIMITED	SURGIPHARM (U) LIMITED	VAPTOR 20MG	ROSUVASTATIN	20MG	SEARLE PAKISTAN LTD..F-319, S.I.T.E., OPP. KESC POWER STATION, KARACHI	PAKISTAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	03/05/2023
934	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
935	NDA/MAL/HDP/10793	THE SEARLE COMPANY LIMITED	SURGIPHARM (U) LIMITED	NUBIN INJECTION 10MG/ML	NALBUPHINE HYDROCHLORIDE	10MG/1ML	SEARLE PAKISTAN LTD..F-319, S.I.T.E., OPP. KESC POWER STATION, KARACHI	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	03/05/2023

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936	NDA/MAL/HDP/10794	THE SEARLE COMPANY LIMITED	SURGIPHARM (U) LIMITED	MORCET 10 MG	ESCITALOPRAM OXALATE	10MG	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	03/05/2023
937	NDA/MAL/HDP/10795	PROFARMA SH.A	JOINT MEDICAL STORE (UPMB - UCMB)	DIAZEPAM 10MG/2ML	DIAZEPAM	10MG/2ML	PROFARMA SH.AMYSLYM KETA,TIRANA	ALBANIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X2.0 ML AMPOULE	03/05/2023
938	NDA/MAL/HDP/10796	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	SECNIZOLE TABLETS	SECNIDAZOLE	1000MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X2.0 TABLET BLISTER	03/05/2023

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939	NDA/MAL/HDP/10797	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	APREZO	APREMILAST	10MG TABLETS CO-PACKED WITH 20MG TABLETS AND 30MG TABLETS	GLENMARK PHARMACEUTICALS LIMITED PLOT NO. 2, PHASE-II, PHARMA ZONE, INDORE SPECIAL ECONOMIC ZONE, PITHAMPUR DIST. DHAR, (M.P.) PIN CODE 454775 - INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0 CARTON CARTON [4*10MG CO-PACKED WITH 4*20MG CO-PACKED WITH 19*30MG TABLETS], 1.0X1.0 CARTON CARTON [4*10MG CO-PACKED WITH 4*20MG CO-PACKED WITH 47*30MG	03/05/2023
940	NDA/MAL/HDP/10798	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	STEDNAC PLUS	ACECLOFENAC + PARACETAMOL	100 MG + 325 MG	STEDMAN PHARMACEUTICALS PVT LTD C-4 SIDCO PHARMACEUTICAL COMPLEX ALATHUR THIRUPORUR 603 110 TAMILNADU	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	03/05/2023
941	NDA/MAL/HDP/10799	CIPLA LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	GEFITINIB 250MG TABLETS	GEFITINIB	250MG	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 FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	03/05/2023

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942	NDA/MAL/HDP/1080	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZOCEF 250 TABLETS	CEFUROXIME AXETIL	250MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA ALKEM LABORATORIES LIMITED.VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER, 1.0X1.0X10.0 TABLET BLISTER	01/07/2009
943	NDA/MAL/HDP/10800	HILTON PHARMA PVT LTD	BOOTS PHARMACEUTICALS LIMITED	ROLIPEZE	ROSUVASTATIN CALCIUM + EZETIMIBE	10 MG + 10 MG	HILTON PHARMACEUTICALS (PVT) LIMITED PLOT NO. 13-14, SECTOR 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	03/05/2023
944	NDA/MAL/HDP/10801	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PERGOVERIS (900 IU + 450 IU)/1.44ML	FOLLITROPIN ALFA + LUTROPIN ALFA	(900 IU + 450 IU)/1.44ML	MERCK SERONO S.P.A., VIA DELLE MAGNOLIE 15 (LOC FRANZIONE ZONA INDUSTRIALE) 70026, MODUGNO BA	ITALY	PARENTERAL ORDINARY PRE-FILLED PENS	1.0X1.0X1.44 ML PREFILLED PEN + 14 INJECTION NEEDLES	03/05/2023

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945	NDA/MAL/HDP/10 802	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PERGOVERIS (300 IU + 150 IU)/1.44ML	FOLLITROPIN ALFA + LUTROPIN ALFA	(300 IU + 150 IU)/1.44ML	MERCK SERONO S.P.A.,VIA DELLE MAGNOLIE 15 (LOC FRANZIONE ZONA IDUSTRIALE) 70026, MODUGNO BA	ITALY	PARENTERAL ORDINARY PRE- FILLED PENS	1.0X1.0X1.44 ML PREFILLED PEN + 5 INJECTION NEEDLES	03/05/2023
946	NDA/MAL/HDP/10 803	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PERGOVERIS (450 IU + 225 IU)/0.72 ML	FOLLITROPIN ALFA + LUTROPIN ALFA	(450 IU + 225 IU)/0.72ML	MERCK SERONO S.P.A.,VIA DELLE MAGNOLIE 15 (LOC FRANZIONE ZONA IDUSTRIALE) 70026, MODUGNO BA	ITALY	PARENTERAL ORDINARY PRE- FILLED PENS	1.0X1.0X0.72 ML PREFILLED PEN	03/05/2023
947	NDA/MAL/HDP/10 804	WALLACE PHARMACEUTICAL S PVT. LTD	STAR PHARMACEUTICALS LTD	COLIMEX TABLETS	DICYCLOVERINE HYDROCHLORIDE + PARACETAMOL	20MG + 500MG	WALLACE PHARMACEUTICALS PVT LTDBHATIAN, NALAGARH, DIST. SOLAN HP 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	03/05/2023

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948	NDA/MAL/HDP/10805	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BISODAC-HF 5	BISOPROLOL FUMARATE	5 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	1.0X2.0X14.0 TABLET BLISTER	03/05/2023
949	NDA/MAL/HDP/10806	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	LOSARZED-50	LOSARTAN POTASSIUM	50MG	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	1.0X3.0X10.0 TABLET BLISTER	03/05/2023
950	NDA/MAL/HDP/10807	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	RESTOCIN PLUS	PARACETAMOL + DEXTROMETHORPHAN HYDROBROMIDE + CHLORPHENAMINE 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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951	NDA/MAL/HDP/10 808	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
952	NDA/MAL/HDP/10 810	BRAWN LABORATORIES LTD	TATA UGANDA LIMITED	BUCLAPOXIM E 200	CEFPODOXIME PROXETIL	200 MG	BRAWN LABORATORIES LIMITED 13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	03/05/2023
953	NDA/MAL/HDP/10 812	MICRO LABS LTD	LABOREX UGANDA LIMITED	URYSOREN-5	SOLIFENACIN SUCCINATE	5 MG	MICRO LABS LIMITED, HOSURNO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	03/05/2023

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954	NDA/MAL/HDP/10813	MICRO LABS LTD	LABOREX UGANDA LIMITED	URYSOREN-10	SOLIFENACIN SUCCINATE	10 MG	MICRO LABS LIMITED, HOSURNO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	03/05/2023
955	NDA/MAL/HDP/10814	CACHET PHARMACEUTICALS PRIVATE LIMITED	ASTRA PHARMA (U) LIMITED	CAVIT SUSPENSION	ELEMENTAL CALCIUM (IN CALCIUM PHOSPHATE) + ELEMENTAL PHOSPHORUS (IN CALCIUM PHOSPHATE) + MAGNESIUM HYDROXIDE + ZINC GLUCONATE + VITAMIN D3	300 MG + 150 MG + 75 MG + 4 MG + 200 IU	CACHET PHARMACEUTICALS PVT LTD .VILLAGE THANA, BADDI, TEHSIL-NALAGARH DIST. SOLAN, HIMACHAL PRADESH-173205	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X150.0 ML BOTTLE	03/05/2023
956	NDA/MAL/HDP/10816	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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957	NDA/MAL/HDP/10817	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	CELOFEN 100	CELECOXIB	100 MG	HETERO LABS LIMITED (UNIT V)SY. NO. 439, 440, 441 & 458, POLEPALLY VILLAGE, JADCHERLA MANDAL MAHABOBNAGAR DISTRICT, PIN-509 301, TELANGANA, INDIA HETERO LABS LIMITED (UNIT III)VILLAGE KALYANPUR, CHAKKAN ROAD, BADDI, DIST. SOLAN HIMACHAL	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	03/05/2023
958	NDA/MAL/HDP/10818	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS 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
959	NDA/MAL/HDP/1082	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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960	NDA/MAL/HDP/10820	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	OLOPAT EYE DROPS	OLOPATADINE HYDROCHLORIDE	0.1%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	1.0X1.0X15.0 ML CONTAINER	03/05/2023
961	NDA/MAL/HDP/10821	PROFARMA SH.A	JOINT MEDICAL STORE (UPMB - UCMB)	ADRENALINE 1 MG/1ML	ADRENALINE HYDROGENTARTRATE	1 MG/1ML	PROFARMA SH.AMYSLYM KETA,TIRANA	ALBANIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE	03/05/2023
962	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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963	NDA/MAL/HDP/10 823	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
964	NDA/MAL/HDP/10 824	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), TSIIC, 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
965	NDA/MAL/HDP/10 825	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

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966	NDA/MAL/HDP/10 826	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
967	NDA/MAL/HDP/10 827	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
968	NDA/MAL/HDP/10 828	TORRENT PHARAMACEUTICA LS LTD	KARURI PHARMACEUTICALS 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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969	NDA/MAL/HDP/10829	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
970	NDA/MAL/HDP/1083	GALPHA LABORATORIES LTD	DAWASANA PHARMACEUTICALS LTD	CHOCOFER SYRUP	IRON + FOLIC ACID	50MG + 0.5MG /5ML	GALPHA LABORATORIES LIMITED VILLAGE "THANA BADDI, TEHSIL BADDI SOLAN HIMACHAL PRADESH-173 205 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2013
971	NDA/MAL/HDP/10830	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	MUSCUREL	THIOLCHICOSIDE	8 MG	BILIM ILAC SAN.VE TIC.A.SGEBZE ORGANIZASYONU SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY	TURKEY	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	06/06/2023

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972	NDA/MAL/HDP/10 831	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
973	NDA/MAL/HDP/10 832	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
974	NDA/MAL/HDP/10 833	AUROBINDO PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	MOLNAFLU	MOLNUIRAVIR	200MG	AUROBINDO PHARMA LIMITED, UNIT - XVLOT 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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975	NDA/MAL/HDP/10834	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	PANSIPTIN 100	SITAGLIPTIN HYDROCHLORIDE	100MG	SAG MANUFACTURING S.L.CARRETERA 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
976	NDA/MAL/HDP/10835	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	PANSIPTIN 50	SITAGLIPTIN HYDROCHLORIDE	50MG	SAG MANUFACTURING S.L.CARRETERA 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
977	NDA/MAL/HDP/10836	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	PANSIPTIN 25	SITAGLIPTIN HYDROCHLORIDE	25MG	SAG MANUFACTURING S.L.CARRETERA 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

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978	NDA/MAL/HDP/10838	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
979	NDA/MAL/HDP/10839	STEDMAN PHARMACEUTICALS 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
980	NDA/MAL/HDP/1084	DAWA LIMITED	SUPER MEDIC LTD	DAWA-CPM	CHLORPHENIRAMINE 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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981	NDA/MAL/HDP/10 840	STEDMAN PHARMACEUTICAL S 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	1.0X1.0X50.0 ML CONTAINER	06/06/2023
982	NDA/MAL/HDP/10 841	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), TSIIC, 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
983	NDA/MAL/HDP/10 842	WOCKHARDT LTD	PHILLIPS PHARMACEUTICALS (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

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984	NDA/MAL/HDP/10845	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TURBOVAS-20	ROSUVASTATIN CALCIUM	20MG	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	03/05/2023
985	NDA/MAL/HDP/10846	ZIM LABORATORIES LTD-	REDDYS PHARMA LIMITED	CEFRAZ SUSPENSION	CEFIXIME	100MG/5ML	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X1.0X60.0 ML BOTTLE (AMBER PET BOTTLE)	03/05/2023
986	NDA/MAL/HDP/10847	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	BUDESMA	BUDESONIDE	200 MCG/ACTUATION	GLENMARK PHARMACEUTICALS LIMITED-UNIT IIIVILLAGE KISHANPURA, BADDI-NALAGARH ROAD TEHSIL BADDI, DIST. SOLAN, BADDI 173205 INDIA	INDIA	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER	02/06/2023

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987	NDA/MAL/HDP/10 848	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	MEFENA FORTE-500	MEFENAMIC ACID	500MG	AGOG PHARMA LIMITED .PLOT 33, SECTOR II THE VASAI TALUKA INDUSTIRAL COOP ESTE LTD GAURAIKADA, VASAI (E) DIST. THANE-401208	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100. 0X10.0 TABLET BLISTER	03/05/2023
988	NDA/MAL/HDP/10 849	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICALS LTD	LIRAPYN 25	PREGABALIN	25MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X7.0 CAPSULE BLISTER	03/05/2023
989	NDA/MAL/HDP/10 850	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	OLMAT-H	OLMESARTAN MEDOXOMIL + HYDROCHLOROTH IAZIDE	20MG + 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	03/05/2023

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990	NDA/MAL/HDP/10 851	DEVA HOLDING A.S	SHREEJI PHARMACEUTICALS LIMITED	LOSAPRES PLUS 50 MG / 12.5 MG	LOSARTAN POTASSIUM + HYDROCHLOROTH IAZIDE	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/TURK EY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	03/05/2023
991	NDA/MAL/HDP/10 853	SAVA HEALTHCARE LIMITED -	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	FLUTIAIR-S 250	SALMETEROL + FLUTICASONE PROPIONATE	(50 MCG + 250 MCG)/CAPSULE	SAVA HEALTHCARE LIMITED.PLOT NO 507B - 512, G.I.D.C. ESTATE, WADHWANCITY-363 035 SURENDRANAGAR, GUJARAT, INDIA	INDIA	LUNG ADMINISTRATION INHALER CAPSULES	1.0X30.0X1.0X250 .0 MU CAPSULE,1.0X30.0 X1.0X250.0 MCG CAPSULE	02/06/2023
992	NDA/MAL/HDP/10 854	CENTAUR PHARMACEUTICAL S PVT. LTD.	GITTOES PHARMACEUTICALS 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	03/05/2023

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993	NDA/MAL/HDP/10 855	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	TECAVIR 0.5	ENTECAVIR MONOHYDRATE	0.5MG	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	1.0X3.0X10.0 TABLET BLISTER	03/05/2023
994	NDA/MAL/HDP/10 856	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	KEPAM 500MG/5ML	LEVETIRACETAM	500MG/5ML	MS PHARMA - JORDANPLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL- HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY VIALS	1.0X10.0X5.0 ML VIAL (CLEAR GLASS VIAL)	03/05/2023
995	NDA/MAL/HDP/10 857	AL ANDALOUS FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ANDOPOXETI NE 60 MG	DAPOXETINE HYDROCHLORIDE	60MG	AL ANDALOUS FOR PHARMACEUTICAL INDUSTRIESPART NO. 7/6 6TH INDUSTRIAL AREA - 6TH OCTOBER CITY - GIZA	EGYPT	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	03/05/2023

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996	NDA/MAL/HDP/10858	SYNOKEM PHARMACEUTICALS LIMITED	BIOGEN PHARMA LIMITED	DEFLAGEN	DEFLACORT	6MG	SYNOKEM PHARMACEUTICALS LIMITEDSYNOKEM PHARMACEUTICALS LIMITED, PLOT NO. 35-36, SECTOR-6A, IIE, (SIDCUL), RANIPUR (BHEL), HARIDWAR, 249403, (UTTARAKHAND) - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X2.0X10.0 TABLET BLISTER	03/05/2023
997	NDA/MAL/HDP/10859	AL ANDALOUS FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	PERFORMA 5% EXTRA	MINOXIDIL	5G/100ML	AL ANDALOUS FOR PHARMACEUTICAL INDUSTRIESPART NO. 7/6 6TH INDUSTRIAL AREA - 6TH OCTOBER CITY - GIZA	EGYPT	TOPICAL EXTERNAL LIQUIDS	1.0X60.0 ML BOTTLE	03/05/2023
998	NDA/MAL/HDP/1086	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

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999	NDA/MAL/HDP/10 860	ASPIRO PHARMA LIMITED	AIVEEN (U) LIMITED	YESOM 40	ESOMEPRAZOLE SODIUM	40MG	ASPIRO PHARMA LIMITEDSY. NO. 321, BIOTECH PARK, PHASE-III, KARKAPATLA, MARKOOK MANDAL, SIDDIPET DISTRICT-502 281, TELANGANA, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X5.0 ML VIAL (CLEAR GLASS VIAL)	03/05/2023
1000	NDA/MAL/HDP/10 862	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BIFRIL 7.5MG	ZOFENOPRIL CALCIUM	7.5MG	A. MENARINI MANUFACTURING LOGISTICS AND SERVICES SRLVIA CAMPO DI PILE 67100 L'AQUILA (AQ)	ITALY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X12.0 TABLET BLISTER	03/05/2023
1001	NDA/MAL/HDP/10 865	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	LOREZE	LORATADINE	10MG	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	1.0X5.0X1.0X1.0X 10.0 CAPSULE BLISTER	02/06/2023

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1002	NDA/MAL/HDP/10866	LES LABORATOIRES SERVIER	HARLEYS UGANDA LIMITED	COVERSYL 10MG	PERINDOPRIL ARGININE	10MG	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	1.0X1.0X30.0 TABLET CONTAINER (OPAQUE WHITE PLASTIC CONTAINER)	02/06/2023
1003	NDA/MAL/HDP/10867	LES LABORATOIRES SERVIER	HARLEYS UGANDA LIMITED	COVERSYL 5 MG	PERINDOPRIL ARGININE	5MG	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	1.0X1.0X30.0 TABLET CONTAINER (OPAQUE WHITE PLASTIC CONTAINER)	02/06/2023
1004	NDA/MAL/HDP/1087	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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

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1005	NDA/MAL/HDP/10873	MARCYRL PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TORSAMOLE X 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
1006	NDA/MAL/HDP/10874	: ALKEM LABORATORIES LIMITEDv	ABACUS PHARMA (AFRICA) LIMITED	PAN IV	PANTOPRAZOLE SODIUM	40MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY 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
1007	NDA/MAL/HDP/10877	CRATUS PHARMA PVT. LTD. 7,	ABACUS PHARMA (AFRICA) LIMITED	RABEGUARD IV	RABEPRAZOLE SODIUM	20 MG/VIAL	RATNAMANI HEALTHCARE PRIVATE LIMITED SURVEY NO. 750/1, AHMEDABAD - MEHSANA HIGHWAY, VILLAGE-INDRAD, NR. CHHATRAL G.I.D.C., TALUKA-KADI, DIST-MEHSANA, PIN-382721 (NG), GUJARAT - INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X20.0 MG VIAL + 1*10 ML WATER FOR INJECTION IN LDPE CONTAINER	17/08/2023

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1008	NDA/MAL/HDP/10878	LUPIN LIMITED-	AIVEEN (U) LIMITED	LINEZOLID 600MG 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
1009	NDA/MAL/HDP/10879	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
1010	NDA/MAL/HDP/1088	GALPHA LABORATORIES LTD	DAWASANA PHARMACEUTICALS LTD	RESTUM	CEFUROXIME SODIUM	750MG	ALKEM LABORATORIES LIMITED.-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X750.0 MG VIAL	01/07/2015

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1011	NDA/MAL/HDP/10880	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
1012	NDA/MAL/HDP/10881	MEGA LIFESCIENCES 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
1013	NDA/MAL/HDP/10882	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

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1014	NDA/MAL/HDP/10 883	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	DAPAGLIFLOZ IN TABLETS 10 MG	DAPAGLIFLOZIN PROPANEDIOL	10MG	CIPLA LIMITED PLOT 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
1015	NDA/MAL/HDP/10 884	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
1016	NDA/MAL/HDP/10 885	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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1017	NDA/MAL/HDP/10886	LINCOLN PHARMACEUTICALS LIMITED	METRO PHARMACEUTICALS LIMITED	CLOTRILIN-V	CLOTRIMAZOLE	2%W/W	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	VAGINAL CREAMS	1.0X1.0X15.0 G TUBE	17/08/2023
1018	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
1019	NDA/MAL/HDP/10889	WORLD MEDICINE S.A. SAN. VE TIC. A.Ž.	GOODMAN INTERNATIONAL LTD	PIRETIKOL PLUS	PARACETAMOL + CHLORPHENIRAMINE MALEATE + PHENYLEPHRINE HYDROCHLORIDE	(160 MG + 1 MG + 2.5 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/INSTANBUL, TURKEY	TURKEY	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	16/04/2024

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1020	NDA/MAL/HDP/10890	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	ZIQUANTA	PRAZIQUANTEL	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,1.0X100.0 TABLET CONTAINER,1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER	17/08/2023
1021	NDA/MAL/HDP/10891	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	BINAFIN	TERBINAFINE HYDROCHLORIDE	1%W/W	LINCOLN PHARMACEUTICALS LTD10, 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	17/08/2023
1022	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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1023	NDA/MAL/HDP/10896	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
1024	NDA/MAL/HDP/10897	HILTON PHARMA (PVT) LTD	BOOTS PHARMACEUTICALS 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
1025	NDA/MAL/HDP/10898	HILTON PHARMA (PVT) LTD	BOOTS PHARMACEUTICALS LIMITED	ROLIP EZE TABLETS	ROSUVASTATIN CALCIUM + EZETIMIBE	20MG +10MG	HILTON PHARMACEUTICALS (PVT) LIMITEDPLOT 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

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1026	NDA/MAL/HDP/10900	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
1027	NDA/MAL/HDP/10903	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	BIDSIPTIN	VILDAGLIPTIN	50MG	SAG MANUFACTURING S.L.CARRETERA NACIONAL 1 KM 36, SAN AGUSTIN DEL GUADALIX, 28750, SPAIN	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023
1028	NDA/MAL/HDP/10904	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	UROKA PLUS	DUTASTERIDE + TAMSULOSIN HYDROCHLORIDE	0.5MG + 0.4MG	SAG MANUFACTURING S.L.CARRETERA 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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1029	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	17/08/2023
1030	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	17/08/2023
1031	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	17/08/2023

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1032	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
1033	NDA/MAL/HDP/10909	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
1034	NDA/MAL/HDP/10910	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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1035	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
1036	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
1037	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

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1038	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
1039	NDA/MAL/HDP/10916	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
1040	NDA/MAL/HDP/10917	DAVIMED PHARMA LIMITED	DAVIMED PHARMA LIMITED	CEFTRIAXONE	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	1.0X25.0X1.0X1.0 G VIAL	17/08/2023

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1041	NDA/MAL/HDP/10918	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
1042	NDA/MAL/HDP/10919	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	SANFIXIME 400	CEFIXIME TRIHYDRATE	400MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	17/08/2023
1043	NDA/MAL/HDP/10920	ACINO AG.	GOODMAN INTERNATIONAL LTD	PARACONICA™ PLUS 500 MG/150 MG	PARACETAMOL + IBUPROFEN	500 MG + 150 MG	SIGMA LABORATORIES PRIVATE LIMITED 6, 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

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1044	NDA/MAL/HDP/10921	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/INSTANBUL, TURKEY	TURKEY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X7.0 TABLET BLISTER	17/08/2023
1045	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
1046	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	17/08/2023

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1047	NDA/MAL/HDP/10924	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	METOPRIX 10	METOCLOPRAMIDE	10 MG	BIOMATRIX HEALTHCARE PRIVATE LIMITED SURVEY 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
1048	NDA/MAL/HDP/10925	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	HERPIRAX 200	ACICLOVIR	200 MG	BIOMATRIX HEALTHCARE PRIVATE LIMITED SURVEY 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
1049	NDA/MAL/HDP/10926	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	ACELEVO 500	LEVOFLOXACIN HEMIHYDRATE	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	1.0X1.0X10.0 TABLET BLISTER	17/08/2023

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1050	NDA/MAL/HDP/10927	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
1051	NDA/MAL/HDP/10928	FAROMED LIFESCIENCES LLP	METRO PHARMACEUTICALS LIMITED	FIX-A	CEFIXIME TRIHYDRATE	100MG/5ML	THE ACME LABORATORIES LIMITEDDHULIVITA, DHAMRAI, DHAKA - 1350, BANGLADESH	BANGLADESH	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X1.0X75.0 ML BOTTLE	17/08/2023
1052	NDA/MAL/HDP/10930	RATNATRIS PHARMACEUTICALS PVT. LTD	JEET PHARMACEUTICALS LIMITED	DIKOPAR	DICLOFENAC SODIUM + PARACETAMOL	50MG + 500MG	RATNAMANI HEALTHCARE PRIVATE LIMITEDSURVEY NO. 750/1, AHMEDABAD - MEHSANA HIGHWAY, VILLAGE-INDRAD, NR. CHHATRAL G.I.D.C., TALUKA-KADI, DIST-MEHSANA, PIN-382721 (NG), GUJARAT - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	17/08/2023

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1053	NDA/MAL/HDP/10931	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	UNIDROL 10	ALFUZOSIN HYDROCHLORIDE	10 MG	UNICHEM LABORATORIES LTD UNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023
1054	NDA/MAL/HDP/10932	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
1055	NDA/MAL/HDP/10933	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	P-ALAXIN	DIHYDROARTEMISININ + PIPERAQUINE PHOSPHATE	20 MG + 160 MG	BLISS GVS PHARMA LIMITED 10,11 & 12, DEWAN UDYOG NAGAR, ALIYALI, PALGHAR, 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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1056	NDA/MAL/HDP/10934	FAROMED LIFESCIENCES LLP	METRO PHARMACEUTICALS 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
1057	NDA/MAL/HDP/10935	FAROMED LIFESCIENCES LLP	METRO PHARMACEUTICALS 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
1058	NDA/MAL/HDP/10936	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	TEARLIN-0.5 %	CARMELLOSE SODIUM	0.5% W/V	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML BOTTLE	17/08/2023

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1059	NDA/MAL/HDP/10937	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	TEARLIN-1 %	CARMELLOSE SODIUM	1.0% W/V	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML BOTTLE	17/08/2023
1060	NDA/MAL/HDP/10938	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (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
1061	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

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1062	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
1063	NDA/MAL/HDP/10944	TORRENT PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS 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
1064	NDA/MAL/HDP/10945	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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1065	NDA/MAL/HDP/10946	MACLEODS PHARMACEUTICALS 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
1066	NDA/MAL/HDP/10947	MACLEODS PHARMACEUTICALS LTD	AIVEEN (U) LIMITED	OLMESAR H	OLMESARTAN MEDOXOMIL + HYDROCHLOROTHIAZIDE	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
1067	NDA/MAL/HDP/10948	WALLACE PHARMACEUTICALS PVT. LTD	STAR PHARMACEUTICALS LTD	FLUCOLD	PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + CHLORPHENAMINE 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

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1068	NDA/MAL/HDP/10949	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	CLAMOXIN-375 TABLETS	AMOXICILLIN SODIUM + POTASSIUM CLAVULANATE	250MG + 125 MG	MEDOPHARM PVT LIMITED NO. 50 KAYARAMBEDU VILLAGE, GUDUVANCHERY-603202	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	17/08/2023
1069	NDA/MAL/HDP/1095	MICRO LABS LTD	LABOREX UGANDA LIMITED	EROSTINE-20	EBASTINE	20MG	MICRO LABS LTD 92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2012
1070	NDA/MAL/HDP/10950	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICALS LTD	DICORATE ER 500	DIVALPROEX SODIUM	500 MG	SUN PHARMA LABORATORIES LIMITED 6-9, 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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1071	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 COMPANYAL-RAGEEM, SAHAB, P.O. BOX 60, AMMAN 11591 - JORDAN	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023
1072	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
1073	NDA/MAL/HDP/10953	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

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1074	NDA/MAL/HDP/10954	RENATA LIMITED	UHAI PHARMACY	FUROCEF®	CEFUROXIME AXETIL	500MG	RAJENDRAPUR POTENT PRODUCT FACILITY (RPPF), RENATA LIMITED NOYAPARA, BHAWAL MIRZAPUR, RAJENDRAPUR, GAZIPUR 1700 - BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X6.0 TABLET BLISTER	17/08/2023
1075	NDA/MAL/HDP/10956	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
1076	NDA/MAL/HDP/10957	ORCHIDIA PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CO-AVAZIR	TOBRAMYCIN + DEXAMETHASONE	(3 MG + 1 MG)/ML	ORCHIDIA PHARMACEUTICAL INDUSTRIES AL 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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1077	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
1078	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
1079	NDA/MAL/HDP/1096	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ARTEMETHER	ARTEMETHER	80MG/ML	SANJAR PHARMA LLP HIMATNAGAR-VIOPUR HIGHWAY, DEDHROTA HIMATNAGAR 383 220, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE,1.0X1.0X8.0X1.0 ML AMPOULE	01/07/2014

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1080	NDA/MAL/HDP/10 960	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
1081	NDA/MAL/HDP/10 961	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
1082	NDA/MAL/HDP/10 962	MYLAN LABORATORIES LIMITED-	KIMSY MEDS LTD	DARUNAVIR/ RITONAVIR 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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1083	NDA/MAL/HDP/10963	PHARMATHEN S.A	GOODMAN INTERNATIONAL LTD	MEPERYA	MEROPENEM TRIHYDRATE	1G	DEMO S.A. PHARMACEUTICAL INDUSTRY-21ST KM NATIONAL ROAD ATHENS LAMIA 14568 KRYONERI ATHENS - GREECE	GREECE	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL	17/08/2023
1084	NDA/MAL/HDP/10964	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
1085	NDA/MAL/HDP/10965	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	MPHETAS-500	MYCOPHENOLATE 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

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1086	NDA/MAL/HDP/10966	EUGIA PHARMA SPECIALITIES LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SKYTINIB 12.5	SUNITINIB MALATE	12.5 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
1087	NDA/MAL/HDP/10967	EUGIA PHARMA SPECIALITIES LIMITED	PHILLIPS PHARMACEUTICALS (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
1088	NDA/MAL/HDP/10968	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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1089	NDA/MAL/HDP/10969	FDC LTD	AIVEEN (U) LIMITED	VITCOFOL	FERROUS FUMARATE + FOLIC ACID + CYANOCOBALAMIN	(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
1090	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
1091	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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1092	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
1093	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-MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X7.0 CAPSULE BLISTER	17/08/2023
1094	NDA/MAL/HDP/10975	VERVE HUMAN CARE LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	BUPIVER-H	BUPIVACAINE HYDROCHLORIDE	5MG/ML	VERVE HUMAN CARE LABORATORIES PLOT NO. 15A PHARMACY, SELAQUI, DEHRADUN, UTTARAKHAND, 248011, INDIA.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X4.0 ML AMPOULE	17/08/2023

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1095	NDA/MAL/HDP/10976	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
1096	NDA/MAL/HDP/10977	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	FIRIALTA®	FINERENONE	10MG	BAYER PHARMA AG 51368 LEVERKUSEN,	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	17/08/2023
1097	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

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1098	NDA/MAL/HDP/10979	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	FIRIALTA®	FINERENONE	20MG	BAYER PHARMA AG 51368 LEVERKUSEN,	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	17/08/2023
1099	NDA/MAL/HDP/10980	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
1100	NDA/MAL/HDP/10982	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

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1101	NDA/MAL/HDP/10983	AGIO PHARMACEUTICALS 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
1102	NDA/MAL/HDP/10984	AGIO PHARMACEUTICALS 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
1103	NDA/MAL/HDP/10985	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	(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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1104	NDA/MAL/HDP/10986	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
1105	NDA/MAL/HDP/10987	LUPIN LIMITED-	AIVEEN (U) LIMITED	LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS 300MG AND 300 MG	LAMIVUDINE + TENOFOVIR 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
1106	NDA/MAL/HDP/10988	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

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1107	NDA/MAL/HDP/10989	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	BINFIN 5	FINASTERIDE	5MG	HETERO LABS LIMITED (UNIT III)...22-110, I.D.A, JEEDIMETLA, HYDERABAD-500 055, ANDHRA PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER	17/08/2023
1108	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
1109	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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1110	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	17/08/2023
1111	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	17/08/2023
1112	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	17/08/2023

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1113	NDA/MAL/HDP/10 994	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
1114	NDA/MAL/HDP/10 998	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
1115	NDA/MAL/HDP/10 999	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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1116	NDA/MAL/HDP/1100	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE, 1.0X5.0 G TUBE	01/07/2013
1117	NDA/MAL/HDP/11000	JOHNSON & JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SINUTAB SINUS PAIN NON-DROWSY	PARACETAMOL + PSEUDOEPHEDRINE HYDROCHLORIDE	500 + 30 MG	JOHNSON & JOHNSON (PTY) LTD 241 MAIN ROAD, RETREAT, 7945, CAPE TOWN	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	17/08/2023
1118	NDA/MAL/HDP/11001	UNISON PHARMACEUTICALS PVT. LTD.	HARLEYS UGANDA LIMITED	AKILOS-CR	ACECLOFENAC	200MG	UNISON PHARMACEUTICALS PRIVATE LIMITED – UNIT 1 UNIT 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

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1119	NDA/MAL/HDP/11002	CENTAUR PHARMACEUTICALS PVT. LTD.	GITTOES PHARMACEUTICALS 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	17/08/2023
1120	NDA/MAL/HDP/11003	MEGA LIFESCIENCES 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
1121	NDA/MAL/HDP/11004	FAROMED LIFESCIENCES LLP	METRO PHARMACEUTICALS 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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1122	NDA/MAL/HDP/11012	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
1123	NDA/MAL/HDP/11015	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	HYDROCORTISONE CREAM BP	HYDROCORTISONE ACETATE	1% W/W	CIRON DRUGS PHARMACEUTICALS PRIVATE LIMITED PLOT 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
1124	NDA/MAL/HDP/11016	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	LEDOBOOK 15	LENALIDOMIDE	15MG	EUGIA PHARMA SPECIALITIES LIMITED SURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL-MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X7.0 CAPSULE BLISTER	12/13/2023

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1125	NDA/MAL/HDP/11017	AUROBINDO	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	LEDOBOOK 25	LENALIDOMIDE	25MG	EUGIA PHARMA SPECIALITIES LIMITED SURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL-MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X7.0 CAPSULE BLISTER	12/13/2023
1126	NDA/MAL/HDP/11018	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MEDWIN	MEDROXYPROGESTERONE	150MG/ML	EUGIA PHARMA SPECIALITIES LIMITED SURVEY 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
1127	NDA/MAL/HDP/11019	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	LEDOBOOK 5	LENALIDOMIDE	5MG	EUGIA PHARMA SPECIALITIES LIMITED SURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL-MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X7.0 CAPSULE BLISTER	12/13/2023

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1128	NDA/MAL/HDP/1102	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
1129	NDA/MAL/HDP/11020	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
1130	NDA/MAL/HDP/11021	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

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1131	NDA/MAL/HDP/11022	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
1132	NDA/MAL/HDP/11023	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/SYRUPS/DROPS	1.0X1.0X100.0 ML CONTAINER	12/13/2023
1133	NDA/MAL/HDP/11024	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS 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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1134	NDA/MAL/HDP/11025	LINCOLN PHARMACEUTICALS LIMITED	METRO PHARMACEUTICALS 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
1135	NDA/MAL/HDP/11026	LINCOLN PHARMACEUTICALS LIMITED	METRO PHARMACEUTICALS 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
1136	NDA/MAL/HDP/11027	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

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1137	NDA/MAL/HDP/11028	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	APLENE 50	PREGABALIN	50MG	AJANTA PHARMA LIMITED AJANTA 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
1138	NDA/MAL/HDP/11029	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	APLENE 75	PREGABALIN	75MG	AJANTA PHARMA LIMITED AJANTA 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
1139	NDA/MAL/HDP/1103	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2014

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1140	NDA/MAL/HDP/11030	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	APLENE 150	PREGABALIN	150MG	AJANTA PHARMA LIMITED AJANTA 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
1141	NDA/MAL/HDP/11031	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	NIZACARD 500	RANOLAZINE	500MG	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
1142	NDA/MAL/HDP/11032	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

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1143	NDA/MAL/HDP/11033	KESAR PHARMA	JEET PHARMACEUTICALS LIMITED	FLUPLEX	PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + CHLORPHENIRAMINE 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
1144	NDA/MAL/HDP/11034	ARCELIA LIFE SCIENCES LTD.	PLUTO PHARMACEUTICALS LIMITED	ARCELIA® 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
1145	NDA/MAL/HDP/11035	ARCELIA LIFE SCIENCES LTD.	PLUTO PHARMACEUTICALS LIMITED	ARCELIA® 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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1146	NDA/MAL/HDP/11036	ARCELIA LIFE SCIENCES LTD.	PLUTO PHARMACEUTICALS 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
1147	NDA/MAL/HDP/11037	FERRER INTERNATIONAL, S.A.	LABOREX 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
1148	NDA/MAL/HDP/11038	AUROBINDO	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DELOHIST 5	DESLORATADINE	5MG	AUROBINDO PHARMA LIMITED, UNIT - XVLOT 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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1149	NDA/MAL/HDP/11039	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
1150	NDA/MAL/HDP/1104	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
1151	NDA/MAL/HDP/11041	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS 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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1152	NDA/MAL/HDP/11042	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
1153	NDA/MAL/HDP/11043	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
1154	NDA/MAL/HDP/11044	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DIAZAC 10	DAPAGLIFLOZIN	10MG	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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1155	NDA/MAL/HDP/11047	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
1156	NDA/MAL/HDP/11048	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	APRETUDE 600 MG	CABOTEGRAVIR	200MG/ML	GLAXO OPERATIONS UK LIMITED HARMIRE 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
1157	NDA/MAL/HDP/11049	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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1158	NDA/MAL/HDP/11050	SURGE LABORATORIES (PVT) LTD,	JEET PHARMACEUTICALS LIMITED	SERGIFEX 1G	CEFTRIAZONE 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
1159	NDA/MAL/HDP/11051	SURGE LABORATORIES (PVT) LTD,	JEET PHARMACEUTICALS LIMITED	SERGIFEX 2G	CEFTRIAZONE 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
1160	NDA/MAL/HDP/11052	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AKO-PAS	ACECLOFENAC + PARACETAMOL + SERRATIOPEPTIDASE	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

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1161	NDA/MAL/HDP/11053	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	OLODINE	OLOPATADINE HYDROCHLORIDE	0.1% W/V	ABACUS PARENTERAL DRUGS LIMITED PLOT 114, BLOCK 191, KINGA	UGANDA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML CONTAINER	12/13/2023
1162	NDA/MAL/HDP/11054	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	TORA	TOBRAMYCIN SULPHATE	0.3% W/V	ABACUS PARENTERAL DRUGS LIMITED PLOT 114, BLOCK 191, KINGA	UGANDA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML CONTAINER	12/13/2023
1163	NDA/MAL/HDP/11055	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	TORA-D	TOBRAMYCIN SULPHATE + DEXAMETHASONE SODIUM PHOSPHATE	0.3%W/V + 0.1%W/V	ABACUS PARENTERAL DRUGS LIMITED PLOT 114, BLOCK 191, KINGA	UGANDA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML CONTAINER	12/13/2023

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1164	NDA/MAL/HDP/11056	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
1165	NDA/MAL/HDP/11057	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
1166	NDA/MAL/HDP/11058	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

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1167	NDA/MAL/HDP/11059	AURA LIFECARE PVT. LTD.	REDDYS PHARMA LIMITED	AURADERM-0.05	CLOBETASOL	0.05%W/W	AURA LIFECARE PRIVATE LIMITED SURVEY 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
1168	NDA/MAL/HDP/1106	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	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
1169	NDA/MAL/HDP/11060	WORLD MEDICINE Ä°LAÄ± SAN. VE TIC. A.Äž.	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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1170	NDA/MAL/HDP/11061	MIDASCARE PHARMACEUTICALS 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
1171	NDA/MAL/HDP/11062	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
1172	NDA/MAL/HDP/11063	PHARMA BAVARIA INTERNACIONAL(PBI) 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

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1173	NDA/MAL/HDP/11064	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	ISONIAZID DISPERSIBLE TABLETS 100 MG	ISONIAZID	100 MG	OXALIS LABS LIMITED VILLAGE 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
1174	NDA/MAL/HDP/11065	JAMJOOM PHARMACEUTICALS 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
1175	NDA/MAL/HDP/11066	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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1176	NDA/MAL/HDP/11067	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
1177	NDA/MAL/HDP/11068	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
1178	NDA/MAL/HDP/11069	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

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1179	NDA/MAL/HDP/1107	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	HEPATITIS B VACCINE(RDNA) (PAEDIATRIC)	HEPATITIS B VACCINE(RDNA)	10MCG /0.5ML	SERUM INSTITUTE OF INDIA LTD212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY I M VIALS	1.0X25.0X5.0 ML VIAL (10 DOSES),1.0X10.0X0.5 ML VIAL (1 DOSE)	01/07/2005
1180	NDA/MAL/HDP/11070	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
1181	NDA/MAL/HDP/11071	MYLAN PHARMACEUTICALS PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	OGIVRIÄ,,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

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1182	NDA/MAL/HDP/11072	MEDOPHARM	NUGEN PHARMACEUTICALS 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
1183	NDA/MAL/HDP/11073	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	PARACO-DENK 500/30	PARACETAMOL + CODEINE PHOSPHATE HEMIHYDRATE	500 MG + 30 MG	BENE-ARZNEIMITTEL GMBH PRODUCTION AND WAREHOUSING-HERTERICHSTR. 1-3 D-81479 MUNICH GERMANY. QUALITY CONTROL LABORATORY - BAYERWALDSTR. 7-9 D-82538 GERETSRIED, GERMANY. HIGH-RACK WAREHOUSING "G" GEWERBERING 11 D-82140 OLCHING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	12/13/2023
1184	NDA/MAL/HDP/11074	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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1185	NDA/MAL/HDP/11075	HEALTH LINK PHARMACY LTD	HEALTH LINK PHARMACY LIMITED	ROLXIN OD	DIHYDROARTEMISININ + PIPERAQUINE PHOSPHATE	120 MG + 960 MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN Å€" 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	12/13/2023
1186	NDA/MAL/HDP/11076	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	G-COSPEÅ®	SULFADOXINE + PYRIMETHAMINE	500MG + 25MG	GUILIN PHARMACEUTICAL CO LTD .NO. 43, QULIDIAN ROAD, GUILIN 541004	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X3.0 TABLET BLISTER	12/13/2023
1187	NDA/MAL/HDP/11078	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	B-LACT	LACTULOSE	3.35GM/5ML	FRESENIUS KABI AUSTRIA GMBHESTERMANNSTRASSE 17, A-4020 LINZ	AUSTRIA	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	02/02/2024

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1188	NDA/MAL/HDP/11079	MEDOPHARM	PLANET PHARMACEUTICALS 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
1189	NDA/MAL/HDP/11080	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	OLMAT-AMH	OLMESARTAN MEDOXOMIL + AMLODIPINE BESILATE + HYDROCHLOROTHIAZIDE	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
1190	NDA/MAL/HDP/11081	INFUGEN PHARMA PVT. LTD.	GITTOES PHARMACEUTICALS LIMITED	INFUROXIM	CEFUROXIME SODIUM	750MG	ZEISS PHARMACEUTICALS PRIVATE LIMITEDPLOT 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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1191	NDA/MAL/HDP/11082	UNITED PHARMACEUTICALS MANUFACTURING LIMITED COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VIVAZAC PLUS	IRBESARTAN + HYDROCHLOROTHIAZIDE	150 MG + 12.5 MG	UNITED PHARMACEUTICALS MANUFACTURING LIMITED COMPANY- 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
1192	NDA/MAL/HDP/11083	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
1193	NDA/MAL/HDP/11084	MEGA LIFESCIENCES 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

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1194	NDA/MAL/HDP/11085	CACHET PHARMACEUTICALS 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
1195	NDA/MAL/HDP/11086	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
1196	NDA/MAL/HDP/11087	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	AMICINE	AMIKACIN SULPHATE	500MG/2ML	MS PHARMA - JORDANPLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH-WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY VIALS	1.0X5.0X2.0 ML VIAL	02/02/2024

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1197	NDA/MAL/HDP/11088	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
1198	NDA/MAL/HDP/1109	DAWA LIMITED	SUPER MEDIC LTD	DAWA-CPM	CHLORPHENIRAMINE MALEATE	2MG/5ML	DAWA PHARMACEUTICALS LIMITEDPLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2014
1199	NDA/MAL/HDP/11090	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

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1200	NDA/MAL/HDP/11093	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	XERATEC	IRON SUCROSE	100MG	MS PHARMA - JORDANPLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL- HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY VIALS	1.0X5.0X5.0 ML VIAL	02/02/2024
1201	NDA/MAL/HDP/11094	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
1202	NDA/MAL/HDP/11098	VERVE HUMAN CARE LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	ADEVER	ADRENALINE ACID TARTRATE	1MG/ML	VERVE HUMAN CARE LABORATORIESPLOT NO. 15A PHARMACY, SELAQUI, DEHRADUN, UTTARAKHAND, 248011, INDIA.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	02/02/2024

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1203	NDA/MAL/HDP/11 101	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	CLARITHROM YCIN 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
1204	NDA/MAL/HDP/11 102	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
1205	NDA/MAL/HDP/11 103	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

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1206	NDA/MAL/HDP/11 104	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
1207	NDA/MAL/HDP/11 105	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
1208	NDA/MAL/HDP/11 106	SCOTT-EDIL ADVANCE RESEARCH LABORATORIES & EDUCATION LTD.,	ROYAL PHARMA 2011 LIMITED	SCOTXONE- 1G	CEFTRIAZONE 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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1209	NDA/MAL/HDP/11 107	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
1210	NDA/MAL/HDP/11 109	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
1211	NDA/MAL/HDP/11 11	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 LIMITEDPLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE	01/07/2013

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1212	NDA/MAL/HDP/11110	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
1213	NDA/MAL/HDP/11111	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 KUTCH 370 230 GUJARAT	INDIA	ORAL SOLID ORDINARY SUBLINGUAL TABLETS	1.0X1.0X7.0 TABLET BLISTER, 1.0X4.0X7.0 TABLET BLISTER	02/02/2024
1214	NDA/MAL/HDP/11112	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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1215	NDA/MAL/HDP/11113	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	ATRONA-20	ATORVASTATIN CALCIUM	20MG	ZOTA HEALTHCARE 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
1216	NDA/MAL/HDP/11117	FAROMED LIFESCIENCES LLP	METRO PHARMACEUTICALS LIMITED	FAST 250 SUPPOSITORY	PARACETAMOL	250MG	THE ACME LABORATORIES LIMITED DHULIVITA, DHAMRAI, DHAKA - 1350, BANGLADESH	BANGLADESH	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY STRIP	02/02/2024
1217	NDA/MAL/HDP/11118	LUPIN LIMITED-	AIVEEN (U) LIMITED	MOXIFLOXACIN	MOXIFLOXACIN HYDROCHLORIDE	400 MG	LUPIN LIMITED UNIT-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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1218	NDA/MAL/HDP/11 119	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (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), TSIIC, 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
1219	NDA/MAL/HDP/11 120	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	VALABIN 500	VALACICLOVIR HYDROCHLORIDE	500MG	AUROBINDO PHARMA LIMITED, UNIT IISURVEY 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
1220	NDA/MAL/HDP/11 128	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

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1221	NDA/MAL/HDP/11 129	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
1222	NDA/MAL/HDP/11 13	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
1223	NDA/MAL/HDP/11 130	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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1224	NDA/MAL/HDP/11 135	MEGA LIFESCIENCES 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
1225	NDA/MAL/HDP/11 136	KESAR PHARMA	ABACUS PHARMA (AFRICA) LIMITED	ALZOL	ALBENDAZOLE	400 MG	KESAR PHARMA PVT LTD- PLOT SURVEY NO. 50/2. VILLAGE BILESHPURPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X1.0 TABLET BLISTER	12/13/2023
1226	NDA/MAL/HDP/11 137	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,1.0X1 80.0 TABLET CONTAINER	12/13/2023

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1227	NDA/MAL/HDP/11138	CACHET PHARMACEUTICALS 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
1228	NDA/MAL/HDP/11139	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
1229	NDA/MAL/HDP/1114	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	TRANGEL ULTRA	DICLOFENAC/METHYL SALICYLATE/MENTHOL/CAPVICUM OLEORESIN	10MG/80MG/60MG/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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1230	NDA/MAL/HDP/11 140	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
1231	NDA/MAL/HDP/11 141	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
1232	NDA/MAL/HDP/11 142	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

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1233	NDA/MAL/HDP/11 143	HILTON PHARMA (PVT) LTD	BOOTS PHARMACEUTICALS 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
1234	NDA/MAL/HDP/11 144	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	EFAVIRENZ, LAMIVUDINE AND TENOFIVIR DISOPROXIL FUMARATE TABLETS	EFAVIRENZ + LAMIVUDINE + TENOFIVIR 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
1235	NDA/MAL/HDP/11 145	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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1236	NDA/MAL/HDP/11 147	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
1237	NDA/MAL/HDP/11 148	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
1238	NDA/MAL/HDP/11 149	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	LICAN	LULICONAZOLE	1% W/W	CIPLA LTD, GOA UNIT V & UNIT X-L-139, S-103&M- 62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA	SAUDI ARABIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	12/13/2023

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1239	NDA/MAL/HDP/11 150	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,1.0X2.0X 10.0 TABLET BLISTER,1.0X2.0X 7.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	12/13/2023
1240	NDA/MAL/HDP/11 151	BAROQUE PHARMACEUTICALS PVT LTD	JEET PHARMACEUTICALS 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
1241	NDA/MAL/HDP/11 152	BAROQUE PHARMACEUTICALS PVT LTD	JEET PHARMACEUTICALS 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

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1242	NDA/MAL/HDP/11 153	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
1243	NDA/MAL/HDP/11 154	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
1244	NDA/MAL/HDP/11 155	IDA FOUNDATYION	KIMSY MEDS LTD	BENZATHINE BENZYLPENIC ILLIN 1.2MIU	BENZATHINE BENZYLPENICILLIN	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

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1245	NDA/MAL/HDP/11 156	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
1246	NDA/MAL/HDP/11 157	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
1247	NDA/MAL/HDP/11 158	MARCYRL PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TORSAMOLE X 20MG	TORSEMIDE	20MG	MARCYRL PHARMACEUTICAL INDUSTRIES WESTERN EXTENSION-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

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1248	NDA/MAL/HDP/11 159	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
1249	NDA/MAL/HDP/11 160	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
1250	NDA/MAL/HDP/11 161	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ASTRA PHARMA (U) LIMITED	EMITINO-8 INJECTION	ONDANSETRON HYDROCHLORIDE	8MG/4ML	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACY SELAQUI DEHRADUN " 248011 (U.K), INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0X4.0 ML AMPOULE	02/02/2024

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1251	NDA/MAL/HDP/11 162	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICAL S 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
1252	NDA/MAL/HDP/11 163	UNIMED LABORATORIES.	OMAB UGANDA LIMITED	CIPROJECT	CIPROFLOXACIN	200MG	UNIMED LABORATORIESP.O. BOX 38 - I.Z. KALAA KEBIRA - 4060 KALAA KEBIRA - TUNISIA	TUNISIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X100.0 ML BAG	02/02/2024
1253	NDA/MAL/HDP/11 164	IDA FOUNDATION	KIMSY MEDS LTD	BENZATHINE BENZYLPENIC ILLIN 5MIU	BENZATHINE BENZYLPENICILLIN	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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1254	NDA/MAL/HDP/11 165	IDA FOUNDATION	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
1255	NDA/MAL/HDP/11 166	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
1256	NDA/MAL/HDP/11 167	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

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1257	NDA/MAL/HDP/11 168	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
1258	NDA/MAL/HDP/11 169	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
1259	NDA/MAL/HDP/11 17	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	TETRACYCLIN E 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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1260	NDA/MAL/HDP/11 170	JEVIANA HEALTH CARE LLP,	MARVIN PHARMA LIMITED	MARIPRAZO LE	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
1261	NDA/MAL/HDP/11 171	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
1262	NDA/MAL/HDP/11 172	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

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1263	NDA/MAL/HDP/11 173	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
1264	NDA/MAL/HDP/11 174	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
1265	NDA/MAL/HDP/11 175	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

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1266	NDA/MAL/HDP/11 176	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
1267	NDA/MAL/HDP/11 177	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
1268	NDA/MAL/HDP/11 178	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

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1269	NDA/MAL/HDP/11 179	UNIMED LABORATORIES.	OMAB UGANDA LIMITED	TAZOBACT 4G/500 MG	PIPERACILLIN SODIUM + TAZOBACTAM SODIUM	4G + 500MG	UNIMED LABORATORIES P.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
1270	NDA/MAL/HDP/11 18	EMCURE PHARMACEUTICAL S 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
1271	NDA/MAL/HDP/11 182	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

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1272	NDA/MAL/HDP/11 189	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
1273	NDA/MAL/HDP/11 190	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
1274	NDA/MAL/HDP/11 191	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

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1275	NDA/MAL/HDP/11 192	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
1276	NDA/MAL/HDP/11 193	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
1277	NDA/MAL/HDP/11 194	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

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1278	NDA/MAL/HDP/11 195	FAROMED LIFESCIENCES LLP	METRO PHARMACEUTICALS LIMITED	CONTR	KETOROLAC TROMETHAMINE	60MG/2ML	THE ACME LABORATORIES LIMITED- DHULIVITA, DHAMRAI, DHAKA - 1350, BANGLADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X2.0 ML AMPOULE	12/13/2023
1279	NDA/MAL/HDP/11 196	FAROMED LIFESCIENCES LLP	METRO PHARMACEUTICALS 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
1280	NDA/MAL/HDP/11 197	LINCOLN PHARMACEUTICAL S LIMITED	METRO PHARMACEUTICALS LIMITED	MYCOFIL	MYCOPHENOLATE 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

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1281	NDA/MAL/HDP/11 198	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
1282	NDA/MAL/HDP/11 199	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICALS (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
1283	NDA/MAL/HDP/11 200	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICALS (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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1284	NDA/MAL/HDP/11201	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICALS (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
1285	NDA/MAL/HDP/11202	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (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
1286	NDA/MAL/HDP/11203	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (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 DISTTELANGANA502307	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X1.0X100.0 ML BOTTLE	12/13/2023

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1287	NDA/MAL/HDP/11 204	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
1288	NDA/MAL/HDP/11 205	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
1289	NDA/MAL/HDP/11 206	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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1290	NDA/MAL/HDP/11 208	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
1291	NDA/MAL/HDP/11 209	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	RO-VIT-K 10	PHYTOMENADION E	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
1292	NDA/MAL/HDP/11 22	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

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1293	NDA/MAL/HDP/1123	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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
1294	NDA/MAL/HDP/11230	SERUM INSTITUTE OF INDIA PVT LTD	NORVIK ENTERPRISES LIMITED	CYVAC	R21 MALARIA VACCINE (RECOMBINANT, ADJUVANTED)	5 μ G OF MALARIA ANTIGEN & 50 μ G OF MATRIX-M1 PER DOSE OF 0.5ML	SERUM INSTITUTE OF INDIA PVT LTD .212/2, HADAPSAR, PUNE-411028, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0X0.5 ML VIAL, 1.0X50.0X1.0 ML VIAL	22/03/2024
1295	NDA/MAL/HDP/11232	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	PLERISTEM	PLERIXAFOR	24MG/1.2ML	EUGIA PHARMA SPECIALITIES LIMITED SURVEY 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

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1296	NDA/MAL/HDP/11233	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICALS LTD)	PLANET PHARMACEUTICALS 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
1297	NDA/MAL/HDP/11234	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
1298	NDA/MAL/HDP/11235	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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1299	NDA/MAL/HDP/11 236	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 LIMITED SURVEY 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
1300	NDA/MAL/HDP/11 237	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICALS LIMITED	PERILIN	METOCLOPRAMID E 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
1301	NDA/MAL/HDP/11 238	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICALS 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

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1302	NDA/MAL/HDP/11 239	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
1303	NDA/MAL/HDP/11 24	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS 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. THAN E INDIA	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X1.0X500.0 ML BOTTLE	01/07/2013
1304	NDA/MAL/HDP/11 241	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	TERBINAFINE TABLETS USP, 250 MG	TERBINAFINE HYDROCHLORIDE	250MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN " 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/03/2024

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1305	NDA/MAL/HDP/11 242	FAROMED LIFESCIENCES LLP	METRO PHARMACEUTICALS LIMITED	SITAP 50	SITAGLIPTIN PHOSPHATE MONOHYDRATE	50MG	ADVANCED CHEMICAL INDUSTRIES (ACI) LIMITED7, HAJEONGJ ROAD, GOODNYL, NARAYANGONJ - 1400	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/03/2024
1306	NDA/MAL/HDP/11 243	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
1307	NDA/MAL/HDP/11 244	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICALS 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

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1308	NDA/MAL/HDP/11 245	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICALS 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
1309	NDA/MAL/HDP/11 246	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
1310	NDA/MAL/HDP/11 248	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICALS 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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1311	NDA/MAL/HDP/11249	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS 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/SYRUPS/DROPS	1.0X1.0X60.0 ML BOTTLE	22/03/2024
1312	NDA/MAL/HDP/1125	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (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 DISTTELANGANA502307	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2009
1313	NDA/MAL/HDP/11250	AUROCHEM LABORATORIES(I) PVT LTD	SUPER MEDIC LTD	DOBESIL H	CALCIUM DOBESILATE MONOHYDRATE + LIDOCAINE HYDROCHLORIDE + HYDROCORTISONE 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

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1314	NDA/MAL/HDP/11 252	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TELMICLAR HTZ 40/12.5	TELMISARTAN + HYDROCHLOROTH IAZIDE	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
1315	NDA/MAL/HDP/11 253	FRESENIUS KABI MANUFACTURING S.A. (PTY) LTD	SURGIPHARM (U) LIMITED	CLINDAMYCI N 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	PORTUGALSOUT H AFRICA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X4.0 ML AMPOULE	22/03/2024
1316	NDA/MAL/HDP/11 254	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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1317	NDA/MAL/HDP/11 255	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
1318	NDA/MAL/HDP/11 256	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
1319	NDA/MAL/HDP/11 257	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

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1320	NDA/MAL/HDP/11 258	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ADERAN HTZ 16/12.5	CANDESARTAN CILEXETIL + HYDROCHLOROTH IAZIDE	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
1321	NDA/MAL/HDP/11 259	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
1322	NDA/MAL/HDP/11 260	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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1323	NDA/MAL/HDP/11 261	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
1324	NDA/MAL/HDP/11 262	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/SYRU PS/DROPS	1.0X1.0X60.0 ML BOTTLE	22/03/2024
1325	NDA/MAL/HDP/11 263	ORCHIDIA PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NORMOPROS T	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

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1326	NDA/MAL/HDP/11 264	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	FLAIROF	ROFLUMILAST	250MCG	HETERO LABS LIMITED (UNIT III)...22-110, I.D.A, JEEDIMETLA, HYDERABAD- 500 055, ANDHRA PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X15.0 TABLET BLISTER	16/03/2024
1327	NDA/MAL/HDP/11 265	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
1328	NDA/MAL/HDP/11 266	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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1329	NDA/MAL/HDP/11 267	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
1330	NDA/MAL/HDP/11 268	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	PARACO- DENK 1000/60	PARACETAMOL + CODEINE PHOSPHATE HEMIHYDRATE	1000 MG + 60 MG	BENE-ARZNEIMITTEL GMBHHERTERTICHSTR. 1- 3, 81479 MUNCHEN - GERMANY	GERMANY	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY STRIP	16/03/2024
1331	NDA/MAL/HDP/11 269	INTAS PHARMACUITICALS LTD	NORVIK ENTERPRISES LIMITED	DOXORUBICI N 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

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1332	NDA/MAL/HDP/11 270	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
1333	NDA/MAL/HDP/11 271	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
1334	NDA/MAL/HDP/11 273	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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1335	NDA/MAL/HDP/11 274	HILTON PHARMA (PVT) LTD	BOOTS PHARMACEUTICALS 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
1336	NDA/MAL/HDP/11 275	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	SPIRONOLAC TONE	SPIRONOLACTONE	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
1337	NDA/MAL/HDP/11 276	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES 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 33, A-2 & A-37/2/2 (UNIT- I), A-42(UNIT-II), MIDC PATANGANGA, 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

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1338	NDA/MAL/HDP/11 277	SQUARE PHARMACEUTICAL S LTD	GAMA PHARMACEUTICALS (U) LIMITED	ANGILOCK 50	LOSARTAN POTASSIUM	50 MG	SQUARE PHARMACEUTICALS LIMITED - DHAKA UNITKALIAKOIR GAZIPUR	BANGLADESH	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	16/03/2024
1339	NDA/MAL/HDP/11 278	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS 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
1340	NDA/MAL/HDP/11 279	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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1341	NDA/MAL/HDP/11 28	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICALS 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
1342	NDA/MAL/HDP/11 280	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
1343	NDA/MAL/HDP/11 281	WORLD MEDICINE Ä°LAÄ± SAN. VE TIC. A.Äž.	GOODMAN INTERNATIONAL LTD	SERTOFEN	DEKTOPROFEN TROMETAMOL	25MG	WORLD MEDICINE ILAC SAN VE TIC A.S.15 TEMMUZ MAHALLESİ, CAMI YOLU CADDESİ, NO: 50 K:4 WM PLAZA, GUNESIL- BAGCILAR/INSTANBUL, TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	16/03/2024

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1344	NDA/MAL/HDP/11 282	WORLD MEDICINE Ä°LAÄ± SAN. VE TIC. A.Äž.	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/INSTANBUL, TURKEY	TURKEY	ORAL SOLID ORDINARY GRANULES	1.0X28.0 SACHET CARTON	16/03/2024
1345	NDA/MAL/HDP/11 283	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
1346	NDA/MAL/HDP/11 284	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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1347	NDA/MAL/HDP/11 285	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
1348	NDA/MAL/HDP/11 286	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
1349	NDA/MAL/HDP/11 287	LABORATÁRIOS BASI	ONCOPHARM (U) LTD	MIDAZOLAM BASI	MIDAZOLAM	15 MG/3 ML	LABORATORIOS BASI - INDUSTRIA FARMACEUTICAPARQUE 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

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1350	NDA/MAL/HDP/11 288	MICRO LABS LIMITED	PHARMA VILLE LIMITED	PARACETAM OL 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
1351	NDA/MAL/HDP/11 289	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
1352	NDA/MAL/HDP/11 290	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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1353	NDA/MAL/HDP/11 291	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
1354	NDA/MAL/HDP/11 293	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MOFECON 500	MYCOPHENOLATE 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
1355	NDA/MAL/HDP/11 294	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MOFECON C- 250	MYCOPHENOLATE 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

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1356	NDA/MAL/HDP/11 295	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICALS (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
1357	NDA/MAL/HDP/11 296	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICALS (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
1358	NDA/MAL/HDP/11 297	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (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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1359	NDA/MAL/HDP/11298	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (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
1360	NDA/MAL/HDP/11299	LABORATĂRIOS VITĂRIA, S.A	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TRAUSAN	CITICOLINE SODIUM	100MG/ML	FAES FARMA SAMAXIMO AGUIRRE 14. 48940 LEIOA Ă SPAIN	SPAIN	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X50.0 ML BOTTLE	22/03/2024
1361	NDA/MAL/HDP/1130	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS 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

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1362	NDA/MAL/HDP/11309	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
1363	NDA/MAL/HDP/1131	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
1364	NDA/MAL/HDP/1132	STEDMAN PHARMACEUTICALS 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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1365	NDA/MAL/HDP/1134	FEROZSONS LABORATORIES LTD	HEALTHCARE LTD.	XAVOR DIU	LOSARTAN AND HYDROCHLORTHIAZIDE	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
1366	NDA/MAL/HDP/1136	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOS CAB 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
1367	NDA/MAL/HDP/1138	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THAN E INDIA	INDIA	TOPICAL EXTERNAL LOTIONS	1.0X1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2013

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1368	NDA/MAL/HDP/1139	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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
1369	NDA/MAL/HDP/1140	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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
1370	NDA/MAL/HDP/1142	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.THAN E INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2013

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1371	NDA/MAL/HDP/11 43	LINCOLN P'CAL LTD	METRO PHARMACEUTICALS LIMITED	LOSA-H	LOSARTAN + HYDROCHLOROTH IAZIDE	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
1372	NDA/MAL/HDP/11 45	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
1373	NDA/MAL/HDP/11 54	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS LTD	BACQUIRE	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

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1374	NDA/MAL/HDP/1158	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
1375	NDA/MAL/HDP/1160	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
1376	NDA/MAL/HDP/1163	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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1377	NDA/MAL/HDP/1164	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
1378	NDA/MAL/HDP/1166	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
1379	NDA/MAL/HDP/1167	CIRON DRUGS AND PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	METOCLOPRAMIDE INJECTION	METOCLOPRAMIDE	5MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD .N-118,M.I.D.C, TARAPUR,BOISAR, DIST.THANE-401506, MAHARASHTRA,INDIA.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE	01/07/2010

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1380	NDA/MAL/HDP/1168	DAWA LIMITED	SUPER MEDIC LTD	DAWA-CORT CREAM	HYDROCORTISONE	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
1381	NDA/MAL/HDP/1169	ARISTO PHARMACEUTICALS 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,1.0X10.0 X10.0 TABLET BLISTER,1.0X3.0X3.0X10.0 TABLET BLISTER	01/07/2013
1382	NDA/MAL/HDP/1172	CIRON DRUGS AND PHARMACEUTICALS 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,INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL,1.0X30.0 ML VIAL	01/07/2010

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1383	NDA/MAL/HDP/1178	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
1384	NDA/MAL/HDP/1179	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	OVITRELLE	CHORIOGONADOT ROPIN ALFA	250MCG/0.5ML	MERCK SERONO S.P.A-VIA DELLE MAGNOLIE,15.70026 MODUGNO (BA).ITALY MERCK SERONO SA-1170 AUBONNE(SWITZERLAND)	ITALY, SWITZERLAND	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X1.0 PREFILLED SYRINGE CARTON	01/07/2015
1385	NDA/MAL/HDP/1184	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

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1386	NDA/MAL/HDP/1185	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
1387	NDA/MAL/HDP/1186	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
1388	NDA/MAL/HDP/1188	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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1389	NDA/MAL/HDP/1189	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
1390	NDA/MAL/HDP/1198	THEMIS MEDICARE LTD.	STAR PHARMACEUTICALS 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
1391	NDA/MAL/HDP/1199	THEMIS MEDICARE LTD	STAR PHARMACEUTICALS LTD	THEMISSET 75	PALONOSETRON HYDROCHLORIDE	0.075MG/1.5ML	THEMIS MEDICARE LIMITEDSECTOR 6A, PLOT NO. 16 TO18, IIE, BHEL HARIDWA, UTTARAKHAND	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.5 ML VIAL	01/07/2013

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1392	NDA/MAL/HDP/1201	THEMIS MEDICARE LTD	STAR PHARMACEUTICALS LTD	THEMISET	PALONOSETRON HYDROCHLORIDE	0.25MG/5ML	THEMIS MEDICARE LIMITED SECTOR 6A, PLOT NO. 16 TO18, IIE, BHEL HARIDWA, UTTARAKHAND	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.5 ML VIAL	01/07/2013
1393	NDA/MAL/HDP/1204	THEMIS MEDICARE LTD	STAR PHARMACEUTICALS LTD	DEXEM INJECTION	DEXMEDETOMIDINE HYDROCHLORIDE	100	THEMIS MEDICARE LTD SECTOR 6A, PLOT NO. 16 TO18, IIE, BHEL HARIDWA, UTTARAKHAND	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE	01/07/2013
1394	NDA/MAL/HDP/1206	THE METHOLATUM CO. LTD	HARLEYS UGANDA LIMITED	DEEP RELIEF	IBUPROFEN + MENTHOL	5%W/W + 3% W/W	THE METHOLATUM 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

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1395	NDA/MAL/HDP/1208	ARISTO PHARMACEUTICALS 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
1396	NDA/MAL/HDP/1209	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ARBITEL-80	TELMISARTAN	80MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
1397	NDA/MAL/HDP/1211	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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1398	NDA/MAL/HDP/12 14	FERRER INTERNACIONAL S.A	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NUCLEO C.M.P FORTE	CYTIDINE+URIDIN E	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
1399	NDA/MAL/HDP/12 15	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GYNANFORT VAGINAL PESSARY	METRONIDAZOLE +NEOMYCIN SULPHATE+NYSTA TIN	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
1400	NDA/MAL/HDP/12 19	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

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1401	NDA/MAL/HDP/12 20	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	LONART	ARTEMETHER + LUMEFANTRINE	180 MG + 1080 MG	BLISS GVS PHARMA LIMITED NO.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
1402	NDA/MAL/HDP/12 23	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,KENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X25.0 G TUBE	01/07/1997
1403	NDA/MAL/HDP/12 26	AFRICURE PHARMACEUTICALS (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,1.0X1 000.0 TABLET CONTAINER,10.0X 10.0 TABLET BLISTER	01/07/2005

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1404	NDA/MAL/HDP/12 34	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
1405	NDA/MAL/HDP/12 42	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS 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
1406	NDA/MAL/HDP/12 44	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS 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

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1407	NDA/MAL/HDP/12 45	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS 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
1408	NDA/MAL/HDP/12 47	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS LIMITED	PROCIP	CYPROHEPTADINE	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
1409	NDA/MAL/HDP/12 52	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	ZOY	SILDENAFIL	50MG	TORQUE PHAMACEUTICALS 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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1410	NDA/MAL/HDP/12 54	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,1.0X1 00.0 TABLET CONTAINER	01/07/1998
1411	NDA/MAL/HDP/12 55	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
1412	NDA/MAL/HDP/12 59	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

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1413	NDA/MAL/HDP/12 61	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
1414	NDA/MAL/HDP/12 64	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS 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
1415	NDA/MAL/HDP/12 65	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	COMBIPLIX	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.THAN E INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X1 0.0X10.0 TABLET BLISTER	01/07/2008

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1416	NDA/MAL/HDP/1275	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
1417	NDA/MAL/HDP/1278	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP	DIHYDROARTEMESININ + PIPERAQUINE PHOSPHATE	40MG +320MG	GUILIN PHARMACEUTICAL CO LTD NO.43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X9.0 TABLET BLISTER, 1.0X8.0 TABLET BLISTER, 1.0X25.0 X1.0X9.0 TABLET BLISTER	01/07/2013
1418	NDA/MAL/HDP/1282	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS 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

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1419	NDA/MAL/HDP/1285	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANFUR-750	CEFUROXIME	750MG	SANCE LABORATORIES PRIVATE LTD P.B. 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
1420	NDA/MAL/HDP/1287	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANIX- DS 100	CEFIXIME	100MG/5ML	SANCE LABORATORIES PVT LTD P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE, 1.0X60.0 ML BOTTLE	01/07/2014
1421	NDA/MAL/HDP/1290	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANIX 400 CAP	CEFIXIME	400MG	SANCE LABORATORIES PVT LTD 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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1422	NDA/MAL/HDP/1291	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
1423	NDA/MAL/HDP/1293	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS 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
1424	NDA/MAL/HDP/1294	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

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1425	NDA/MAL/HDP/1295	SHAIGAN PHARMACEUTICALS (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
1426	NDA/MAL/HDP/1299	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANAXONE PLUS-1000	CEFTRIAXONE+SULBACTAM	1000MG+500MG	SANCE LABORATORIES PRIVATE LTD PB 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
1427	NDA/MAL/HDP/1302	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	HIPEN CAPSULES	AMOXYCILLIN	250MG	SPARSH BIO-TECH PVT. LIMITED PLOT NO. 1; SURVEY NO. 242/243/244, LAKHABAVA D, JAMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1997

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1428	NDA/MAL/HDP/1303	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (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,1.0X10.0 X10.0 CAPSULE BLISTER	01/07/2013
1429	NDA/MAL/HDP/1304	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (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
1430	NDA/MAL/HDP/1307	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

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1431	NDA/MAL/HDP/13 12	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
1432	NDA/MAL/HDP/13 19	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	ZESTAVAL 200 F.C TABLETS	ALBENDAZOLE	200MG	REMEDICA LTDAHARNON 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
1433	NDA/MAL/HDP/13 24	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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1434	NDA/MAL/HDP/13 28	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ENGERIX-B VACCINE	HEPATITIS B SURFACE ANTIGEN	20MCG/ML	GLAXOSMITHKLINE BOIOLOGICALSS.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
1435	NDA/MAL/HDP/13 31	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
1436	NDA/MAL/HDP/13 35	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

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1437	NDA/MAL/HDP/13 37	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	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
1438	NDA/MAL/HDP/13 38	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
1439	NDA/MAL/HDP/13 41	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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1440	NDA/MAL/HDP/13 45	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 ALKEM LABORATORIES LTD VILLAGE – THANA, BADDI TEHSIL – NALAGARH, DIST-SOLAN (HP), INDIA – 173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2010
1441	NDA/MAL/HDP/13 47	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	ORNILOX	ORNIDAZOLE + OFLOXACIN	500MG + 200MG	MICRO LABS LTD 92, SIPCOT INDUSTRIAL COMPLEX HOSUR- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2010
1442	NDA/MAL/HDP/13 48	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	VALPARIN CHRONO 500	SODIUM VALPROATE (CONTROLLED RELEASE)	500MG	TORRENT PHARMACEUTICAL LTD AHMEDABAD- MEHSANA HIGHWAY, TALUKA- KADI, DIST. MEHSANA, INDIA RAD-382721	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2009

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1443	NDA/MAL/HDP/1353	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
1444	NDA/MAL/HDP/1359	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
1445	NDA/MAL/HDP/1361	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS 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 NAACL AMPOULE + 1*1ML OF 5%W/V NAHCO3 AMPOULE	01/07/2016

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1446	NDA/MAL/HDP/13 62	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
1447	NDA/MAL/HDP/13 67	DAWA LIMITED	SUPER MEDIC LTD	ACEPAR	ACECLOFENAC + PARACETAMOL	100 MG + 500 MG	DAWA LTD BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2013
1448	NDA/MAL/HDP/13 68	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	D5	GLUCOSE	5%W/V	ABACUS PARENTERAL DRUGS LIMITED BLOCK 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

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1449	NDA/MAL/HDP/1369	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,UGANDA MEDICAMEN BIOTECH LTD, .SP-1192 A&B PHASE IV INDUSTRIAL AREA BHIWADI 301019 DIST. ALWAR (RAJASTHAN) - INDIA AGOG PHARMA LTD PLOT NO.33,SECTOR II VASAI TALUKA INDI CO-	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X2.0X20.8 G SACHET + 1.0 *10.0 TABLET BLISTER	01/07/2016
1450	NDA/MAL/HDP/1370	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	STERILIZED WATER FOR INJECTION	WATER FOR INJECTION	NEUTRAL	ABACUS PARENTERAL DRUGS LIMITED BLOCK 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
1451	NDA/MAL/HDP/1372	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 LTD KISHNPUR, JAMALPUR ROORKEE-247677	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2014

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1452	NDA/MAL/HDP/1377	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
1453	NDA/MAL/HDP/1380	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	HYCORT CREAM	HYDROCORTISONE	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
1454	NDA/MAL/HDP/1382	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

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1455	NDA/MAL/HDP/1383	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
1456	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
1457	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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1458	NDA/MAL/HDP/1390	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
1459	NDA/MAL/HDP/1392	ASTRA ZENECA	MACNAUGHTON LIMITED	ZOLADEX	GOSERELIN	3.6MG	ASTRA ZENECA UK LIMITED ASTRAZENECA 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
1460	NDA/MAL/HDP/1393	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

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1461	NDA/MAL/HDP/13 94	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANPIME - 1000	CEFEPIME	1000MG	SANCE LABORATORIES PRIVATE LTD 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
1462	NDA/MAL/HDP/13 95	ASTRA ZENECA AB	MACNAUGHTON LIMITED	NEXIUM 40MG IV	ESOMEPRAZOLE	40MG/5ML	ASTRA ZENECA- KVARNBERGAGATAN12, SE-151 SODERTALIJE	SWEDEN	PARENTERAL ORDINARY VIALS	1.0X1.0X5.0 ML VIAL,1.0X10.0X5.0 ML VIAL	01/07/2010
1463	NDA/MAL/HDP/13 97	ASTRA ZENECA	MACNAUGHTON LIMITED	PLENDIL	FELODIPINE	10MG	ASTRAZENECA SWEDEN OPERATIONS ASTRAZENECA A 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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1464	NDA/MAL/HDP/1400	MEGA LIFESCIENCES (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
1465	NDA/MAL/HDP/1402	MEGA LIFESCIENCES (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
1466	NDA/MAL/HDP/1406	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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2014

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1467	NDA/MAL/HDP/1409	PHARMACTIV FZCO	JEET PHARMACEUTICALS LIMITED	ROMYCIN	AZITHROMYCIN	200MG/5ML	NABIQASIM INDUSTRIES (PVT) LTD- 17/24,KORANGI INDUSTRIAL AREA, KORANGI, KARACHI- PAKISTAN.	PAKISTAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X1.0X15.0 ML BOTTLE	01/07/2007
1468	NDA/MAL/HDP/1411	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	CIPIUM	CHLORPHENIRAMINE	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,1.0X10.0X10.0 TABLET BLISTER	01/07/2011
1469	NDA/MAL/HDP/1413	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,MOGADISHU 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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1470	NDA/MAL/HDP/14 14	UNIQUE PHARMACEUTICAL S 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
1471	NDA/MAL/HDP/14 17	GLENMARK PHARMACEUTICAL 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
1472	NDA/MAL/HDP/14 18	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	AMINOPHYLL INE 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, 1.0X1 0.0X10.0 TABLET BLISTER	01/07/2011

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1473	NDA/MAL/HDP/1419	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
1474	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
1475	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.THANE 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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1476	NDA/MAL/HDP/1431	INTAS PHARMACUTICALS 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
1477	NDA/MAL/HDP/1433	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	NORISTERAT	NORETHISTERONE ENANTATE	200MG	BAYER PHARMA A.GMULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	PARENTERAL ORDINARY VIALS	1.0 ML PRE-FILLED SYRINGE,1.0X100.0X1.0 ML VIAL	01/07/1997
1478	NDA/MAL/HDP/1436	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CONCOR 10	BISOPROLOL HEMIFUMARATE	10MG	WINTHROP PHARMACEUTICALS(PTY) LTD,315 WATLOO ROAD,WATLOO,PRETORIA,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

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1479	NDA/MAL/HDP/1441	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
1480	NDA/MAL/HDP/1445	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	AXONE 1000	CEFTRIAXONE SODIUM	1000MG	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL	01/07/2003
1481	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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1482	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
1483	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
1484	NDA/MAL/HDP/1450	GLAXOSMITHKLINE LIMITED LIKONI	UNITED HEALTHCARE DISTRIBUTORS LTD	VOLTAREN EMULGEL 1%	DICLOFENAC DIETHYLAMMONIUM	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

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1485	NDA/MAL/HDP/1451	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN INJECTION	DICLOFENAC	25MG/ML	NOVARTIS PHARMA STEIN AGSCHAFFHARVSESTRASSE CH-4332 STEIN SWITZERLAND.	SWITZERLAND	PARENTERAL ORDINARY AMPOULES	1.0X3.0 ML AMPOULE	01/07/1997
1486	NDA/MAL/HDP/1454	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
1487	NDA/MAL/HDP/1456	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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1488	NDA/MAL/HDP/1457	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS 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
1489	NDA/MAL/HDP/1458	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
1490	NDA/MAL/HDP/1460	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

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1491	NDA/MAL/HDP/14 63	ARISTO PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	ARISTOZYME LIQUID	DIASTASE+PEPSIN	50MG+10MG	ARISTO PHARMACEUTICALS PVT. LIMITED PLOT 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
1492	NDA/MAL/HDP/14 65	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, 9.0X1.0X 3.0X3.0 SACHET CARTON	01/07/2014
1493	NDA/MAL/HDP/14 68	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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1494	NDA/MAL/HDP/14 69	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/SYRU PS/DROPS	1.0X100.0 ML BOTTLE	01/07/2007
1495	NDA/MAL/HDP/14 74	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS 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
1496	NDA/MAL/HDP/14 76	GITTOES PHARMACEUTICAL S 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

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1497	NDA/MAL/HDP/1478	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	KAMAGRA	SILDENAFIL	50MG	AJANTA PHARMA LIMITED PAITHANMANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2001
1498	NDA/MAL/HDP/1482	SANOFI PASTEUR	LABOREX UGANDA LIMITED	STAMARIL PASTEUR	YELLOW FEVER VIRUS 17D-204 STRAIN(LIVE ATTENUATED)	NLT 1000 I.U	SANOFI PASTEUR1541 AVENUE MARCEL MERIEUX, 69280 MARCY, LETOILE SANOFI 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, 1.0X10.0 X10.0 DOSE VIAL + 1*10*10 DOSE AMPOULE OF NS	01/07/1997
1499	NDA/MAL/HDP/1485	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DICLOFEN 25	DICLOFENAC	25MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD P.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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1500	NDA/MAL/HDP/14 86	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
1501	NDA/MAL/HDP/14 88	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
1502	NDA/MAL/HDP/14 92	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DICLO-DENK 75 INJECTION	DICLOFENAC SODIUM	25MG/ML	HAUPT PHARMA WULFING GMBH;- BETHELNER LANDSTR. 18, 31028 GRONAU,LEIRE, GERMANY.	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X10.0X3.0 ML AMPOULE	01/07/1998

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1503	NDA/MAL/HDP/14 93	AUROBINDO PHARMA LTD UNIT VII	GITTOES PHARMACEUTICALS LIMITED	KOACT 1000	AMOXICILLIN/CLA VULANATE POTASSIUM	875MG/125MG	AUROBINDO PHARMA LIMITED, UNIT IISURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELENGANA (STATE)	INDIA	ORAL SOLID RETARD TABLETS	1X4 TABLET BLISTER	01/07/2007
1504	NDA/MAL/HDP/14 94	FERRER INTERNACIONAL S.A	PHILLIPS PHARMACEUTICALS (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
1505	NDA/MAL/HDP/14 97	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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1506	NDA/MAL/HDP/1499	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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
1507	NDA/MAL/HDP/1500	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	ATRIPLA	EFAVIRENZ+EMTRICITABINE + TENOFOVIR	600MG +200MG+300MG	PATHEON INCMISSISSAUGA, ON L5N 7K9 CANADA	CANADA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2008
1508	NDA/MAL/HDP/1503	MEDICAL UNION PHARMACUITICALS	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

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1509	NDA/MAL/HDP/1505	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	SERETIDE EVOHALER	SALMETEROL/ FLUTICASON E 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
1510	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
1511	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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1512	NDA/MAL/HDP/1516	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	URGENDOL P	TRAMADOL/ PARACETAMOL	37.5MG/ 325MG	WIN MEDICARE PVT LIMITED MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2011
1513	NDA/MAL/HDP/1523	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMPIREN	AMPICILLIN	125MG/5ML	RENE INDUSTRIES LIMITED PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2007
1514	NDA/MAL/HDP/1524	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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2008

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1515	NDA/MAL/HDP/15 26	FERRER INTERNACIONAL S.A	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	GAMALATE B6	MAGNESIUM GLUTAMATE HYDROBROMIDE + AMINO BUTYRIC 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
1516	NDA/MAL/HDP/15 27	MICRO LABS LTD	LABOREX UGANDA LIMITED	BACTOCLAV	AMOXYCILLIN + CLAVULANATE POTASSIUM	200MG + 28.5MG/ 5ML	MICRO LABS LIMITED.PLOT 16, VEERASANDRA IND. AREA,ANEKAL TALUK, BANGALORE INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRU PS/DROPS	1.0X1.0X100.0 ML BOTTLE	01/07/2012
1517	NDA/MAL/HDP/15 28	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,1.0X2.0X 10.0 TABLET BLISTER	01/07/2007

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1518	NDA/MAL/HDP/1529	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	PROVIRON	MESTEROLONE	25MG	BAYER WEIMAR GMBH & CO. KGDOBEREINERSTRASSE 20 D-99427 WEIMAR, GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/1997
1519	NDA/MAL/HDP/1532	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
1520	NDA/MAL/HDP/1533	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	5D	GLUCOSE	50G/L	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE, 1.0X250.0 ML BOTTLE	01/07/2007

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1521	NDA/MAL/HDP/1535	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 LTDPLOT 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
1522	NDA/MAL/HDP/1537	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
1523	NDA/MAL/HDP/1538	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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1524	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
1525	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
1526	NDA/MAL/HDP/1551	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	CALOSHELL-500	CALCIUM CARBONATE + VITAMIN D3	1250MG + 250IU	EMCURE PHARMACEUTICALS LTD LANE 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

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1527	NDA/MAL/HDP/1553	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	VIFEX	SALBUTAMOL + BROMHEXINE + GUAIFENESIN	1MG/5ML+2MG/5ML+50MG/5ML	EMCURE PHARMACEUTICALS LTD LANE 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
1528	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
1529	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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1530	NDA/MAL/HDP/1557	GLAXOSMITHKLINE	UNITED HEALTHCARE DISTRIBUTORS LTD	SYNFLORIX VACCINE	PNEUMOCOCCAL POLYSACCHARIDE SEROTYPES (1,5,6B,7F,9V,14,23F) + (4,18C,19F) + PROTEIN D+TETANUS TOXOID+DIPHTHERIA TOXOID CARRIER PROTEINS AND ALUMINIUM PHOSPHATE	1MCG+3MCG+13MCG+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
1531	NDA/MAL/HDP/1563	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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997
1532	NDA/MAL/HDP/1566	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THANE INDIA	NULL	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2009

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1533	NDA/MAL/HDP/1569	ABBVIE (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	KALETRA	LOPINAVIR+RITONAVIR	80MG + 20MG	AESICA PHARMACEUTICALS SRLQUEENBOROUGH KENT ME 11 5EL, UNITED KINGDOM	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X5.0X1.0X60.0 ML BOTTLE	01/07/2007
1534	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
1535	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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1536	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
1537	NDA/MAL/HDP/1579	PT SANBE FARMA	MEDVIN PHARMA LIMITED	PLASMINEX	TRANEXAMIC ACID	100MG/ML	PT SANBE FARMA JI INDUSTRI NO.8 KOMPLEKS INDUSTRI CIMAREME PADALARANG BANDUNG	INDONESIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X5.0 ML AMPOULE	01/07/2011
1538	NDA/MAL/HDP/1581	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

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1539	NDA/MAL/HDP/1582	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
1540	NDA/MAL/HDP/1584	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
1541	NDA/MAL/HDP/1585	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	UDIHEP FORTE	URSODEOXYCHOLIC ACID	300MG	WIN-MEDICARE PRIVATE LIMITED MEERUT- MUZAFFARNAGAR ROAD, MODIPURAM - 250110 UTTAR PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2010

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1542	NDA/MAL/HDP/1588	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	TOZAAR-H	LOSARTAN POTASSIUM + HYDROCHLOROTHIAZIDE	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
1543	NDA/MAL/HDP/1589	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	CENTACID SUSPENSION	MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE+SIME THICONE	40MG+200MG+250MG/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
1544	NDA/MAL/HDP/1591	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS 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

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1545	NDA/MAL/HDP/1598	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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
1546	NDA/MAL/HDP/1605	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
1547	NDA/MAL/HDP/1615	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	APCALIS SX	TADALAFIL	20MG	AJANTA PHARMA LIMITED PAITHAN MANUFACTURING 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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1548	NDA/MAL/HDP/1616	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE, 1.0X30.0 ML BOTTLE, 1.0X60.0 ML BOTTLE	01/07/2011
1549	NDA/MAL/HDP/1627	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS 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
1550	NDA/MAL/HDP/1629	INTAS PHARMACEUTICALS 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

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1551	NDA/MAL/HDP/1631	AUROBINDOM PHARMA LIMITED	GITTOES PHARMACEUTICALS 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
1552	NDA/MAL/HDP/1632	ALKEM LABORATORIES LIMITEDv	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM 1.2G	AMOXICILLIN SODIUM + CLAVULANATE POTASSIUM	1000MG +200MG	ALKEM LABS LTD.- VILLAGE THANA, BADDI, THE NALAGARH, DIST SOLAN (HP) 173205	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1 AMPOULE OF WFI	01/07/2005
1553	NDA/MAL/HDP/1635	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS 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

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1554	NDA/MAL/HDP/1636	NORVATIS PHARMA AG-SWITZERLAND	LABOREX UGANDA LIMITED	VIGAMOX	MOXIFLOXACIN	5MG/ML	S.A.ALCON COUVREUR N.VRIJKSWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2013
1555	NDA/MAL/HDP/1638	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
1556	NDA/MAL/HDP/1639	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 - MALKHAJIRI DISTRICT - 500043 TELENGANA	IRELAND INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER,1.0X100.0 TABLET CARTON	01/07/2003

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1557	NDA/MAL/HDP/1641	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	UNIENZYM 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
1558	NDA/MAL/HDP/1646	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	BETROZOLE TABLETS	METRONIDAZOLE +DIOXANIDE	200MG+250MG	BETA HEALTHCARE INTERNATIONAL LTD - PLOT NO.209/6554,MOGADISHU 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
1559	NDA/MAL/HDP/1650	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

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1560	NDA/MAL/HDP/1651	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/SYRUPS/DROPS	, 1X60 ML BOTTLE	01/07/1997
1561	NDA/MAL/HDP/1652	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	VALPARIN CHRONO 300	SODIUM VALPROATE	300MG	TORRENT PHARMACEUTICAL LTD AHMEDABAD-MEHSANA HIGHWAY, TALUKA-KADI, DIST. MEHSANA, INDIA - 382721	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2009
1562	NDA/MAL/HDP/1656	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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1563	NDA/MAL/HDP/1660	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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, 1.0X100.0X10.0 TABLET STRIP	01/07/2005
1564	NDA/MAL/HDP/1661	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
1565	NDA/MAL/HDP/1663	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	ALCID-PINK	ALUMINIUM HYDROXIDE/MAGNESIUM TRISILICATE	400MG+400MG/50ML	TORQUE PHARMACEUTICALS PVT LTD DISAAPUR P.O DAPPAR 140056 INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X400.0 ML BOTTLE, 1.0X160.0 ML BOTTLE	01/07/2003

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1566	NDA/MAL/HDP/1665	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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(WORKSHOP 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
1567	NDA/MAL/HDP/1675	MERCK SHARP & DOHME BV	SURGIPHARM (U) LIMITED	GARDASIL	QUADRIVALENT HUMAN PAPILOMAVIRUS RECOMBINANT VACCINE (TYPES 6, 11, 16, 18)	(20MCG+40MCG+40MCG+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
1568	NDA/MAL/HDP/1676	KOPRAN LIMITED	TATA UGANDA LIMITED	CLOXIN-250	CLOXACILLIN	250MG	KOPRAN LTD VILLAGE SAVROLI TAL KHARAPUR DIST RAIGAD 410 202	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CONTAINER,1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER	01/07/1997

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1569	NDA/MAL/HDP/1678	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	HYDROCORTISONE SODIUM SUCCINATE	HYDROCORTISONE 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
1570	NDA/MAL/HDP/1679	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
1571	NDA/MAL/HDP/1680	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	H-CORT	HYDROCORTISONE	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

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1572	NDA/MAL/HDP/1682	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICALS 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, 1.0X10.0 X1.0X10.0 TABLET BLISTER	01/07/2005
1573	NDA/MAL/HDP/1689	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
1574	NDA/MAL/HDP/1690	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	FINALLERG	CETIRIZINE DIHYDROCHLORIDE	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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1575	NDA/MAL/HDP/1692	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/SYRUPS/DROPS	1.0X50.0 ML BOTTLE	01/07/2007
1576	NDA/MAL/HDP/1693	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
1577	NDA/MAL/HDP/1697	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	FINALLERG	CETIRIZINE DIHYDROCHLORIDE	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

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1578	NDA/MAL/HDP/1698	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 CIPLA LTD ;VILLAGE UPPER MALPUR P.O BHUD THE NALAGARH DIST. SOLAN HIMACHAL PRADESH PIN 173205	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X1.0X3.0 TABLET BLISTER	01/07/2009
1579	NDA/MAL/HDP/1701	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
1580	NDA/MAL/HDP/1702	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	DELOR	CLOBETASOL PROPIONATE	0.05%W/W	PHARMA INTERNATIONAL COMPANY MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	TOPICAL EXTERNAL OINTMENTS	1.0X25.0 G TUBE	01/07/2005

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1581	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
1582	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
1583	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

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1584	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
1585	NDA/MAL/HDP/1711	KOPRAN LIMITED	TATA UGANDA LIMITED	AMYN-250	AMOXYCILLIN	250MG	KOPRAN LIMITEDVILLAGE-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
1586	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 IIPLOT 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 1.0X1.0X	01/07/2007

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1587	NDA/MAL/HDP/17 15	SHELYS PHARMACEUTICAL S LTD	BETA HEALTHCARE UGANDA LIMITED	MUCOLYN SYRUP	AMMONIUM CHLORIDE+CHLOR PHENIRAMINE+DE XTROMETHORPHA N+BROMHEXINE	50MG+2MG+5MG +4MG	BETA HEALTHCARE INTERNATIONAL LTD - - PLOT NO.209/6554,MOGADISH U 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
1588	NDA/MAL/HDP/17 23	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
1589	NDA/MAL/HDP/17 24	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	AVAMYS NASAL SPRAY	FLUTICASONE FUROATE	27.5MCG/ACTUA TION	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

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1590	NDA/MAL/HDP/17 25	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
1591	NDA/MAL/HDP/17 28	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, 1.0X10.0X1 4.0 TABLET STRIP	01/07/2007
1592	NDA/MAL/HDP/17 30	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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1593	NDA/MAL/HDP/1731	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,KENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997
1594	NDA/MAL/HDP/1732	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
1595	NDA/MAL/HDP/1734	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,IRUHULAM,P SOT,SATYAVEDU 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

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1596	NDA/MAL/HDP/17 36	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	KLERIMED	CLARITHROMYCIN	500MG	MEDOCHEMIE (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
1597	NDA/MAL/HDP/17 39	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MELOX	MELOXICAM	15MG	MEDOCHEMIE 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
1598	NDA/MAL/HDP/17 41	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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1599	NDA/MAL/HDP/17 43	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	DAPRIL	LISINAPRIL 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
1600	NDA/MAL/HDP/17 45	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
1601	NDA/MAL/HDP/17 47	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	PRESARTAN H 50	LOSARTAN POTASSIUM + HYDROCHLOROTH IAZIDE	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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2008

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1602	NDA/MAL/HDP/1748	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0 CAPSULE BLISTER	01/07/2011
1603	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
1604	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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1605	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
1606	NDA/MAL/HDP/1756	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APICROM 2%	SODIUM CROMOGLYCAT	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
1607	NDA/MAL/HDP/1758	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

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1608	NDA/MAL/HDP/1760	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEODEX	NEOMYCIN +DEXAMETHASONE	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
1609	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
1610	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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1611	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
1612	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
1613	NDA/MAL/HDP/1766	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	COLDEASE CAPSULES	PARACETAMOL+CITRATE+CHLORPHENIRAMINE MALEATE+PSEUDOEPHEDRINE HYDROCHLORIDE	400MG+30MG+4MG+30MG	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2005

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1614	NDA/MAL/HDP/17 69	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
1615	NDA/MAL/HDP/17 72	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
1616	NDA/MAL/HDP/17 73	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,1.0X1.0X 10.0 TABLET BLISTER	01/07/2005

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1617	NDA/MAL/HDP/1777	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
1618	NDA/MAL/HDP/1779	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
1619	NDA/MAL/HDP/1780	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENETRIM SUSPENSION	CO-TRIMOXAZOLE	240MG/5ML	RENE INDUSTRIES LIMITED PLOT 680 KAMULI KIREKA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE	01/07/2000

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1620	NDA/MAL/HDP/1781	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
1621	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. THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE, 1.0X30.0 ML BOTTLE	01/07/2010
1622	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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1623	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
1624	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,MOGADISHU 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,1.0X10.0 TABLET STRIP,1.0X12.0 TABLET BLISTER	01/07/1997
1625	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

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1626	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,1.0X1000.0 TABLET CONTAINER	01/07/1997
1627	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
1628	NDA/MAL/HDP/1795	KOPRAN LIMITED	TATA UGANDA LIMITED	AMPIK-250	AMPICILLIN	250MG	KOPRAN LIMITEDVILLAGE-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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1629	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 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER, 1.0X10.0X1.0X6.0 TABLET BLISTER	01/07/2006
1630	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
1631	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

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1632	NDA/MAL/HDP/1800	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AMLONG-10	AMLODIPINE	10MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2009
1633	NDA/MAL/HDP/1801	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
1634	NDA/MAL/HDP/1803	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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1635	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
1636	NDA/MAL/HDP/1809	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOVIT-6	PYRIDOXINE	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
1637	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

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1638	NDA/MAL/HDP/18 11	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
1639	NDA/MAL/HDP/18 12	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,1.0X1 0.0X10.0 TABLET BLISTER	01/07/2001
1640	NDA/MAL/HDP/18 13	DAWA LIMITED	SUPER MEDIC LTD	MOXAFORTE	AMOXICILLIN + FLUCLOXACILLIN	125 MG + 125MG	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRU PS/DROPS	1.0X100.0 ML BOTTLE	01/07/2014

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1641	NDA/MAL/HDP/18 15	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS 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
1642	NDA/MAL/HDP/18 16	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
1643	NDA/MAL/HDP/18 20	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	AZICIN-250	AZITHROMYCIN	250MG	EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	01/07/2009

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1644	NDA/MAL/HDP/18 21	BLUE CROSS LABORATORIES LTD	STAR PHARMACEUTICALS 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
1645	NDA/MAL/HDP/18 22	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
1646	NDA/MAL/HDP/18 25	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	COLDEASE SYRUP	PARACETAMOL+C HLORPHENIRAMI NE MALEATE+PSEUD OEPHEDRINE HYDROCHLORIDE	120MG+2MG+15 MG	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2005

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1647	NDA/MAL/HDP/18 27	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	ALBASOL SUSPENSION	ALBENDAZOLE	200MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	01/07/2006
1648	NDA/MAL/HDP/18 40	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
1649	NDA/MAL/HDP/18 41	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

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1650	NDA/MAL/HDP/1842	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	SUGAQUIN TABLETS	CHLOROQUINE PHOSPHATE	250MG	KAMPALA PHARMACEUTICALS INDUSTRIES PLOT 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
1651	NDA/MAL/HDP/1843	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
1652	NDA/MAL/HDP/1844	GUILIN PHARMACEUTICALS CO.LTD	TRIDEM PHARMA UGANDA LIMITED	SULFAMETH OXAZOLE / TRIMETHOPRIM	SULFAMETHOXAZOLE / 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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1653	NDA/MAL/HDP/1846	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
1654	NDA/MAL/HDP/1848	LABORATORY&ALLIED 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,1.0X10.0 X10.0 TABLET BLISTER	01/07/1997
1655	NDA/MAL/HDP/1849	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

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1656	NDA/MAL/HDP/1850	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, 1.0X1000.0 TABLET CONTAINER	01/07/2010
1657	NDA/MAL/HDP/1851	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICALS (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
1658	NDA/MAL/HDP/1852	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICALS 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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

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1659	NDA/MAL/HDP/1854	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	FUROSEMIDE INJECTION	FUROSEMIDE	10MG/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, 1.0X10.0X2.0 ML AMPOULE	01/07/2004
1660	NDA/MAL/HDP/1856	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
1661	NDA/MAL/HDP/1861	GUILIN PHARMACEUTICALS CO LTD	TRIDEM PHARMA UGANDA LIMITED	SULFAMETHOXAZOLE / TRIMETHOPRIM	SULFAMETHOXAZOLE / 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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1662	NDA/MAL/HDP/1863	AMOUN PHARMACEUTICALS 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
1663	NDA/MAL/HDP/1864	NORVATIS PHARMA AG-SWITZERLAND	LABOREX UGANDA LIMITED	PATANOL	OLOPATADINE HYDROCHLORIDE	0.1%W/V	ALCON COUVREUR NVRIKSWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML VIAL	01/07/2009
1664	NDA/MAL/HDP/1877	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, 1.0X1000.0 TABLET CONTAINER	01/07/2007

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1665	NDA/MAL/HDP/1879	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
1666	NDA/MAL/HDP/1880	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,1.0X100.0X10.0 CAPSULE BLISTER	01/07/2004
1667	NDA/MAL/HDP/1881	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, LAKHABAVA D, JAMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0X10.0 CAPSULE BLISTER,1.0X1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER	01/07/2004

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1668	NDA/MAL/HDP/1882	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
1669	NDA/MAL/HDP/1887	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,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER	01/07/1997
1670	NDA/MAL/HDP/1889	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,1.0X500.0 TABLET CONTAINER,1.0X250.0 TABLET CONTAINER,1.0X1000.0 TABLET CARTON,1.0X10.0 TABLET CARTON	01/07/1997

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1671	NDA/MAL/HDP/1891	MACLEODS PHARMACEUTICALS 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
1672	NDA/MAL/HDP/1892	MACLEODS PHARMACEUTICALS 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
1673	NDA/MAL/HDP/1894	KOPRAN LIMITED	TATA UGANDA LIMITED	TRIM-480	CO-TRIMOXAZOLE	480MG	KOPRAN LIMITED VILLAGE-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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1674	NDA/MAL/HDP/1895	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X1000.0 TABLET CONTAINER, 1.0X100.0X10.0 TABLET BLISTER	01/07/2007
1675	NDA/MAL/HDP/1898	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
1676	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. THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER, 1.0X10.0X10.0 CAPSULE STRIP	01/07/2007

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1677	NDA/MAL/HDP/1901	AJANTA PHARMA LTD 31-0	ABACUS PHARMA (AFRICA) LIMITED	IBUMOL	IBUPROFEN + PARACETAMOL	100MG + 162.5 MG /5ML	AJANTA PHARMA LIMITED31-0 MIDC INDUSTRIAL AREA CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA STATE	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2013
1678	NDA/MAL/HDP/1902	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
1679	NDA/MAL/HDP/1911	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,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER	01/07/1998

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1680	NDA/MAL/HDP/19 12	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
1681	NDA/MAL/HDP/19 14	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	CHLORPHENI RAMINE	CHLORPHENIRAMI NE	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
1682	NDA/MAL/HDP/19 19	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS 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

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1683	NDA/MAL/HDP/1922	IPCA LABORATORIES	MEDVIN PHARMA LIMITED	AZIFAST-500	AZITHROMYCIN	500MG	IPCA LABORATORIES LTD,PLOT NO. T-139 SEJAVTA, RATLAM-457002 (M.P.) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X3.0 TABLET BLISTER	01/07/2007
1684	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(WORKSHOP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X500.0 MG VIAL	01/07/2013
1685	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,KENYA	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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1686	NDA/MAL/HDP/1928	STEDMAN PHARMACEUTICALS 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
1687	NDA/MAL/HDP/1931	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
1688	NDA/MAL/HDP/1932	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

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1689	NDA/MAL/HDP/19 34	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENECHLOR SUSPENSION	CHLORAMPHENIC OL	125MG/5ML	RENE INDUSTRIES LIMITED PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2001
1690	NDA/MAL/HDP/19 37	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
1691	NDA/MAL/HDP/19 38	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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1692	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
1693	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
1694	NDA/MAL/HDP/1943	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

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1695	NDA/MAL/HDP/1946	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	SOLUDOL TABLETS	DICLOFENAC SODIUM	50MG	WIN MEDICARE PVT LIMITED MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	10.0X10.0 TABLET STRIP	01/07/1998
1696	NDA/MAL/HDP/1948	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
1697	NDA/MAL/HDP/1949	MACLEODS PHARMACEUTICALS 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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1698	NDA/MAL/HDP/1951	MACLEODS PHARMACEUTICALS 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
1699	NDA/MAL/HDP/1954	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	RAPEED-20	RABEPRAZOLE	20MG	ALKEM LABORATORIES LTD .VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP,1.0X1.0X10.0 TABLET STRIP	01/07/2011
1700	NDA/MAL/HDP/1956	MILAN LABORATORIES LTD	GITTOES PHARMACEUTICALS 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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1701	NDA/MAL/HDP/1958	MILAN LABORATORIES LTD	GITTOES PHARMACEUTICALS 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
1702	NDA/MAL/HDP/1959	MILAN LABORATORIES PVT LTD	GITTOES PHARMACEUTICALS 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
1703	NDA/MAL/HDP/1960	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

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1704	NDA/MAL/HDP/1966	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	PARACIN	PARACETAMOL	500MG	TORQUE PHARMACEUTICALS LTD DISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER	01/07/2005
1705	NDA/MAL/HDP/1969	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
1706	NDA/MAL/HDP/1970	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	CETRAMAC	CETIRIZINE	10MG	TORQUE PHARMACEUTICALS LTD DISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

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1707	NDA/MAL/HDP/1971	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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, MAHARASTRA-410209, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1998
1708	NDA/MAL/HDP/1974	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
1709	NDA/MAL/HDP/1975	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	BET-CODERMIN	BETAMETHASONE + NEOMYCIN	0.1 W/W + 0.5 W/W	LINCOLN PHARMACEUTICALS LTD 10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI , KHATRAJ-382721, GHANDINAGAR GUJARAT , INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2007

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1710	NDA/MAL/HDP/1977	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	LOSAR-H	LOSARTAN + HYDROCHLOROTHIAZIDE	50MG + 12.5MG	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 TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
1711	NDA/MAL/HDP/1984	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
1712	NDA/MAL/HDP/1987	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	FOMYCETIN	CHLORAMPHENIC OL	250MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDALUR ROAD,KELAMBAKKAM-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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1713	NDA/MAL/HDP/1989	FERRER INTERNACIONAL S.A	PHILLIPS PHARMACEUTICALS (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
1714	NDA/MAL/HDP/1990	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TAGERA FORTE	SECNIDAZOLE	1G	UNICHEM LABORATORIES LTD UNIT 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
1715	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. THANE 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

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1716	NDA/MAL/HDP/1999	TORRENT PHARAMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	CARBATOL 200	CARBAMAZEPINE	200MG	TORRENT PHARMACEUTICALS LTDINDRAD-382721, TAL KADI, AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,2.0X5.0X10.0 TABLET BLISTER	01/07/2000
1717	NDA/MAL/HDP/2000	TORRENT PHARAMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	CALCIGARD RETARD	NIFEDIPINE(SR)	20MG	TORRENT PHARMACEUTICALS LTDINDRAD-382721, TAL KADI, AHMEDABAD, INDIA	INDIA	ORAL SOLID RETARD TABLETS	1.0X2.0X5.0X10.0 TABLET BLISTER	01/07/2000
1718	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 LTDPLOT 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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1719	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 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2005
1720	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
1721	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

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1722	NDA/MAL/HDP/2012	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS LTD	CANDID -B-LOTION	CLOTRIMAZOLE + BECLOMETHASON E 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
1723	NDA/MAL/HDP/2014	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
1724	NDA/MAL/HDP/2016	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS 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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1725	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
1726	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
1727	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

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1728	NDA/MAL/HDP/2022	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	TORACTIN	CYPROHEPTADINE	2MG/5ML	TORQUE PHARMACEUTICALS LTD DISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE, 1.0X60.0 ML BOTTLE	01/07/1997
1729	NDA/MAL/HDP/2024	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	NEXPRO - 40	ESOMEPRAZOLE MAGNESIUM TABLET	40MG	TORRENT PHARMACEUTICALS LTD INDRAD-382 721, DIST.MEHSANA,INDIA.AT: VILL.MANAKPUR,TEH.NAL AGARH,DIST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2004
1730	NDA/MAL/HDP/2025	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	FERRO-B COMPLEX SYRUP	MULTI-INGREDIENT	MULTI-INGREDIENT	REGAL PHARMACEUTICALS LTD BABA 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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1731	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, 1.0X10.0 X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	01/07/2009
1732	NDA/MAL/HDP/2027	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CO-ANGINET 160/12.5MG	VALSARTAN + HYDROCHLOROTHIAZIDE	160MG + 12.5MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD P.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
1733	NDA/MAL/HDP/2029	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	CHLORAMPHENICOL PALMITATE	CHLORAMPHENICOL PALMITATE	125MG/5ML	MEDICAMEN BIOTECH LTD SP-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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1734	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
1735	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
1736	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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1737	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, 1.0X30.0X6.0 TABLET BLISTER, 1.0X1.0X6.0 TABLET BLISTER 1.0X1.0X	01/07/2006
1738	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
1739	NDA/MAL/HDP/2046	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, 1.0X10.0X10.0 TABLET BLISTER	01/07/2005

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1740	NDA/MAL/HDP/2047	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
1741	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 181133, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2005
1742	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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1743	NDA/MAL/HDP/2056	WOCKHARDT LTD	STAR PHARMACEUTICALS 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
1744	NDA/MAL/HDP/2058	MACLEODS PHARMACEUTICALS 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
1745	NDA/MAL/HDP/2061	RENE PHARMACY(R) LTD..	RENE PHARMACY LTD	ADSOARB 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

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1746	NDA/MAL/HDP/2062	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	MUCOLYN PAEDIATRIC SYRUP	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
1747	NDA/MAL/HDP/2063	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	MICROGYNO N FE	LEVONORGESTREL / ETHINYLESTRADIOL.	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
1748	NDA/MAL/HDP/2066	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	METHOTREXATE	METHOTREXATE	2.5MG	REMEDICA LIMITED LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

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1749	NDA/MAL/HDP/2067	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	ZYNCET	CETIRIZINE DIHYDROCHLORIDE	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
1750	NDA/MAL/HDP/2068	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
1751	NDA/MAL/HDP/2069	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	SK DERM	BETAMETHASONE + CLOTRIMOXAZOLE + 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

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1752	NDA/MAL/HDP/2070	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	MIRENA	LEVONORGESTREL	52MG	BAYER OYPANSIONATE 47 20210 TURKU FINLAND	FINLAND	PARENTERAL RETARD IMPLANTS	1.0X1.0 IMPLANT CARTON	01/07/2009
1753	NDA/MAL/HDP/2071	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	CEFAMOR DRY SYRUP	CEFALEXIN	125MG/5ML	CADILA PHARMACEUTICALS LIMITED1389, 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
1754	NDA/MAL/HDP/2073	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	SII MEASLES VACCINE LIVE ATTENUATED (FREEZE- DRIED)	MEASLES VIRUS	NOT LESS THAN 1000CCID50/ DOSE	SERUM INSTITUTE OF INDIA LTD212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 DOSE VIAL + 0.5ML AMPOULE OF STERILE WATER FOR INJECTION,1.0X10 .0 DOSE VIAL + 5ML AMPOULE OF STERILE WATER FOR INJECTION	01/07/1997

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1755	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
1756	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
1757	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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1758	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
1759	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 KOLTHER (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
1760	NDA/MAL/HDP/2087	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

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1761	NDA/MAL/HDP/2089	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
1762	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
1763	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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1764	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
1765	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
1766	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.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2010

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1767	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
1768	NDA/MAL/HDP/2099	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	HYDROCORTISONE 1% CREAM	HYDROCORTISONE	1%W/W	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD 1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1998
1769	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, SARKHEJBAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, AHMEDABAD, GUJARAT, INDIA 382213 MYLAN LABORATORIES LIMITED.-PLOT NO. 1606-1609, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM TAL-	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X28.0 TABLET BLISTER	01/07/2007

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1770	NDA/MAL/HDP/2101	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CARDISPRIN	ACETYL SALICYLIC ACID	75MG	COSMOS LIMITEDRANGWE ROAD, OFF LUNGA ROAD - INDUSTRIAL AREA NAROBI	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2010
1771	NDA/MAL/HDP/2104	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LAMIVUDINE /NEVIRAPINE /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
1772	NDA/MAL/HDP/2108	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

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1773	NDA/MAL/HDP/2111	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
1774	NDA/MAL/HDP/2112	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
1775	NDA/MAL/HDP/2116	MACLEODS PHARMACEUTICALS 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,1.0X10.0 X10.0 TABLET STRIP	01/07/2005

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1776	NDA/MAL/HDP/21 20	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. ALKEM LABORATORIES LTD.VILLAGE THANA, BADDI, DISTT. SOLAN,HIMACHAL PRADESH 173205 INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL	01/07/2011
1777	NDA/MAL/HDP/21 24	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/SYRU PS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997
1778	NDA/MAL/HDP/21 25	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

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1779	NDA/MAL/HDP/21 28	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
1780	NDA/MAL/HDP/21 29	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (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
1781	NDA/MAL/HDP/21 32	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	LOPINAVIR/ RITONAVIR	LOPINAVIR/ RITONAVIR	200MG/ 50MG	AUROBINDO PHARMA LTD UNIT III-SURVEY NO.313,BACHUPALLY VILLAGE,QUTHUBULLAPU R MANDAL R.R DISTRICT(A.P),INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET CONTAINER	01/07/2010

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1782	NDA/MAL/HDP/21 33	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
1783	NDA/MAL/HDP/21 36	MEDICAL UNION PHARMACEUTICAL S	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
1784	NDA/MAL/HDP/21 40	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS 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

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1785	NDA/MAL/HDP/2141	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	INFLAZONE	MULTIINGREDIENT	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
1786	NDA/MAL/HDP/2143	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
1787	NDA/MAL/HDP/2144	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPICOTIL	TENOXCAM	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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1788	NDA/MAL/HDP/21 45	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
1789	NDA/MAL/HDP/21 47	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
1790	NDA/MAL/HDP/21 49	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

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1791	NDA/MAL/HDP/2150	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,INDIANA 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
1792	NDA/MAL/HDP/2155	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	DOXEFIL	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
1793	NDA/MAL/HDP/2160	EMCURE PHARMACEUTICALS 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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1794	NDA/MAL/HDP/2161	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CYCLOVAX CREAM	ACICLOVIR	5%W/W	REMEDICA LIMITED LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE	01/07/1997
1795	NDA/MAL/HDP/2170	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ALSARTAN-AM	LOSARTAN + AMLODIPINE	50MG + 5MG	ARISTO PHARMACEUTICALS PVT. LIMITED PLOT 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
1796	NDA/MAL/HDP/2173	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS 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

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1797	NDA/MAL/HDP/2176	INTAS PHARMACUTICALS LTD	NORVIK ENTERPRISES LIMITED	RISPITAS-2	RISPERIDONE	2MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2011
1798	NDA/MAL/HDP/2178	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
1799	NDA/MAL/HDP/2181	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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1800	NDA/MAL/HDP/21 85	GLAXOSMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ROTARIX	LIVE ATTENUATED RIX4414 STRAIN OF HUMAN ROTAVIRUS OF THE G1P[8] TYPE	NOT LESS THAN 10 ⁶ CCID ₅₀ 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
1801	NDA/MAL/HDP/21 86	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL DIPHENHYDR AMINE 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
1802	NDA/MAL/HDP/21 91	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,1.0X1 0.0X10.0 CAPSULE BLISTER	01/07/1997

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1803	NDA/MAL/HDP/2195	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
1804	NDA/MAL/HDP/2197	LABORATORY&ALLIED 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
1805	NDA/MAL/HDP/2199	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

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1806	NDA/MAL/HDP/2201	SHAIGAN PHARMACEUTICALS 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
1807	NDA/MAL/HDP/2208	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
1808	NDA/MAL/HDP/2211	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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1809	NDA/MAL/HDP/2212	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
1810	NDA/MAL/HDP/2214	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
1811	NDA/MAL/HDP/2216	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	METOCLOPRAMIDE	METOCLOPRAMIDE	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

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1812	NDA/MAL/HDP/22 19	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	PRIMOLUT N	NORETHISTERONE	5MG	BAYER WEIMAR GMBH & CO. KGDOBEREINERSTRASSE 20 D-99427 WEIMAR, GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X30.0 TABLET CONTAINER,1.0X2 .0X15.0 TABLET BLISTER	01/07/1997
1813	NDA/MAL/HDP/22 23	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(WORKSHOP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1X2.4 MU VIAL	01/07/2002
1814	NDA/MAL/HDP/22 24	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,1.0X10.0 X10.0 CAPSULE BLISTER	01/07/2013

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1815	NDA/MAL/HDP/22 26	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	HEPA-MERZ GRANULES	L-ORNITHINE-L- ASPARTATE	3G/5G	WIN-MEDICARE PRIVATE LIMITED MEERUT- MUZAFFARNAGAR ROAD, MODIPURAM - 250110 UTTAR PRADESH	INDIA	ORAL LIQUID ORDINARY OTHER POWDERS/GRANUL ES	1.0X10.0X5.0 G SACHET	01/07/2004
1816	NDA/MAL/HDP/22 31	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,UGANDA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997
1817	NDA/MAL/HDP/22 32	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNICAST	MONTELUKAST	10MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD P.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

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1818	NDA/MAL/HDP/22 33	ASTRAZENECA	MACNAUGHTON LIMITED	PULMICORT NEBULISER	BUDESONIDE	0.25MG/ML	ASTRA ZENECA SWEDEN OPERATIONS LIQUID PRODUCTION KVARNBERGAGATANLZ SE 151-85,SWEDEN	SWEDEN	LUNG ADMINISTRATION LIQUID FOR INHALATION	1.0X4.0X5.0X2.0 ML VIAL	01/07/2011
1819	NDA/MAL/HDP/22 35	WOCKHARDT LTD	ABACUS PHARMA (AFRICA) LIMITED	WOSULIN-N	INSULIN HUMAN(RECOMBI NANT DNA ORIGIN)	100IU/ML	WOCKHARDTWOCKHARD T 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
1820	NDA/MAL/HDP/22 36	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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1821	NDA/MAL/HDP/22 37	WOCKHARDT LTD	ABACUS PHARMA (AFRICA) LIMITED	WOSULIN- 30/70	INSULIN HUMAN(RECOMBI NANT 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
1822	NDA/MAL/HDP/22 39	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
1823	NDA/MAL/HDP/22 42	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

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1824	NDA/MAL/HDP/22 43	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED	AFRICURE PHARMACEUTICALS 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
1825	NDA/MAL/HDP/22 45	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
1826	NDA/MAL/HDP/22 48	GALENTIC PHARMA (PVT)LTD	VITACARE LIMITED	TETRACYCLIN E 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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1827	NDA/MAL/HDP/22 49	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
1828	NDA/MAL/HDP/22 52	JOHNSON&JOHNSO N PTY LTD	PHILLIPS PHARMACEUTICALS (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
1829	NDA/MAL/HDP/22 54	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

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1830	NDA/MAL/HDP/22 56	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/SYRU PS/DROPS	1.0X1.0X70.0 ML BOTTLE	01/07/2010
1831	NDA/MAL/HDP/22 58	MYLAN LABORATORIES LIMITED (OTL)	KIMSY MEDS LTD	TENOFOVIR DISOPROXIL + LAMIVUDINE + EFAVIRENZ	TENOFOVIR DISOPROXIL + LAMIVUDINE + EFAVIRENZ	300MG/300MG/6 00MG	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- 13 MIDCWALUI	INDIA KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET BOTTLE,1.0X1.0X3 0.0 TABLET BOTTLE	01/07/2009
1832	NDA/MAL/HDP/22 63	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 LTDVILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X500.0 ML BOTTLE	01/07/2001

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1833	NDA/MAL/HDP/22 65	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.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2010
1834	NDA/MAL/HDP/22 67	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- 13 MIDCWALUI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2007
1835	NDA/MAL/HDP/22 69	DAWA LIMITED	SUPER MEDIC LTD	DAWAMOX	AMOXYCILLIN TRIHYDRATE	125MG/5ML	DAWA PHARMACEUTICALS LIMITEDPLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRU PS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

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1836	NDA/MAL/HDP/22 71	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	ARTEMETHER 20MG/LUME FANTRINE 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,1.0X30.0 X18.0 TABLET BLISTER,1.0X30.0 X24.0 TABLET BLISTER,1.0X10.0 X1.0X6.0 TABLET BLISTER,1.0X10.0 X2.0X6.0 TABLET BLISTER,1.0X30.0 X12.0 TABLET BLISTER 1.0X30.0	01/07/2010
1837	NDA/MAL/HDP/22 72	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	CLARANTA - 500	CLARITHROMYCIN	500MG	AJANTA PHARMA LTD .B- 4//5/6, MIDC INDUSTRIAL AREA, PAITHAN-431 128, AURANGBAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X2.0X10. 0 TABLET BLISTER	01/07/2005
1838	NDA/MAL/HDP/22 80	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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1839	NDA/MAL/HDP/2281	PHARMACTIV FZCO	JEET PHARMACEUTICALS 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
1840	NDA/MAL/HDP/2282	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	PROPAN	PROPRANOLOL	40MG	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	01/07/2011
1841	NDA/MAL/HDP/2283	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	SII DIPHThERIA TETANUS PERTUSIS	DIPThERIA TOXOID+TETANUS TOXOID+B.PERTUSIS ADSORBED ON ALUMINIUM PHOSPHATE	>25LF(>30IU)+>5LF(>40IU)+<16OU(>4PU) ADSORBED ON ≥1.5MG	SERUM INSTITUTE OF INDIA LTD 212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL (20 DOSES), 1.0X5.0 ML VIAL (10 DOSES), 1.0X0.5 ML AMPOULE (1 DOSE)	01/07/1997

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1842	NDA/MAL/HDP/22 87	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
1843	NDA/MAL/HDP/22 90	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,AURANGABAD- 431136 MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2008
1844	NDA/MAL/HDP/22 95	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	ROZITTA 10	ROSUVASTATIN CALCIUM	10MG	DAR AI DAWANA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013

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1845	NDA/MAL/HDP/22 97	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
1846	NDA/MAL/HDP/22 98	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS 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, 1.0X1.0X 10.0 TABLET BLISTER	01/07/2013
1847	NDA/MAL/HDP/22 99	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	ROZITTA 20	ROSUVASTATIN CALCIUM	20MG	DAR AI DAWANA UR PLANT, AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013

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1848	NDA/MAL/HDP/23 03	MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZIAK 5/6.25	BISOPROLOL + HYDROCHLOROTH IAZIDE	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
1849	NDA/MAL/HDP/23 04	MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZIAK 10/6.25	BISOPROLOL + HYDROCHLOROTH IAZIDE	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
1850	NDA/MAL/HDP/23 05	MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZIAK 2.5/6.25	BISOPROLOL + HYDROCHLOROTH IAZIDE	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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1851	NDA/MAL/HDP/23 06	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	MICROLUT	LEVONORGESTREL	0.03MG	BAYER PHARMA A.GMULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X35.0 TABLET BLISTER	01/07/2010
1852	NDA/MAL/HDP/23 12	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
1853	NDA/MAL/HDP/23 13	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

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1854	NDA/MAL/HDP/23 14	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
1855	NDA/MAL/HDP/23 15	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/SYRU PS/DROPS	1.0X30.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2006
1856	NDA/MAL/HDP/23 18	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (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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1857	NDA/MAL/HDP/23 19	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
1858	NDA/MAL/HDP/23 20	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS 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/SYRU PS/DROPS	1.0X100.0 ML BOTTLE	01/07/2006
1859	NDA/MAL/HDP/23 22	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

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1860	NDA/MAL/HDP/23 24	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS 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
1861	NDA/MAL/HDP/23 30	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	COARTEM	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	NOVARTIS PHARMA AG- SCHAFFHAUSERSTRASSE 4332 STEIN SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X24.0 TABLET BLISTER,1.0X30.0 X24.0 TABLET BLISTER,1.0X30.0 X6.0 TABLET BLISTER,1.0X36.0 X6.0 TABLET BLISTER,1.0X3.0X 8.0 TABLET BLISTER,1.0X30.0 X12.0 TABLET BLISTER,1.0X30.0 X18.0 TABLET	01/07/2005
1862	NDA/MAL/HDP/23 33	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	SII DIPHThERIA & TETANUS VACCINE ADSORBED(P EDIATRIC)	DIPHThERIA TOXOID+TETANUS TOXOID ADSORBED ON ALUMINIUM PHOSPHATE	>25LF(>30IU)+>5L F(>40IU) ADSORBED ON ≥1.5MG	SERUM INSTITUTE OF INDIA LTD212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0 ML VIAL (20 DOSES),1.0X5.0 ML VIAL (10 DOSES),1.0X0.5 ML AMPOULE (1 DOSE)	01/07/1997

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1863	NDA/MAL/HDP/2334	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	SII MEASLES MUMPS & RUBELLA	MEASLES VIRUS+MUMPS VIRUS+RUBELLA VIRUS	NLT 1000 CCID50+NLT 5000 CCID50 +NLT1000 CCID50	SERUM INSTITUTE OF INDIA LTD212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 DOSE VIAL + 0.5ML OF THE DILUENT	01/07/1997
1864	NDA/MAL/HDP/2335	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THANE INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	10.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER,1.0X250.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER	01/07/2001
1865	NDA/MAL/HDP/2338	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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE,1.0X70.0 ML BOTTLE	01/07/2003

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1866	NDA/MAL/HDP/23 48	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	HEPATITIS B VACCINE(RD NA) ADULT	HEPATITIS B VACCINE(RDNA) ADULT	20MCG/ML	SERUM INSTITUTE OF INDIA LTD212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY I M VIALS	1.0X10.0X10.0 ML VIAL (10 DOSE VIAL),1.0X50.0X1. 0 ML VIAL (1 DOSE VIAL)	01/07/2005
1867	NDA/MAL/HDP/23 50	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
1868	NDA/MAL/HDP/23 52	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	COLD CAP DAY TIME	PARACETAMOL/P SEUDOEPHEDRINE HCL/CAFFEINE	500MG+30MG+3 0MG	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

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1869	NDA/MAL/HDP/23 53	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
1870	NDA/MAL/HDP/23 56	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS 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
1871	NDA/MAL/HDP/23 57	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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1872	NDA/MAL/HDP/23 59	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
1873	NDA/MAL/HDP/23 60	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
1874	NDA/MAL/HDP/23 61	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CLAREM 500	CLARITHROMYCIN	500MG	REMEDICA LTD STREET, LIMASSOL INDUSTRIAL ESTATE, 3056 LIMASSOL	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2007

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1875	NDA/MAL/HDP/23 62	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
1876	NDA/MAL/HDP/23 63	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS 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. 0X10.0X2.0 ML AMPOULE	01/07/2005
1877	NDA/MAL/HDP/23 64	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

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1878	NDA/MAL/HDP/23 66	UNIQUE PHARMACEUTICAL S LTD	PLANET PHARMACEUTICALS 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
1879	NDA/MAL/HDP/23 68	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	DERMIDEX CREAM	MICONAZOLE NITRATE	2%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2007
1880	NDA/MAL/HDP/23 69	ARISTO PHARMACEUTICAL S	NORVIK ENTERPRISES LIMITED	TRANLOK 500MG INJECTION	TRANEXAMIC ACID	500MG/5ML	ARISTO PHARMACEUTICALS PVT. LIMITEDPLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X5.0 ML AMPOULE	01/07/2010

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1881	NDA/MAL/HDP/23 71	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	TOPIZONE CREAM	FUSIDIC ACID + BETAMETHASONE VALERATE	20MG/G+1MG/G	PHARMA INTERNATIONAL COMPANYMAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2007
1882	NDA/MAL/HDP/23 75	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	CLAVULIN 1G	AMOXICILLIN + CLAVULANIC ACID	875 MG + 125 MG	SMITHKLINE BEECHAM PHARMACEUTICALS,CLAR ENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X1.0X7.0 TABLET BLISTER	01/07/2010
1883	NDA/MAL/HDP/23 79	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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1884	NDA/MAL/HDP/23 84	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CLARIX 500	CLARITHROMYCIN	500MG	PHARMA INTERNATIONAL COMPANYMAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2007
1885	NDA/MAL/HDP/23 85	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
1886	NDA/MAL/HDP/23 87	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

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1887	NDA/MAL/HDP/23 88	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/SYRU PS/DROPS	1.0X70.0 ML BOTTLE	01/07/2011
1888	NDA/MAL/HDP/23 89	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
1889	NDA/MAL/HDP/23 90	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	P-ALAXIN	DIHYDROARTEMIS ININ/ 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/SYRU PS/DROPS	1.0X80.0 ML BOTTLE,1.0X120.0 ML BOTTLE	01/07/2008

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1890	NDA/MAL/HDP/23 91	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
1891	NDA/MAL/HDP/23 95	A.MENARINI INDUSTRIE FARMACEUTICHE S.R.I	PHILLIPS PHARMACEUTICALS (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
1892	NDA/MAL/HDP/23 97	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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1893	NDA/MAL/HDP/23 99	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS 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-403404	INDIA	TOPICAL EXTERNAL OTHER GELS/SOLS	1.0X1.0X30.0 G TUBE	01/07/2005
1894	NDA/MAL/HDP/24 01	MEGA LIFESCIENCES (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
1895	NDA/MAL/HDP/24 04	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

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1896	NDA/MAL/HDP/2408	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	RENIRON TONIC	MULTI-INGREDIENT	MULTI-INGREDIENT	RENE INDUSTRIES LIMITED PLOT 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
1897	NDA/MAL/HDP/2410	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	DOXYREN	DOXYCYCLINE	100MG	RENE INDUSTRIES LIMITED PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2007
1898	NDA/MAL/HDP/2411	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	DREZ	POVIDONE IODINE + METRONIDAZOLE	5%W/W + 1%W/W	STEDMAN PHARMACEUTICALS PVT LIMITED NO. 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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1899	NDA/MAL/HDP/24 14	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/SYRU PS/DROPS	1.0X100.0 ML BOTTLE	01/07/1998
1900	NDA/MAL/HDP/24 15	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICALS 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,1.0X1 0.0X10.0 TABLET BLISTER,1.0X100. 0X10.0 TABLET BLISTER	01/07/1997
1901	NDA/MAL/HDP/24 26	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

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1902	NDA/MAL/HDP/24 27	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
1903	NDA/MAL/HDP/24 28	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
1904	NDA/MAL/HDP/24 29	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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1905	NDA/MAL/HDP/24 34	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
1906	NDA/MAL/HDP/24 38	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
1907	NDA/MAL/HDP/24 52	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	DELADED CHEST COUGH SYRUP (NON DROWSY)	GUAIFENESIN + MENTHOL	100MG/5ML + 1.1MG/5ML	REGAL PHARMACEUTICALS PLOT 7879/18 BABA DOGO ROAD NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2007

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1908	NDA/MAL/HDP/2458	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
1909	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, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM TAL-	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X2.0 TABLET BLISTER	01/07/2007
1910	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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1911	NDA/MAL/HDP/24 71	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
1912	NDA/MAL/HDP/24 72	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
1913	NDA/MAL/HDP/24 73	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

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1914	NDA/MAL/HDP/2475	WIN-MEDICURE LTD	SURGIPHARM (U) LIMITED	URGENDOL INJECTION	TRAMADOL HYDROCHLORIDE	50MG/ML	WIN- MEDICARE LTD MODIPURAM -250 110,UTTAR PRAADESH, INDIA.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE,1.0X2.0 ML AMPOULE	01/07/2001
1915	NDA/MAL/HDP/2476	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS 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
1916	NDA/MAL/HDP/2478	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	DICLOMOL PLUS	PARACETAMOL+DICLOFENAC	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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1917	NDA/MAL/HDP/2479	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
1918	NDA/MAL/HDP/2481	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
1919	NDA/MAL/HDP/2492	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

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1920	NDA/MAL/HDP/2502	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
1921	NDA/MAL/HDP/2504	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	RESTOCIN	PARACETAMOL + CHLORPHENIRAMINE 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
1922	NDA/MAL/HDP/2507	CIPLA LTD	ABACUS PHARMA (AFRICA) LIMITED	EXERMET 1000	METFORMIN HCL	1000MG	CIPLA LTD ---D-7 MIDC INDUSTRIAL AREA, KURKUMBH, TAL CIPLA LIMITED ,,,VILLAGE UPPER MALPUR, P.O. BHUD, THE. NALAGARH DISTRICT SOLAN HIMACHAL PRADESH PIN 173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2007

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1923	NDA/MAL/HDP/2509	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	OPELE LOTION	BENZYL BENZOATE	25%W/V	BETA HEALTHCARE INTERNATIONAL LTD - PLOT NO.209/6554,MOGADISH U 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
1924	NDA/MAL/HDP/2510	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
1925	NDA/MAL/HDP/2513	REGAL PHARMACEUCIALS LTD	REGAL PHARMA (U) LTD	UNIPEN DRY SYRUP	PHENOXYMETHYL PENICILLIN	125MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

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1926	NDA/MAL/HDP/25 15	AFRICURE PHARMACEUTICALS (INDIA) LTD	ROYAL PHARMA 2011 LIMITED	SIMFEN 200 TABLETS	IBUPROFEN	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
1927	NDA/MAL/HDP/25 21	MEDLEY PHARMACEUTICALS 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
1928	NDA/MAL/HDP/25 23	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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1929	NDA/MAL/HDP/25 25	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
1930	NDA/MAL/HDP/25 26	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNISTEN COMBI PACK	CLOTRIMAZOLE	500MG & 1 %W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	VAGINAL COMBINATION PACK TABLETS	1.0X1.0 PESSARY BLISTER + 1*20G TUBE	01/07/2009
1931	NDA/MAL/HDP/25 28	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

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1932	NDA/MAL/HDP/25 29	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
1933	NDA/MAL/HDP/25 45	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
1934	NDA/MAL/HDP/25 52	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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1935	NDA/MAL/HDP/25 53	GLENMARK PHARMACEUTICAL LTD.	STAR PHARMACEUTICALS LTD	ES0Z-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
1936	NDA/MAL/HDP/25 54	GLENMARK PHARMACEUTICAL LTD.	STAR PHARMACEUTICALS LTD	ES0Z	ESOMEPRAZOLE	40MG	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET STRIP,1.0X10.0X1 0.0 TABLET STRIP	01/07/2005
1937	NDA/MAL/HDP/25 55	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PHENOBARBI TONE 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,1.0X1 00.0 TABLET CONTAINER	01/07/1998

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1938	NDA/MAL/HDP/25 56	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
1939	NDA/MAL/HDP/25 57	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
1940	NDA/MAL/HDP/25 58	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	MYCOREN SUSPENSION	NYSTATIN	100000 I.U./ML	RENE INDUSTRIES LTD680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL TOPICAL SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2007

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1941	NDA/MAL/HDP/25 59	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
1942	NDA/MAL/HDP/25 62	ACINO PHARMA AG	LABOREX UGANDA LIMITED	TRABILIN-100	TRAMADOL	100MG/2ML	MERCKLE GMBH, LUDWIG MERCKLE STRASSE 3 D- 89143 BLAUBEUREN	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X2.0 ML AMPOULE	01/07/2005
1943	NDA/MAL/HDP/25 65	ZYDUS LIFESCIENCES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TRAMAZAC INJECTION	TRAMADOL HYDROCHLORIDE	50MG/ML	FARBE FIRMAPLOT NO. 1508, GIDC ANKLESHWAR - 393002, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	, 1X5X2 ML AMPOULE, 1X2 ML VIAL	07/01/2016

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1944	NDA/MAL/HDP/25 67	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,GUJ ARAT,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
1945	NDA/MAL/HDP/25 68	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
1946	NDA/MAL/HDP/25 71	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS 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.THAN E INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRU PS/DROPS	1.0X60.0 ML BOTTLE,1.0X30.0 ML BOTTLE	01/07/2010

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1947	NDA/MAL/HDP/2575	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
1948	NDA/MAL/HDP/2576	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEQUINE TABLETS	CHLOROQUINE PHOSPHATE	250MG	RENE INDUSTRIES LTD 680, KAMULI, KIREKA KAMPALA, UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X250.0 TABLET CONTAINER, 1.0X1000.0 TABLET CONTAINER	01/07/2000
1949	NDA/MAL/HDP/2578	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	MAGNOMINT TABLETS	ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE	125MG + 250MG	REGAL PHARMACEUTICALS LTD BABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X100.0X10.0 TABLET BLISTER, 1.0X50.0X2.0 TABLET BLISTER, 1.0X500.0 TABLET CONTAINER, 1.0X1000.0 TABLET CONTAINER	01/07/1997

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1950	NDA/MAL/HDP/2580	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, KENYA MILAN LABORATORIES (INDIA) PVT LTD - 63,67,87,35,36, 64, 65 JAWAHAR CO-OP INDUSTRIAL ESTATE KAMOTHE, PANVEL NAVI MUMBAI LINCOLN PHARMACEUTICALS LTD- TRIMULJI ESTATE AEFER	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X2.0 TABLET STRIP	01/07/1998
1951	NDA/MAL/HDP/2591	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
1952	NDA/MAL/HDP/2593	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

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1953	NDA/MAL/HDP/2594	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER	01/07/2009
1954	NDA/MAL/HDP/2595	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
1955	NDA/MAL/HDP/2597	E DENK OHG	BENLE CONSULT LIMITED	PARA DENK 250	PARACETAMOL	250MG	RUBIEPHARM ARZNEIMITTEL GMHH BRUDER-GRIMM-STRABE 62, 36396, STEINAU AN DER STRABE BENE-ARZNEIMITTEL GMBH HERTERICHSTR. 1, 81479 MUENCHEN, GERMANY	GERMANY	RECTAL SYSTEMIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP, 1.0X2.0X5.0 SUPPOSITORY STRIP	01/07/2005

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1956	NDA/MAL/HDP/2600	IND SWIFT LTD	PLANET PHARMACEUTICALS 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
1957	NDA/MAL/HDP/2601	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
1958	NDA/MAL/HDP/2602	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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE,1.0X70.0 ML BOTTLE	01/07/2010

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1959	NDA/MAL/HDP/2604	USV PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GROVIT SYRUP	MULTI-INGREDIENT	MULTI-INGREDIENT	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	01/07/2000
1960	NDA/MAL/HDP/2612	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
1961	NDA/MAL/HDP/2614	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	DIALIN	LOPERAMIDE HCL	ZMG	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

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1962	NDA/MAL/HDP/2615	ASTRA ZENECA AB	MACNAUGHTON LIMITED	SYMBICORT TURBUHALER	BUDESONIDE+FOR MOTEROL	160MCG+4.5MCG /DOSE	ASTRAZENECA AB,GARTUNA & SNACKVIKEN STOCKHOLM	SWEDEN	LUNG ADMINISTRATION METERED-DOSE POWDER INHALER	1.0X60.0 DOSE CANNISTER,1.0X120.0 DOSE CANNISTER	01/07/2001
1963	NDA/MAL/HDP/2628	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
1964	NDA/MAL/HDP/2641	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	AXETINE 250MG	CEFUROXIME AXETIL	250MG	MEDOCHEMIE 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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1965	NDA/MAL/HDP/2642	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MEDOXANUM	CEFTRIAXONE	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
1966	NDA/MAL/HDP/2645	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
1967	NDA/MAL/HDP/2647	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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2005

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1968	NDA/MAL/HDP/2648	DENK OHG	BENLE CONSULT LIMITED	PARA DENK 125	PARACETAMOL	125MG	RUBIEPHARM ARZNEIMITTEL GMHH BRUDER-GRIMM-STRABE 62, 36396, STEINAU AN DER STRABE BENE-ARZNEIMITTEL GMBHHERTERICHSTR. 1,81479 MUENCHEN, GERMANY	GERMANY	RECTAL SYSTEMIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP,1.0X2.0X5.0 SUPPOSITORY STRIP	01/07/2005
1969	NDA/MAL/HDP/2650	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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2005
1970	NDA/MAL/HDP/2651	REGAL PHARMACEUCIALS LTD	REGAL PHARMA (U) LTD	RINAVIT SYRUP	MULTIVITAMIN	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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1971	NDA/MAL/HDP/2653	BLUE CROSS LABORATORIES LTD	STAR PHARMACEUTICALS 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
1972	NDA/MAL/HDP/2654	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	BEBE VIT	VITAMIN A+ VITAMIN D3+VITAMIN E+ VITAMIN C +VITAMIN B1 + VITAMIN B2	1500IU+ 400IU+ 5MG+ 40MG+0.5MG+0.6MG	MEDICAL UNION PHARMACEUTICAL CO.PLANT: ABU-SULTAN, ISMAILIA, EGYPT	EGYPT	ORAL LIQUID ORDINARY LIQUIDS	1.0X30.0 ML BOTTLE	01/07/2006
1973	NDA/MAL/HDP/2656	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

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1974	NDA/MAL/HDP/2661	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
1975	NDA/MAL/HDP/2671	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
1976	NDA/MAL/HDP/2675	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

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1977	NDA/MAL/HDP/2678	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
1978	NDA/MAL/HDP/2680	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMPIREN CAPSULES	AMPICILLIN TRIHYDRATE	250MG	RENE INDUSTRIES LTD680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER	01/07/2007
1979	NDA/MAL/HDP/2681	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMOXIREN	AMOXICILLIN TRIHYDRATE	250MG	RENE INDUSTRIES LTD680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER	01/07/2007

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1980	NDA/MAL/HDP/2683	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	VITAMIN C	ASCORBIC ACID	100MG	RENE INDUSTRIES LTD680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2005
1981	NDA/MAL/HDP/2685	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEDOL(SUSPENSION)	PARACETAMOL	120MG/5ML	RENE INDUSTRIES LTD680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60.0 ML BOTTLE	01/07/2007
1982	NDA/MAL/HDP/2690	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

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1983	NDA/MAL/HDP/2691	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 LTDPLOT 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
1984	NDA/MAL/HDP/2695	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
1985	NDA/MAL/HDP/2696	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

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1986	NDA/MAL/HDP/2697	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	LUCIN OINTMENT	HYDROCORTISON E	1%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997
1987	NDA/MAL/HDP/2698	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
1988	NDA/MAL/HDP/2703	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	KOACT 312.50	CO-AMOXICLAV (AMOXYCILLIN TRIHYDRATE+POTASSIUM 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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1989	NDA/MAL/HDP/2705	ASTRAZENECA	MACNAUGHTON LIMITED	PULMICORT NEBULISER	BUDESONIDE	0.5MG/ML	ASTRA ZENECA SWEDEN OPERATIONS LIQUID PRODUCTION KVARNBERGAGATANLZ SE 151-85,SWEDEN	SWEDEN	LUNG ADMINISTRATION LIQUID FOR INHALATION	1.0X4.0X5.0X2.0 ML VIAL	01/07/2011
1990	NDA/MAL/HDP/2707	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
1991	NDA/MAL/HDP/2708	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	HYPER TABLETS	PROPRANOLOL HYDROCHLORIDE	40MG	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X2.0X50.0 TABLET BLISTER	01/07/2000

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1992	NDA/MAL/HDP/27 10	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	AUGMENTIN BD	AMOXICILLIN + CLAVULANIC ACID	500 MG + 125 MG	SMITHKLINE BEECHAM PHARMACEUTICALS,CLAR ENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X14.0 TABLET BLISTER	01/07/1997
1993	NDA/MAL/HDP/27 12	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
1994	NDA/MAL/HDP/27 15	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

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1995	NDA/MAL/HDP/2717	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	OCUMYCIN EYE OINTMENT	CHLORAMPHENICOL	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
1996	NDA/MAL/HDP/2721	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	PRIMAFEN TABLET	IBUPROFEN + PARACETAMOL	400MG + 325MG	TORQUE PHARMACEUTICALS LTD DISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007
1997	NDA/MAL/HDP/2722	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	NO SORES	CHOLINE SALICYLATE/LIDOCAINE	8.7%W/W+2%W/W	TORQUE PHARMACEUTICALS LTD DISSAPUR P.O DAPPAR 140506	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X10.0 G TUBE	01/07/2007

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1998	NDA/MAL/HDP/27 23	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
1999	NDA/MAL/HDP/27 28	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	DEXAMETHA SONE 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,1.0X10 0.0X1.0 ML AMPOULE (IN A 2ML AMPOULE)	01/07/2006
2000	NDA/MAL/HDP/27 34	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (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

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2001	NDA/MAL/HDP/2737	SHAIGAN PHARMACEUTICALS 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
2002	NDA/MAL/HDP/2738	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
2003	NDA/MAL/HDP/2739	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	BISPANOL TABLET	HYOSCINE BUTYLBROMIDE	10MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER	01/07/2001

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2004	NDA/MAL/HDP/27 43	BEIJING HOLLEY COTEC PHARMA CHINA	SUPER PHARMACEUTICALS LIMITED	DUO- COTECXIN	DIHYDROARTEMIS ININ + PIPERAQUINE PHOSPHATE	40MG + 320MG	KBN- ZHEJIANG PHARMACEUTICAL CO. LTDNO. 340 YUNHAI ROAD JIAXING ECONOMIC DEVELOPMENT ZONE, JIAXING CITY, ZHEJIANG PROVINCE	CHINA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X9.0 TABLET BLISTER,1.0X1.0X 4.0 TABLET BLISTER,1.0X30.0 X9.0 TABLET BLISTER	01/07/2005
2005	NDA/MAL/HDP/27 45	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
2006	NDA/MAL/HDP/27 46	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

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2007	NDA/MAL/HDP/2753	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	PRASIL	METOCLOPRAMIDE HYDROCHLORIDE	10MG	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
2008	NDA/MAL/HDP/2756	PFIZER LABORATORIES LTD	LABOREX UGANDA LIMITED	CYTOTEC	MISOPROSTOL	200MCG	PIRAMAL HEALTHCARE LIMITED WALTON ROAD MORPETH NORTHUMBERLAND NE 613YA	UNITED KINGDOM	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2010
2009	NDA/MAL/HDP/2760	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	DELADED DRY COUGH SYRUP	DIPHENHYDRAMINE HYDROCHLORIDE+ DEXTROMETHORPHAN+SODIUM CITRATE+MENTHOL	14MG+6.5MG+57MG+2MG	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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2010	NDA/MAL/HDP/27 63	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
2011	NDA/MAL/HDP/27 73	REGAL PHARMACEUTICALS 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,1.0X1.0X1 00.0 ML BOTTLE	01/07/2004
2012	NDA/MAL/HDP/27 74	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

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2013	NDA/MAL/HDP/2776	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS 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,14.0X10.0 TABLET BLISTER	01/07/1997
2014	NDA/MAL/HDP/2777	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	CO-DIOVAN 160/12.5MG TABLETS	VALSARTAN + HYDROCHLOROTHIAZIDE	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
2015	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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2016	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
2017	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
2018	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,1.0X10.0 X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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2019	NDA/MAL/HDP/2788	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	MULTIREN	MULTIINGREDIENT	N/A	RENE INDUSTRIES LIMITED PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER	01/07/2010
2020	NDA/MAL/HDP/2793	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	VIREAD	TENOFOVIR DISOPROXIL FUMARATE	300MG	TAKEDA GMBH, PLANT ORANIENBURG-LEHNITZSTRASSE 70-98, 16515, ORANIENBURG-GERMANY PATHEON YM INC. TORONTO-TORONTO, CANADA	GERMANY CANADA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X30.0 TABLET BOTTLE	01/07/2004
2021	NDA/MAL/HDP/2796	ASTRA PHARMA (UK) LTD	ASTRA PHARMA (U) LIMITED	BENZYL PENICILLIN INJECTION	BENZYL PENICILLIN SODIUM	1,000,000 I.U	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO. LTD NO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE (WORKSHOP 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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2022	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
2023	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 LTDA AV. "C", 1413, DISTRITO INDUSTRIAL - 390404 004 MONTES CLAROS, MINAS GERAIS - BRAZIL NOVO NORDISK	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
2024	NDA/MAL/HDP/2802	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS 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

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2025	NDA/MAL/HDP/2805	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,1.0X10.0 X10.0 TABLET BLISTER	01/07/1997
2026	NDA/MAL/HDP/2807	GUILIN PHARMACEUTICALS 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,1.0X20.0 X6.0 TABLET BLISTER,1.0X25.0 X3.0 TABLET BLISTER,1.0X25.0 X6.0 TABLET BLISTER	01/07/2011
2027	NDA/MAL/HDP/2811	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	SULPHUR OINTMENT	SULPHUR PRECIPITATED	10%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X25.0 G TUBE	01/07/2001

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2028	NDA/MAL/HDP/28 12	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/SYRU PS/DROPS	1.0X60.0 ML BOTTLE	01/07/2005
2029	NDA/MAL/HDP/28 13	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	INTACYCLINE SKIN OINTMENT	TETRACYCLINE HYDROCHLORIDE	3%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997
2030	NDA/MAL/HDP/28 16	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

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2031	NDA/MAL/HDP/28 21	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICALS 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
2032	NDA/MAL/HDP/28 26	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PIRITON SYRUP	CHLORPHENIRAMI NE MALEATE	4MG/10ML	GLAXOSMITHKLINEKONI ROAD IND. AREA, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X2.0 L BOTTLE	01/07/1997
2033	NDA/MAL/HDP/28 35	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICALS LIMITED	SOLUDINE-M	POVIDONE IODINE / METRONIDAZOLE	5%W/W / 1%W/W	LINCOLN PHARMACEUTICALS LIMITEDTRIMUL 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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2034	NDA/MAL/HDP/2837	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
2035	NDA/MAL/HDP/2838	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	01/07/2010
2036	NDA/MAL/HDP/2850	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS 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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2037	NDA/MAL/HDP/28 69	GLAXO SMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PRIORIX VACCINE	MEASLES + MUMPS + RUBELLA	103.OCCID50 + 103.7CCID50 + 103.OCCID50	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
2038	NDA/MAL/HDP/28 73	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	HELIGO KIT	TINIDAZOLE/CLARI THROMYCIN/LANS OPRAZOLE	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
2039	NDA/MAL/HDP/28 75	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

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2040	NDA/MAL/HDP/2880	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
2041	NDA/MAL/HDP/2885	MACLEODS PHARMACEUTICALS 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,1.0X24.0 X28.0 TABLET BLISTER	01/07/2005
2042	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

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2043	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, 1.0X10.0 X10.0 TABLET BLISTER	01/07/1997
2044	NDA/MAL/HDP/2893	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
2045	NDA/MAL/HDP/2894	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 EIPICO 10TH OF RAMADAN CITY-FIRST INDUSTRIAL AREA -EGYPT	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X125.0 ML BOTTLE	01/07/2005

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2046	NDA/MAL/HDP/2896	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
2047	NDA/MAL/HDP/2898	MACLEODS PHARMACEUTICALS 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
2048	NDA/MAL/HDP/2900	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

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2049	NDA/MAL/HDP/2902	MACLEODS PHARMACEUTICALS 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
2050	NDA/MAL/HDP/2905	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BRONCHOPHANE SYRUP	GUAIPHENESIN+EPHEDRINE HYDROCHLORIDE+DIPHENHYDRAMINE HYDROCHLORIDE+DXTROMETHORPHAN	50MG+7.5MG+5MG+4.58MG	ORCHIDIA10TH STREET RAMADAN CITY, FIST INDUSTRIES ARE	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X125.0 ML BOTTLE	01/07/2007
2051	NDA/MAL/HDP/2906	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	RIFAMPICIN/ISONIAZID/ETHAMBUTOL	RIFAMPICIN+ISONIAZID+ETHAMBUTOL	150MG+75MG+275MG	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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2052	NDA/MAL/HDP/2907	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	LONART DS	ARTEMETHER + LUMEFANTRINE	80 MG + 480 MG	BLISS GVS PHARMA LIMITED NO.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
2053	NDA/MAL/HDP/2908	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	PAINGO MEDICATED CREAM	METHYLSALICYLATE+CAPSICUM OLEORESIN+TURPENTINE OIL	15%W/W + 1%W/W + 1.47%W/W	NEM LABORATORIES PVT LTD PLOT 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
2054	NDA/MAL/HDP/2910	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

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2055	NDA/MAL/HDP/2911	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
2056	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
2057	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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2058	NDA/MAL/HDP/29 20	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICALS 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
2059	NDA/MAL/HDP/29 40	CENTAUR PHARMACEUTICAL S PVT. LTD	GITTOES PHARMACEUTICALS 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
2060	NDA/MAL/HDP/29 42	CENTAUR PHARMACEUTICAL S PRIVATE LIMITED	GITTOES PHARMACEUTICALS 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

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2061	NDA/MAL/HDP/2946	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1998
2062	NDA/MAL/HDP/2947	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THANE 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,1.0X250.0 BLISTER CARTON	01/07/1998
2063	NDA/MAL/HDP/2948	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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2064	NDA/MAL/HDP/2951	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	LONART FORTE TABLETS	ARTEMETHER + LUMEFANTRINE	40 MG + 240 MG	BLISS GVS PHARMA LIMITED NO.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
2065	NDA/MAL/HDP/2956	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	TRANLOK 500MG TABLETS	TRANEXAMIC ACID	500MG	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 BLISTER, 1.0X3.0X10.0 TABLET BLISTER	01/07/2010
2066	NDA/MAL/HDP/2957	MEDIPHARM SALES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MEDITROL	CALCITRIOL	0.25MCG	MEGA LIFE SCIENCES LIMITED: PLANT I : 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

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2067	NDA/MAL/HDP/2959	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	CETAMOL SYRUP	PARACETAMOL	120MG/5ML	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
2068	NDA/MAL/HDP/2960	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	CLAVODAR	AMOXICILLIN/CLAVULANIC ACID	400MG/57MG	DAR AL DAWANA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY GRANULES	1.0X70.0 ML BOTTLE	01/07/2010
2069	NDA/MAL/HDP/2969	UNIQUE PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS 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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2070	NDA/MAL/HDP/2971	TORRENT PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	LEFRA-20 TABLETS	LEFLUNOMIDE	20MG	TORRENT PHARMACEUTICALS LTDINDRAD-382 721, DIST.MEHSANA,INDIA.AT: VILL.MANAKPUR,TEH.NAL AGARH,DIST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2004
2071	NDA/MAL/HDP/2974	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
2072	NDA/MAL/HDP/2979	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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2073	NDA/MAL/HDP/2980	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	LONART TABLETS	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	BLISS GVS PHARMA LIMITED NO.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,1.0X3.0X6.0 TABLET BLISTER,1.0X24.0 TABLET BLISTER,1.0X12.0 TABLET BLISTER 1.0X18.0	01/07/2007
2074	NDA/MAL/HDP/2982	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS 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
2075	NDA/MAL/HDP/2983	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

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2076	NDA/MAL/HDP/29 85	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
2077	NDA/MAL/HDP/29 90	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,1.0X3.0X 4.0 TABLET BLISTER	01/07/2004
2078	NDA/MAL/HDP/29 95	GITTOES PHARMACEUTICAL S 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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2079	NDA/MAL/HDP/2997	MEDLEY PHARMACEUTICALS LTD	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
2080	NDA/MAL/HDP/2998	MEDLEY PHARMACEUTICALS LTD	EUROPA HEALTHCARE (U) LTD	FITIN-5	LEVOCETIRIZINE DIHYDROCHLORIDE	5MG	MEDLEY PHARMACEUTICALS LTD PLOT NO 18 & 19, SURVEY NO. 378/7& 8,379/2&3 ZARI BUSEWAY ROAD,, KACHIGAM, DAMAN-396210	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
2081	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

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2082	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
2083	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
2084	NDA/MAL/HDP/3009	VENUS REMEDIES LIMITED	HARLEYS UGANDA LIMITED	SULBACTOM AX 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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2085	NDA/MAL/HDP/3012	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	DICLOMOL TABLETS	DICLOFENAC SODIUM	50MG	WIN MEDICARE PVT LIMITED MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1998
2086	NDA/MAL/HDP/3013	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOZOLE	ALBENDAZOLE	400MG	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 CHEWABLE TABLETS	1.0X1.0X1.0 TABLET BLISTER, 1.0X50.0 TABLET CONTAINER, 1.0X10.0 TABLET BLISTER, 1.0X50.0X1.0 TABLET BLISTER	01/07/2007
2087	NDA/MAL/HDP/3017	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	LIDOCAINE INJECTION	LIDOCAINE HYDROCHLORIDE	20MG/ML	SANJAR PHARMA LLP HIMATNAGAR-VIOPUR 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

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2088	NDA/MAL/HDP/3019	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
2089	NDA/MAL/HDP/3020	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
2090	NDA/MAL/HDP/3021	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	GLIBENCLAMIDE TABLETS	GLIBENCLAMIDE	5MG	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	1.0X100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER	01/07/2007

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2091	NDA/MAL/HDP/3023	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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,1.0X10.0X1.0X3.0 TABLET STRIP,1.0X500.0 TABLET CONTAINER	01/07/2007
2092	NDA/MAL/HDP/3024	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, WALIJI AURANGABAD-	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2008
2093	NDA/MAL/HDP/3029	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	01/07/2007

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2094	NDA/MAL/HDP/3030	MJ BIOPHARM PVT LTD	VITACARE LIMITED	BIOSULIN R	INSULIN SOLUBLE	100 IU/ML	MJ 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
2095	NDA/MAL/HDP/3031	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOMETHASONE	DEXAMETHASONE	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
2096	NDA/MAL/HDP/3032	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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2097	NDA/MAL/HDP/3035	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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 LIMITED PLOT 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,1.0X1.0X100.0 ML BOTTLE	01/07/2007
2098	NDA/MAL/HDP/3037	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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 LIMITED PLOT 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,1.0X1.0X100.0 ML BOTTLE	01/07/2007
2099	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

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2100	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
2101	NDA/MAL/HDP/3046	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/SYRUPS/DROPS	1.0X70.0 ML BOTTLE	01/07/2009
2102	NDA/MAL/HDP/3048	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	TRIMAGO-DS TABLETS	SULFAMETHOXAZOLE/TRIMETHOPRIM	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,1.0X10.0X10.0 TABLET CONTAINER,1.0X3.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2007

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2103	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
2104	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,1.0X10.0 X10.0 CAPSULE BLISTER	01/07/2007
2105	NDA/MAL/HDP/3063	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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,1.0X100.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER	01/07/2007

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2106	NDA/MAL/HDP/3064	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE 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
2107	NDA/MAL/HDP/3067	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	PROMAGO SYRUP	PROMETHAZINE	5MG/5ML	AGOG PHARMA LIMITED PLOT 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
2108	NDA/MAL/HDP/3068	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	OPTACHLOR EYE DROPS	CHLORAMPHENICOL	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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2109	NDA/MAL/HDP/3069	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER, 1.0X100.0 CAPSULE CONTAINER	01/07/2007
2110	NDA/MAL/HDP/3072	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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, 1.0X1000.0 TABLET CONTAINER, 1.0X100.0X10.0 TABLET BLISTER, 1.0X10.0X10.0 TABLET BLISTER	01/07/1998
2111	NDA/MAL/HDP/3076	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO TELVAS 40	TELMISARTAN	40MG	ARISTO PHARMACUTLAB 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

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2112	NDA/MAL/HDP/3077	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNISTEN HC CREAM	CLOTRIMAZOLE + HYDROCORTISONE	1%W/W + 1%W/W	REGAL PHARMACEUTICALS PLOT 7879/18 OFF BABA RWARAKA NAIROBI KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2008
2113	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
2114	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

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2115	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
2116	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
2117	NDA/MAL/HDP/3091	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

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2118	NDA/MAL/HDP/3092	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	EXFORGE HCT 10MG/160MG/12.5MG	AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE	10MG + 160MG +12.5MG	NOVARTIS PHARMA STEIN AGSCHAFFHARVSESTRASSE CH-4332 STEIN SWITZERLAND.	SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER	01/07/2015
2119	NDA/MAL/HDP/3095	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	AMPHEN SUSPENSION	CHLORAMPHENICOL 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
2120	NDA/MAL/HDP/3098	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MOSEDIN	LORATADINE	5MG/5ML	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-BOUR CITY, EGYPT.	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2004

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2121	NDA/MAL/HDP/3099	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
2122	NDA/MAL/HDP/3101	DAWA LIMITED	SUPER MEDIC LTD	DACOLD SYRUP	PARACETAMOL + PSEUDOEPHEDRINE HCL + CHLORPHENIRAMINE MALEATE	120MG/5ML+10MG/5ML+2MG/5ML	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2010
2123	NDA/MAL/HDP/3104	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

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2124	NDA/MAL/HDP/3108	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
2125	NDA/MAL/HDP/3111	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
2126	NDA/MAL/HDP/3116	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/SYRUPS/DROPS	1.0X1.0X100.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/1997

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2127	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
2128	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,1.0X30.0 X18.0 TABLET BLISTER,1.0X30.0 X24.0 TABLET BLISTER,1.0X30.0 X12.0 TABLET BLISTER,1.0X30.0 X6.0 TABLET BLISTER,1.0X1.0X18.0 TABLET BLISTER 1.0X1.0X	01/07/2011
2129	NDA/MAL/HDP/3122	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

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2130	NDA/MAL/HDP/3123	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
2131	NDA/MAL/HDP/3125	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (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
2132	NDA/MAL/HDP/3134	PANACEA BIOTEC PHARMA LTD	VITACARE LIMITED	TOFF PLUS	PARACETAMOL+CHLORPHENIRAMINE MALEATE+ DEXTROMETHORPHAN + PHENYLEPHRINE	500 MG + 2 MG + 15 MG + 10 MG	PANACEA BIOTEC PHARMA LIMITED MALPURI 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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2133	NDA/MAL/HDP/3136	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
2134	NDA/MAL/HDP/3139	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	OMEDAR	OMEPRAZOLE	20MG	DAR AI DAWANA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER,1.0X2.0X14.0 TABLET BLISTER	01/07/2009
2135	NDA/MAL/HDP/3141	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

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2136	NDA/MAL/HDP/31 44	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
2137	NDA/MAL/HDP/31 45	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
2138	NDA/MAL/HDP/31 46	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	ZOKAST	MONTELUKAST SODIUM	10MG	UNICHEM LABORATORIES LTD UNIT 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,1.0X3.0X 10.0 TABLET BLISTER	01/07/2016

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2139	NDA/MAL/HDP/31 47	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
2140	NDA/MAL/HDP/31 56	PFIZER LABORATORIES (PTY)	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN DAYTIME FLU	PSEUDOEPHEDRIN E HCL + IBUPROFEN	30MG + 200MG	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 STRIP	01/07/2008
2141	NDA/MAL/HDP/31 58	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

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2142	NDA/MAL/HDP/31 59	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
2143	NDA/MAL/HDP/31 63	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
2144	NDA/MAL/HDP/31 66	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	SEPTRIN	TRIMETHOPRIM + SULPHAMETHOXAZOLE	40MG/5ML + 200MG/5ML	GLAXO WELLCOME EGYPT CO. S.A.ECAIRO	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X50.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/1997

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2145	NDA/MAL/HDP/31 67	MJ BIOPHARM PVT LTD	KIMSY MEDS LTD	MONAN-0.5G	MEROPENEM	0.5G	MJ 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
2146	NDA/MAL/HDP/31 69	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS 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
2147	NDA/MAL/HDP/31 75	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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2148	NDA/MAL/HDP/3176	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED	AFRICURE PHARMACEUTICALS 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
2149	NDA/MAL/HDP/3177	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
2150	NDA/MAL/HDP/3178	COSMOS LTD	ASTRA PHARMA (U) LIMITED	BENDURIC TABLETS	BENDROFLUMETHIAZIDE	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

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2151	NDA/MAL/HDP/3179	GOOD DAY PHARMACY LIMITED	PLANET PHARMACEUTICALS 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
2152	NDA/MAL/HDP/3181	THEMIS MEDICARE LTD	STAR PHARMACEUTICALS LTD	EMAL	ALPHA & BETA ARTEETHER	150MG/2ML	THEMIS MEDICARE LIMITED SECTOR 6A, PLOT NO. 16 TO18, IIE, BHEL HARIDWA, UTTARAKHAND	INDIA	PARENTERAL ORDINARY AMPOULES	3.0X2.0 ML VIAL	01/07/2009
2153	NDA/MAL/HDP/3184	M.J BOPHARM PUT LTD	KIMSY MEDS LTD	MONAN	MEROPENEM	1G	M.J BIOPHARM PUT LTD L 7 MIDC INDUSTRIAL DIST GAIDED TOLOJA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2008

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2154	NDA/MAL/HDP/31 91	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
2155	NDA/MAL/HDP/31 92	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
2156	NDA/MAL/HDP/31 93	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

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2157	NDA/MAL/HDP/3196	MEDLEY PHARMACEUTICALS 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
2158	NDA/MAL/HDP/3197	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	TRIAM-DENK 40 INJECTION	TRIAMCINOLONE 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
2159	NDA/MAL/HDP/3200	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LETTRAX	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,1.0X200.0 TABLET CONTAINER,1.0X25.0X3.0 TABLET BLISTER,1.0X3.0 TABLET BLISTER	01/07/1997

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2160	NDA/MAL/HDP/3202	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, 1.0X10.0X10.0 TABLET BLISTER	01/07/2008
2161	NDA/MAL/HDP/3204	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	RELCER 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
2162	NDA/MAL/HDP/3206	HEALTHCARE LTD.	HEALTHCARE LTD.	POSTINOR 2	LEVONORGESTREL	0.75MG	GEDEON RICHTER PLC1103 BUDAPEST GYOMROI UT 19-21	HUNGARY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X2.0 TABLET BLISTER	01/07/2010

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2163	NDA/MAL/HDP/3207	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	DILCONTIN XL 90	CONTROLLED RELEASE TABLETS OF DILTIAZEM HYDROCHLORIDE	90MG	MODI MUNDIPHARMA (PVT) LTDMEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID RETARD FILM-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2010
2164	NDA/MAL/HDP/3212	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	CLOPRESS 75MG	CLOPIDOGREL BISULPHATE	75MG	CIPLA LTD-PLOT NO L-139,VERNA IND ESTATE, VERNA GOA-403 INDIA CIPLA LIMITED ,,VILLAGE UPPER MALPUR, P.O. BHUD, THE. NALAGARH DISTRICT SOLAN HIMACHAL PRADESH PIN 173205	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2005
2165	NDA/MAL/HDP/3214	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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2166	NDA/MAL/HDP/32 15	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
2167	NDA/MAL/HDP/32 19	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS 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.THAN E INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/1998
2168	NDA/MAL/HDP/32 20	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	PYLO KIT	LANSOPRAZOLE+T INIDAZOLE+CLARI THROMYCIN	30MG+500MG+2 50 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

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2169	NDA/MAL/HDP/32 21	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	OPTADEX-N EYE DROPS	DEXAMETHASONE /NEOMYCIN	1MG/3MG	REMINGTON PHARMACEUTICAL INDUS. PVT LTD, 117 ALLAM	PAKISTAN	OPHTHALMIC DROPS	1.0X5.0 ML VIAL	01/07/1999
2170	NDA/MAL/HDP/32 24	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
2171	NDA/MAL/HDP/32 25	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICALS 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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2172	NDA/MAL/HDP/32 26	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
2173	NDA/MAL/HDP/32 31	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICALS LIMITED	FLUCOMOL	PARACETAMOL/P HENYLEPHRINE HCL/DEXTROMET HOPHAN 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,1.0X10.0 X1.0X10.0 CAPSULE BLISTER	01/07/2008
2174	NDA/MAL/HDP/32 36	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,1.0X2 50.0 TABLET CONTAINER,1.0X5 00.0 TABLET CONTAINER,1.0X1 000.0 TABLET CONTAINER,1.0X1 00.0X10.0 TABLET BLISTER	01/07/1997

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2175	NDA/MAL/HDP/32 37	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICALS LIMITED	KONAZOL CREAM	KETOCONAZOLE	2% W/W	LINCOLN PHARMACEUTICAL LIMITED TRIMAL ESTATE KHATRAJ KOLOL, GUJARAT INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2008
2176	NDA/MAL/HDP/32 41	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICALS 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
2177	NDA/MAL/HDP/32 43	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	RAPITUS	LEVODROPROPIZINE	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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2178	NDA/MAL/HDP/3244	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
2179	NDA/MAL/HDP/3245	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
2180	NDA/MAL/HDP/3246	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE 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

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2181	NDA/MAL/HDP/3252	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
2182	NDA/MAL/HDP/3255	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2011
2183	NDA/MAL/HDP/3259	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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2184	NDA/MAL/HDP/32 61	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	TENOFOVIR DF + EMTRICITABI NE + EFAVIRENZ	TENOFOVIR DF + EMTRICITABINE + EFAVIRENZ	300MG+200MG+ 600MG	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 LABORATORIES LIMITED PLOT NO. 11 12&13	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2008
2185	NDA/MAL/HDP/32 62	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
2186	NDA/MAL/HDP/32 63	REGAL PHARMACEUCIALS 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,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2009

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2187	NDA/MAL/HDP/32 65	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,10.0X 10.0 CAPSULE BLISTER	01/07/2010
2188	NDA/MAL/HDP/32 66	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,MOGADISH U 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
2189	NDA/MAL/HDP/32 70	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(WORKSHOP 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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2190	NDA/MAL/HDP/3273	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
2191	NDA/MAL/HDP/3275	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS 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
2192	NDA/MAL/HDP/3276	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICALS 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

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2193	NDA/MAL/HDP/3277	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
2194	NDA/MAL/HDP/3279	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
2195	NDA/MAL/HDP/3282	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	KOFF-GO	PHENYLEPHRINE HCL + CHLORPHENIRAMINE MALEATE + DEXTROMETHORPHAN	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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2196	NDA/MAL/HDP/3284	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
2197	NDA/MAL/HDP/3285	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
2198	NDA/MAL/HDP/3288	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	DELASED CHESTY COUGHS SYRUP	DIPHENHYDRAMINE HCL BP+AMMONIUM CHLORIDE BP+SODIUM CITRATE BP+MENTHOL BP	14MG+135MG+57MG+1.1MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1997

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2199	NDA/MAL/HDP/32 89	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS 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
2200	NDA/MAL/HDP/32 91	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICALS 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
2201	NDA/MAL/HDP/32 92	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	DELADED PAEDIATRIC SYRUP	DIPHENHYDRAMINE HYDROCHLORIDE+ SODIUM CITRATE+MENTH OL	7MG+28.5MG+0.5 5MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1997

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2202	NDA/MAL/HDP/32 94	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	URGENDOL CAPSULES	TRAMADOL HYDROCHLORIDE	50 MG	WIN- MEDICARE LTD MODIPURAM -250 110,UTTAR PRAADESH, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2004
2203	NDA/MAL/HDP/32 95	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICALS 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
2204	NDA/MAL/HDP/32 97	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICALS 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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2011

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2205	NDA/MAL/HDP/3300	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS 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
2206	NDA/MAL/HDP/3312	TORRENT PHARAMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	TIDOMET FORTE	CO-CARELDOPA	25MG/250MG	TORRENT PHARMACEUTICALS LTD VILLAGE: BHUD & MAKHNU MAJRA, TEHSIL: BADDI Â€" 173205, DIST: SOLAN, HIMACHAL PRADESH, TORRENT PHARMACEUTICAL LTD AHMEDABAD-MEHSANA HIGHWAY, TALUKA-KADI, DIST. MEHSANA, INDIA-382721	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2004
2207	NDA/MAL/HDP/3314	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS 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

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2208	NDA/MAL/HDP/33 15	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THAN E INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000 .0 TABLET CONTAINER	01/07/2003
2209	NDA/MAL/HDP/33 16	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/SYRU PS/DROPS	1.0X100.0 ML BOTTLE	01/07/1998
2210	NDA/MAL/HDP/33 18	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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2211	NDA/MAL/HDP/3319	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
2212	NDA/MAL/HDP/3321	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	DERMOLIN-GM	CLOBETASOL+GEN TAMICIN+MICONAZOLE	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
2213	NDA/MAL/HDP/3328	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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

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2214	NDA/MAL/HDP/3333	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	NOVACLAV-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
2215	NDA/MAL/HDP/3334	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MYCLAV 375	AMOXICILLIN + CLAVULANIC ACID	250 MG + 125 MG	UNICHEM LABORATORIES LIMITED UNIT II VILLAGE 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
2216	NDA/MAL/HDP/3341	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	AZILIN-250	AZITHROMYCIN	250MG	LINCOLN PHARMACEUTICALS LIMITED TRIMUL 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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2217	NDA/MAL/HDP/33 42	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
2218	NDA/MAL/HDP/33 43	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	MEDIVEN- CREAM	BETAMETHASONE VALERATE	0.1%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997
2219	NDA/MAL/HDP/33 46	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	ZEDEX	BROMHEXINE +AMMONIUM CHLORIDE+ MENTHOL + DXTROMETHORP HAN	8MG+100MG+5M G+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

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2220	NDA/MAL/HDP/33 47	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	UNIPEN TABLETS	PHENOXYMETHYL PENICILLIN	250MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X1 0.0X10.0 TABLET BLISTER	01/07/1997
2221	NDA/MAL/HDP/33 48	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
2222	NDA/MAL/HDP/33 54	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	MEDIVEN OINTMENT	BETAMETHASONE VALERATE	0.1%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997

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2223	NDA/MAL/HDP/33 57	CENTAUR PHAMACUITICALS	GITTOES PHARMACEUTICALS 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
2224	NDA/MAL/HDP/33 59	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS 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
2225	NDA/MAL/HDP/33 64	CENTAUR PHAMACUITICALS	GITTOES PHARMACEUTICALS 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

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2226	NDA/MAL/HDP/33 67	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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
2227	NDA/MAL/HDP/33 69	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS 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
2228	NDA/MAL/HDP/33 70	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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2229	NDA/MAL/HDP/3372	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
2230	NDA/MAL/HDP/3373	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MYCLAV 625	AMOXILLICIN/CLAVULANATE	500MG/125MG	UNICHEM LABORATORIES LIMITED UNIT II VILLAGE 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
2231	NDA/MAL/HDP/3374	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

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2232	NDA/MAL/HDP/3377	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER, 1.0X100.0X10.0 TABLET BLISTER	01/07/2011
2233	NDA/MAL/HDP/3378	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CHLOZINE TABLETS	CHLORPROMAZINE	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
2234	NDA/MAL/HDP/3379	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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2235	NDA/MAL/HDP/3382	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X60.0 ML BOTTLE, 1.0X1.0X100.0 ML BOTTLE	01/07/2010
2236	NDA/MAL/HDP/3383	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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, 1.0X100.0X10.0 TABLET BLISTER	01/07/2010
2237	NDA/MAL/HDP/3384	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

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2238	NDA/MAL/HDP/33 85	BLUE CROSS LABORATORIES LTD	STAR PHARMACEUTICALS LTD	MEFTAL-P- SUSPENSION	MEFENAMIC ACID	100MG/5ML	BLUE CROSS LABORATORIES LTDL-17, VERNA INDUSTRIAL ESTATE,VERNA GOA- 403722	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE	01/07/2007
2239	NDA/MAL/HDP/33 87	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PROXIMEXA 500MG	CEFUROXIME AXETIL	500MG	GLAXOSMITHKLINE UK LTDHARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2007
2240	NDA/MAL/HDP/33 90	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ALUGEL	ALUMINIUM HYDROXIDEL / MAGNESIUM TRISLICATE	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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2241	NDA/MAL/HDP/3391	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE 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
2242	NDA/MAL/HDP/3393	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	AUGMENTIN 375MG	AMOXICILLIN + CLAVULANIC ACID	250 MG + 125 MG	SMITHKLINE BEECHAM PHARMACEUTICALS, CLARENDRON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	2.0X10.0 TABLET BLISTER	01/07/1997
2243	NDA/MAL/HDP/3399	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

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2244	NDA/MAL/HDP/3400	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
2245	NDA/MAL/HDP/3405	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
2246	NDA/MAL/HDP/3406	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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2247	NDA/MAL/HDP/3409	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	CLARITYNE	LORATADINE	10MG	BAYER BITTERFELD GMBH HORTSTEIL 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
2248	NDA/MAL/HDP/3411	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
2249	NDA/MAL/HDP/3414	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	EXFORGE 10MG/160MG	AMLODIPINE + VALSARTAN	10 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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2250	NDA/MAL/HDP/34 15	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS 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
2251	NDA/MAL/HDP/34 23	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	AMOXICLAV- DENK 1000/125	AMOXICILLIN TRIHYDTATE + POTASSIUM CLAVULANATE	1000 MG + 125 MG	PENCEF PHARMA GMBHB RITENBACHSTR ASSE 13 D-13509 BERLIN	GERMANY	ORAL LIQUID ORDINARY UNIT DOSE POWDERS	1.0X12.0X3.0 G SACHET,1.0X8.0X 3.0 G SACHET	01/07/2011
2252	NDA/MAL/HDP/34 26	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	RUBEM CREAM	METHYL NICOTINATE + CAPSICUM OLEORESIN+ METHYLSALICYLAT E	1%W/W+0.1%W/ W+5%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE	01/07/1997

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2253	NDA/MAL/HDP/34 29	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
2254	NDA/MAL/HDP/34 33	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	CO-DIOVAN 80/12.5	VALSARTAN + HYDROCHLOROTH IAZIDE	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
2255	NDA/MAL/HDP/34 34	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	SEPTRIN	CO-TRIMOXAZOLE	480MG	GLAXO WELLCOME EGYPT CO. S.A.ECAIRO BETA HEALTHCARE INTERNATIONAL LTD PLOT NO. LR 209/6554, MOGADISHU ROAD INDUSTRIAL AREA, NAIROBI KENYA	EGYPT KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X1 0.0 TABLET CARTON,1.0X50.0 TABLET CARTON,1.0X10.0 X10.0 TABLET BLISTER,1.0X2.0X 10.0 TABLET BLISTER	01/07/1997

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2256	NDA/MAL/HDP/34 37	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
2257	NDA/MAL/HDP/34 39	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, 10.0X 10.0 CAPSULE BLISTER	01/07/2000
2258	NDA/MAL/HDP/34 40	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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2259	NDA/MAL/HDP/3444	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	CORVADIL 10	AMLODIPINE BESILATE	10MG	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	1.0X3.0X10.0 TABLET STRIP	01/07/2010
2260	NDA/MAL/HDP/3449	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, 1.0X10.0X1.0 X10.0 ML VIAL	01/07/2008
2261	NDA/MAL/HDP/3451	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER, 1.0X100.0 CAPSULE CONTAINER, 1.0X1000.0 CAPSULE CONTAINER, 1.0X500.0 CAPSULE CONTAINER	01/07/1998

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2262	NDA/MAL/HDP/34 58	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNIXIL 250MG	AMOXYCILLIN TRIHYDRATE	250MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000 .0 CAPSULE CONTAINER	01/07/1997
2263	NDA/MAL/HDP/34 59	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
2264	NDA/MAL/HDP/34 60	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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2265	NDA/MAL/HDP/34 64	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TARTAR CONTROL LISTERINE ANTISEPTIC	ZINC CHLORIDE + DENATURED ALCOHOL MENTHOL 95% + THYMOL	18MG/ 20ML + 0.9ML/20ML + 12.7MG/20ML	JOHNSON&JOHNSON 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
2266	NDA/MAL/HDP/34 65	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
2267	NDA/MAL/HDP/34 66	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

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2268	NDA/MAL/HDP/34 67	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
2269	NDA/MAL/HDP/34 73	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,INDIA 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
2270	NDA/MAL/HDP/34 74	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMCLOREN DRY SYRUP	AMPICILLIN + CLOXACILLIN	125MG+125MG/5 ML	RENE INDUSTRIES LTD680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRU PS/DROPS	1.0X100.0 ML BOTTLE	01/07/2008

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2271	NDA/MAL/HDP/3475	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
2272	NDA/MAL/HDP/3476	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	PARAFIL	PARACETAMOL	500MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER	01/07/1997
2273	NDA/MAL/HDP/3478	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	DICLOREN	DICLOFENAC SODIUM BP	50MG	RENE INDUSTRIES LTD680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009

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2274	NDA/MAL/HDP/3483	JOHNSON&JOHNSON PTY LTD. 241	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SINUTAB 3-WAY	IBUPROFEN + PSEUDOEPHEDRINE HCL	200MG + 30MG	JOHNSON&JOHNSON 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
2275	NDA/MAL/HDP/3485	CIRON DRUGS & PHARMACEUTICALS 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
2276	NDA/MAL/HDP/3490	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS 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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2277	NDA/MAL/HDP/34 92	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
2278	NDA/MAL/HDP/34 94	FERRER INTERNATIONAL, S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	GAMALATE B6 SOLUTION	MAGNESIUM GLUTAMATE HYDROBROMIDE + AMINO BUTYRIC 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
2279	NDA/MAL/HDP/34 97	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

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2280	NDA/MAL/HDP/3500	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	GIZLAN 300	IRBESARTAN	300MG	DAR AI DAWANA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014
2281	NDA/MAL/HDP/3502	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HYDROCORTISONE SODIUM SUCCINATE	HYDROCORTISONE 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
2282	NDA/MAL/HDP/3504	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (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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2283	NDA/MAL/HDP/3506	ABBVIE (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ULTANE	SEVOFLURANE	100%W/W	AESICA QUEESNBOROUGH LTD NORTH RD. QUEESNBOROUGH 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
2284	NDA/MAL/HDP/3507	MEDOPHARM PRIVATE LIMITED	PLANET PHARMACEUTICALS 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
2285	NDA/MAL/HDP/3515	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	01/07/2007

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2286	NDA/MAL/HDP/35 16	COSMOS LTD	ASTRA PHARMA (U) LIMITED	BENZHEXOL TABLETS BP 5MG	TRIHENXYPHENIDYL 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,1.0X1 00.0 TABLET BLISTER	01/07/1998
2287	NDA/MAL/HDP/35 17	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TOTO ZINC	ZINC SULPHATE	20MG	MEDICAMEN BIOTECH LTDSP-1192, A & B, PHASE "IV, INDUSTRIAL AREA BHIWADI -301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
2288	NDA/MAL/HDP/35 20	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

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2289	NDA/MAL/HDP/3522	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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
2290	NDA/MAL/HDP/3525	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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, 1.0X100.0X10.0 CAPSULE BLISTER	01/07/1998
2291	NDA/MAL/HDP/3526	CYANO PHARMA(P) LTD	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, 1.0X100.0X10.0 TABLET BLISTER	01/07/2001

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2292	NDA/MAL/HDP/35 27	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
2293	NDA/MAL/HDP/35 33	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	LEVOZIN	LEVOCETIRIZINE	5MG	KESAR PHARMA PVT LTD- PLOT SURVEY NO. 50/2. VILLAGE BILSHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008
2294	NDA/MAL/HDP/35 35	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

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2295	NDA/MAL/HDP/35 40	EAGLEVET UGANDA LIMITED	MEDVIN PHARMA LIMITED	CLOPACT-75	CLOPIDOGREL	75 MG	IPCA LABORATORIESLIMITED- IPCA LABORATORIES LTD P.O SEJANTA DISTRICT RATLAM 457002 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008
2296	NDA/MAL/HDP/35 42	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,MOGADISH U ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X2.0 TABLET STRIP,1.0X110.0X 2.0 TABLET STRIP	01/07/2005
2297	NDA/MAL/HDP/35 45	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS 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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2298	NDA/MAL/HDP/3546	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENETRIM D.S	SULPHAMETHOXAZOLE + TRIMETHOPRIM	800MG + 160MG	RENE INDUSTRIES LIMITED PLOT 680 KAMULI KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X500.0 TABLET CONTAINER, 1.0X1000.0 TABLET CONTAINER	01/07/2013
2299	NDA/MAL/HDP/3547	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	CORBIS-10	BISOPROLOL	10 MG	UNICHEM LABORATORIES LIMITED UNIT II VILLAGE 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
2300	NDA/MAL/HDP/3548	RAJESHI PLASTICS	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

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2301	NDA/MAL/HDP/3549	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	TRIMEX PAEDIATRIC COUGH EXPECTORANT	CHLORPHENIRAMINE MALEATE+PSEUDO EPHEDRINE HCL+GUAIPHENISIN+MENTHOL	1.0MG+15.0MG+50.0MG+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
2302	NDA/MAL/HDP/3551	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ZAHA-500MG	AZITHROMYCIN	500MG	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 FILM-COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER, 1.0X10.0X1.0X3.0 TABLET BLISTER	01/07/2009
2303	NDA/MAL/HDP/3553	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	FALCIMON 25/67.5 B/L	ARTESUNATE+AMODIAQUINE	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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2304	NDA/MAL/HDP/3556	REGAL PHARMACEUTICALS 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
2305	NDA/MAL/HDP/3558	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
2306	NDA/MAL/HDP/3561	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1998

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2307	NDA/MAL/HDP/3566	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 NACL INJECTION	01/07/2008
2308	NDA/MAL/HDP/3571	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	CADIPHEN EXPECTORANT	CHLORPHENIRAMINE/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
2309	NDA/MAL/HDP/3573	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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2310	NDA/MAL/HDP/3574	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	METOZ 2.5 TABLET	METOLAZONE TABLETS USP	2.5MG	CENTAUR PHARMA PVT.LIMITED-PLANT IPLOT3,TIVIM INDUSTRIAL ESTATE,KARASWADA,MA PUSA GOA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2007
2311	NDA/MAL/HDP/3575	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
2312	NDA/MAL/HDP/3577	ASTRA PHARMA (U) LTD	ASTRA PHARMA (U) LIMITED	METOCLOPRAMIDE	METOCLOPRAMIDE	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,1.0X10.0X10.0X2.0 ML AMPOULE	01/07/2009

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2313	NDA/MAL/HDP/3578	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CINNARON 25	CINNARIZINE	25MG	REMEDICA LIMITED LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2005
2314	NDA/MAL/HDP/3580	ARISTO PHARMACEUTICALS 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
2315	NDA/MAL/HDP/3581	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	METZO 5	METOLAZONE	5MG	CENTAUR PHARMA PVT.LTD-PLANT IPLOT 3,TIVIM INDUSTRIAL ESTATE,KARASWADA,MA PUSA 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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2316	NDA/MAL/HDP/3588	ARISTO PHARMACEUTICALS 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
2317	NDA/MAL/HDP/3590	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
2318	NDA/MAL/HDP/3591	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

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2319	NDA/MAL/HDP/3592	FOURRTS (INDIA) LABORATORIES PUT LTD	DELMAW ENTERPRISES LIMITED	MEGATRIM DS	CO-TRIMOXAZOLE BP	960 MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER,1.0X1000 .0 TABLET CONTAINER	01/07/2008
2320	NDA/MAL/HDP/3593	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (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 DISTTELANGANA502307	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER,1.0X10.0 X10.0 CAPSULE BLISTER	01/07/2007
2321	NDA/MAL/HDP/3594	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	STERILE QUININE DIHYDROCHLORIDE	QUININE DIHYDROCHLORIDE	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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2322	NDA/MAL/HDP/3598	WIN-MEDICURE LTD	SURGIPHARM (U) LIMITED	MYOSPAZ	PARACETAMOL + CHLORZOXAZONE	500MG + 250MG	WIN- MEDICARE LTDMODIPURAM -250 110,UTTAR PRAADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
2323	NDA/MAL/HDP/3600	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	P-ALAXIN TABLETS	DIHYDROARTEMISININ + PIPERAQUINE PHOSPHATE	40MG + 320MG	BLISS GVS PHARMA LTDPLOT.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
2324	NDA/MAL/HDP/3601	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	HYDROKANT	HYDROCORTISONE 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

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2325	NDA/MAL/HDP/3603	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
2326	NDA/MAL/HDP/3604	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
2327	NDA/MAL/HDP/3607	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	LINOPRIL	LISINOPRIL DIHYDRATE	20MG	PHARMA INTERNATIONAL COMPANY MAIN 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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2328	NDA/MAL/HDP/3609	AMOUN PHARMACEUTICALS COMPANY	BOOTS PHARMACEUTICALS 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
2329	NDA/MAL/HDP/3610	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,1.0X100.0 TABLET CONTAINER	01/07/1998
2330	NDA/MAL/HDP/3611	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	COLDRIAL SYRUP	PARACETAMOL + CHLORPHENIRAMINE + PSEUDOEPHEDRINE	120MG+1MG+10MG	BETA HEALTHCARE INTERNATIONAL LIMITED-PLOT NUMBER LR 209/6554,MOGADISHU 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

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2331	NDA/MAL/HDP/3612	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LOSARTAS-H 12.5	LOSARTAN POTASSIUM + HYDROCHLOROTHIAZIDE	50MG + 12.5MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
2332	NDA/MAL/HDP/3613	HETERO LABS LTD	AIVEEN (U) LIMITED	ZIDOVUDINE ORAL SOLUTION	ZIDOVUDINE	50MG/5ML	HETERO LABS LTD UNIT IIII22-110 IDA JEEDIMETIA HYDERABAD ANDHRA PRADESH ,	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X240.0 ML BOTTLE	01/07/2013
2333	NDA/MAL/HDP/3614	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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2334	NDA/MAL/HDP/3618	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(WORKSHOP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0 VIAL CARTON, 1.0X10.0 VIAL CARTON	01/07/2011
2335	NDA/MAL/HDP/3619	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
2336	NDA/MAL/HDP/3620	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	HALOXEN 10 TABLETS	HALOPERIDOL BP	10MG	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER	01/07/2004

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2337	NDA/MAL/HDP/3622	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/SYRUPS/DROPS	1.0X1.0X50.0 ML BOTTLE	01/07/2008
2338	NDA/MAL/HDP/3626	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
2339	NDA/MAL/HDP/3628	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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2340	NDA/MAL/HDP/3630	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
2341	NDA/MAL/HDP/3631	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
2342	NDA/MAL/HDP/3634	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPLUS	PARACETAMOL+D EXTROMETHORPHAN HCL+ CHLORPHENIRAMINE+PHENYLEPHRINE HCL	500MG+15MG+2MG+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

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2343	NDA/MAL/HDP/3635	CIRON DRUGS & PHARMACEUTICALS 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
2344	NDA/MAL/HDP/3637	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
2345	NDA/MAL/HDP/3639	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,1.0X10.0 X10.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER	01/07/2010

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2346	NDA/MAL/HDP/3641	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
2347	NDA/MAL/HDP/3642	IND-SWIFT	PLANET PHARMACEUTICALS 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
2348	NDA/MAL/HDP/3647	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THANE INDIA	INDIA	ORAL TOPICAL SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2008

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2349	NDA/MAL/HDP/3648	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	UNICONTIN 400	THEOPHYLLINE	400MG	MODI MUNDIPHARMA (PVT) LTDMEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
2350	NDA/MAL/HDP/3649	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
2351	NDA/MAL/HDP/3650	AMOUN PHARMACEUTICALS COMPANY	BOOTS PHARMACEUTICALS 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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2352	NDA/MAL/HDP/3651	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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997
2353	NDA/MAL/HDP/3653	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 MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASHTRA 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	01/07/2008
2354	NDA/MAL/HDP/3655	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. LIMITED VANDALUR ROAD, KELAMBAKKAM-603 103, TAMIL NADU, INDIA	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X15.0 G TUBE	01/07/2008

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2355	NDA/MAL/HDP/3656	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
2356	NDA/MAL/HDP/3657	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
2357	NDA/MAL/HDP/3664	MACK BROWN PHARMACEUTICALS 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

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2358	NDA/MAL/HDP/3666	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICALS LIMITED	STROM 50	TRAMADOL HYDROCHLORIDE	50MG	LINCOLN PHARMACEUTICAL LIMITED TRIMAL ESTATE KHATRAJ KOLOL, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2008
2359	NDA/MAL/HDP/3668	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/SYRUPS/DROPS	1.0X70.0 ML BOTTLE, 1.0X140.0 ML BOTTLE	01/07/1998
2360	NDA/MAL/HDP/3669	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	CO-TRIMOXAZOLE	SULFAMETHOXAZOLE/TRIMETHOPRIM	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

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2361	NDA/MAL/HDP/3670	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
2362	NDA/MAL/HDP/3671	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	CLAVULIN TABLETS	AMOXICILLIN + CLAVULANIC ACID	500 MG + 125 MG	SMITHKLINE BEECHAM PHARMACEUTICALS, CLAR ENDON 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
2363	NDA/MAL/HDP/3672	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	NITROCONTIN 6.4	NITROGLYCERIN	6.4MG	MODI MUNDIPHARMA (PVT) LTD MEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID ORDINARY SUBLINGUAL TABLETS	1.0X25.0 TABLET CONTAINER	01/07/2008

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2364	NDA/MAL/HDP/3674	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	INTAMINE SYRUP	PROMETHAZINE HYDROCHLORIDE	5MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X5.0 L JERRYCAN	01/07/1997
2365	NDA/MAL/HDP/3677	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	IBUREN	IBUPROFEN	200MG	RENE INDUSTRIES LTD680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008
2366	NDA/MAL/HDP/3678	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

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2367	NDA/MAL/HDP/3681	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
2368	NDA/MAL/HDP/3683	FOURTS (INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	COLD TABS FORTINSA	PARACETAMOL + PHENYLEPHRINE + CHLORPHENIRAMINE + 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
2369	NDA/MAL/HDP/3685	GALPHAR LABORATORIES LTD	DAWASANA PHARMACEUTICALS LTD	ODICEF	CEFTRIAZONE	1G	ALKEM LABORATORIES LIMITED. VILLAGE THANA, BADDI, TEHSIL - NALAGARH, DISTT - SOLAN, (HP), INDIA - 173205 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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2370	NDA/MAL/HDP/3686	ACINO PHARMA AG	LABOREX UGANDA LIMITED	NEURORUBIN E™-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. 0X10.0 TABLET BLISTER	01/07/1997
2371	NDA/MAL/HDP/3687	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
2372	NDA/MAL/HDP/3688	STEDMAN PHARMACEUTICALS 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

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2373	NDA/MAL/HDP/3698	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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997
2374	NDA/MAL/HDP/3699	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
2375	NDA/MAL/HDP/3702	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORFIT-20	ATORVASTATIN	20MG	AJANTA PHARMA LIMITED 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	01/07/2005

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2376	NDA/MAL/HDP/3703	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	SONATEC	CETYLPYRIDINIUM CHLORIDE	0.05%W/V	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL TOPICAL LIQUIDS	1.0X250.0 ML BOTTLE	01/07/2014
2377	NDA/MAL/HDP/3705	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SORAL 20MG CAPSULES	TENOXCAM	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
2378	NDA/MAL/HDP/3707	INTAS PHARMACEUTICALS 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

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2379	NDA/MAL/HDP/3709	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	NIGHT & DAY -N	PARACETAMOL/ DIPHENHYDRAMINE CHLORIDE + PARACETAMOL/ PSEUDOEPHEDRINE	500MG/ 25MG +600MG/ 90MG	MEDICAL UNION PHARMA .COABU-SULTAN ISMAILIA EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2010
2380	NDA/MAL/HDP/3710	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
2381	NDA/MAL/HDP/3711	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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2382	NDA/MAL/HDP/37 12	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (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
2383	NDA/MAL/HDP/37 14	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
2384	NDA/MAL/HDP/37 17	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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

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2385	NDA/MAL/HDP/3723	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/SYRUPS/DROPS	1.0X1.0X100.0 ML BOTTLE	07/07/1997
2386	NDA/MAL/HDP/3724	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (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
2387	NDA/MAL/HDP/3725	MEDLEY PHARMACEUTICALS LTD	EUROPA HEALTHCARE (U) LTD	NEW TUXIRIL	DEXTROMETHORPHAN 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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2388	NDA/MAL/HDP/3728	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
2389	NDA/MAL/HDP/3729	MEDLEY PHARMACEUTICALS	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
2390	NDA/MAL/HDP/3730	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

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2391	NDA/MAL/HDP/3732	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	ALBASOL TABLETS 200MG	ALBENDAZOLE	200MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET STRIP	01/07/2003
2392	NDA/MAL/HDP/3734	XEPA-SOUL PATTINSON	DELMAW ENTERPRISES LIMITED	ZARICORT CREAM	MICONAZOLE + HYDROCORTISONE	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
2393	NDA/MAL/HDP/3736	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	RECTOL 125 SUPPOSITORY	PARACETAMOL	125MG	BLISS GVS PHARMA LIMITED PLOT 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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2394	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)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
2395	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, 1.0X50.0X50.0 MG VIAL	01/07/2010
2396	NDA/MAL/HDP/3741	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

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2397	NDA/MAL/HDP/3744	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,1.0X10.0X 15.0 ML BOTTLE	01/07/2001
2398	NDA/MAL/HDP/3745	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
2399	NDA/MAL/HDP/3746	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	BENDRO	BENDROFLUMETH IAZIDE	5MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO- OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THAN E INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000 .0 TABLET CONTAINER	01/07/2011

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2400	NDA/MAL/HDP/37 47	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
2401	NDA/MAL/HDP/37 53	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	MYFORTIC 180	MYCOPHENOLATE SODIUM	180MG	NORVATIS PHARMA STEIN AGSCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X12.0X10.0 TABLET BLISTER	01/07/2006
2402	NDA/MAL/HDP/37 54	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS 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

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2403	NDA/MAL/HDP/37 57	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNITRIM SUSPENSION	CO-TRIMOXAZOLE	240MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1997
2404	NDA/MAL/HDP/37 60	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED	AFRICURE PHARMACEUTICALS U LIMITED	COMPOUND MAGNESIUM TRISILICATE	MAGNESIUM TRISILICATE	370MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITEDPLOT 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
2405	NDA/MAL/HDP/37 61	COSMOS LTD	ASTRA PHARMA (U) LIMITED	RIFACOS-300	RIFAMPICIN	300 MG	COSMOS LIMITEDRANGWE ROAD, OFF LUNGA ROAD - INDUSTRIAL AREA NAROB	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000 .0 CAPSULE CONTAINER	01/07/1997

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2406	NDA/MAL/HDP/37 65	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,1.0X1 0.0X10.0 TABLET BLISTER	01/07/1997
2407	NDA/MAL/HDP/37 66	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
2408	NDA/MAL/HDP/37 67	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	AMPOXIN 500	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	UNICHEM LABORATORIES LIMITED UNIT II VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER	01/07/1999

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2409	NDA/MAL/HDP/3768	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
2410	NDA/MAL/HDP/3770	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
2411	NDA/MAL/HDP/3771	FAES FARMA S.A	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BRONQUIDIA ZINA C.R	TRIMETHOPRIM/S ULFAMETHOXAZO LE/BROMHEXINE/ SODIUM BENZOATE/TOLU BALSAM	80MG/400MG/4 MG/250MG/325 MG	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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2412	NDA/MAL/HDP/3772	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,INDIANA 46285 USA	UNITED STATES	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE	01/07/2005
2413	NDA/MAL/HDP/3773	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THAN E INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2005
2414	NDA/MAL/HDP/3778	AMOUN PHARMACEUTICALS COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	XITHRONE	AZITHROMYCIN	200MG/5ML	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL BOUR CITY, CAIRO EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X15.0 ML BOTTLE	01/07/2004

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2415	NDA/MAL/HDP/3781	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
2416	NDA/MAL/HDP/3782	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
2417	NDA/MAL/HDP/3784	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	CIPIUM	CHLORPHENIRAMINE	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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2418	NDA/MAL/HDP/3787	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
2419	NDA/MAL/HDP/3789	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
2420	NDA/MAL/HDP/3790	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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,10.0X1.0X10.0 TABLET BLISTER	01/07/2005

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2421	NDA/MAL/HDP/3793	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(WORKSHOP 406 AND 407)	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CONTAINER	01/07/2010
2422	NDA/MAL/HDP/3794	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THAN E INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2005
2423	NDA/MAL/HDP/3798	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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2424	NDA/MAL/HDP/3801	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
2425	NDA/MAL/HDP/3802	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	LEVITRA 10MG	VARDENAFIL MONOHYDROCHLORIDE TRIHYDRATE	10 MG	BAYER PHARMA AG 51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2005
2426	NDA/MAL/HDP/3803	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

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2427	NDA/MAL/HDP/3804	ACINO PHARMA AG	LABOREX UGANDA LIMITED	NEURORUBIN E IM	VITAMIN B1+VITAMIN B6+VITAMIN B12	100MG+100MG+1MG	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
2428	NDA/MAL/HDP/3806	INDOCO REMEDIES LTD	STAR PHARMACEUTICALS 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,1.0X1.0X200.0 ML BOTTLE	01/07/2007
2429	NDA/MAL/HDP/3807	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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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2430	NDA/MAL/HDP/3808	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
2431	NDA/MAL/HDP/3809	MEDLEY PHARMACEUTICALS LTD	EUROPA HEALTHCARE (U) LTD	COLDRID DAY & NIGHT	PARACETAMOL+CHLORPHENIRAMINE MALEATE+PHENYLEPRINE 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
2432	NDA/MAL/HDP/3812	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	B-TONE	PHENOBARBITONE	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

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2433	NDA/MAL/HDP/3813	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
2434	NDA/MAL/HDP/3814	MARTINDALE PHARMACEUTICALS LTD	LABOREX UGANDA LIMITED	PETHIDINE INJECTION	PETHIDINE	50MG/1ML	MARTINDALE PHARMACEUTICAL LIMITED BAMPTON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/1997
2435	NDA/MAL/HDP/3817	ROYAL PHARMA	ROYAL PHARMA 2011 LIMITED	BENZYL PENICILLIN INJECTION	BENZYL PENICILLIN SODIUM	1000000 I.U	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTDNO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSHOP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 MU VIAL	01/07/2002

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2436	NDA/MAL/HDP/38 18	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	REPOITIN	RECOMBINANT HUMAN ERYTHROPOIETIN	2000 I.U./0.5ML	SERUM INSTITUTE OF INDIA LTD212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X0.5 ML VIAL,1.0X0.5 ML PRE- FILLED SYRINGE	01/07/2012
2437	NDA/MAL/HDP/38 23	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
2438	NDA/MAL/HDP/38 25	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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2439	NDA/MAL/HDP/3827	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORFIT-10	ATORVASTATIN	10MG	AJANTA PHARMA LIMITED PAITHANMANUFACTURING 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,1.0X3.0X 10.0 TABLET BLISTER	01/07/2005
2440	NDA/MAL/HDP/3829	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	BETACOOOL	DRIED ALUMINUM HYDROXIDE/MAGNESIUM HYDROXIDE /MAGNESIUM ALUMINUM SILICATE/SIMETHI CANE	300MG / 25MG / 50MG / 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 SOLID ORDINARY TABLETS	1.0X2.0X50.0 TABLET STRIP	01/07/2006
2441	NDA/MAL/HDP/3831	ABBVIE (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	ALUVIA	LOPINAVIR+RITONAVIR	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

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2442	NDA/MAL/HDP/3833	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
2443	NDA/MAL/HDP/3835	GLAXOSMITHKLINE LTD	BETA HEALTHCARE UGANDA LIMITED	HEDEX CAPLETS	PARACETAMOL+ASPIRIN+CAFFEINE ANHYDROUS	200MG+400MG+50MG	SMITHKLINE BEECHAM (NAIROBI)NAIROBI, KENYA DINLAS PHARMA EPZ LIMITEDPLOT NO. LR 7149/121, MOMBASA ROAD, SYOKIMAU BETA HEALTHCARE INTERNATIONAL LTD - PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA P.O.BOX 42569-	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X20.0 TABLET PACK,1.0X110.0 TABLET PACK,1.0X100.0 TABLET PACK	01/07/1997
2444	NDA/MAL/HDP/3837	COSMOS LTD	ASTRA PHARMA (U) LIMITED	NITROFURANTOIN	NITROFURANTOIN	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,1.0X1000.0 TABLET CONTAINER	01/07/1998

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2445	NDA/MAL/HDP/3839	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLURID	ACETAMINOPHEN + PHENIRAMINE MALEATE	500 MG + 10.5 MG	KAMPALA PHARMACEUTICALS INDUSTIESPLOT M 444B STRETCHER NTINDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X4.0 TABLET BLISTER	01/07/2006
2446	NDA/MAL/HDP/3840	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	TORACTIN TABLETS	CYPROHEPTADINE	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
2447	NDA/MAL/HDP/3841	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

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2448	NDA/MAL/HDP/3844	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN RETARD	DICLOFENAC SODIUM	100MG	NOVARTIS PHARMA STEIN AG-SCHAFFHARVSTRASSE CH-4332 STEIN SWITZERLAND.	SWITZERLAND ITALY	ORAL SOLID RETARD TABLETS	1.0X30.0 TABLET CONTAINER	01/07/1997
2449	NDA/MAL/HDP/3845	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
2450	NDA/MAL/HDP/3846	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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2451	NDA/MAL/HDP/3850	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ANGIZAAR-H	LOSARTAN POTASSIUM + HYDROCHLOROTHIAZIDE	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
2452	NDA/MAL/HDP/3854	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
2453	NDA/MAL/HDP/3859	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS 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

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2454	NDA/MAL/HDP/3860	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE,1.0X200.0 ML BOTTLE	01/07/2009
2455	NDA/MAL/HDP/3862	TORRENT PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS 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
2456	NDA/MAL/HDP/3866	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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2457	NDA/MAL/HDP/3867	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
2458	NDA/MAL/HDP/3871	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	DOVERIN 40	DROTAVERINE HYDROCHLORIDE	40MG	INTAS PHARMACEUTICALS LIMITED PLOT 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
2459	NDA/MAL/HDP/3872	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

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2460	NDA/MAL/HDP/3873	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	CHLORPROMAZINE INJECTION B.P	CHLORPROMAZINE	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
2461	NDA/MAL/HDP/3874	AJANTA PHARMA LTD 31-0	ABACUS PHARMA (AFRICA) LIMITED	RIDMAL 40/320	DIHYDROARTEMISININ + 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
2462	NDA/MAL/HDP/3875	PHARMA 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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2463	NDA/MAL/HDP/3881	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	MOXACIL	AMOXYCILLIN TRIHYDRATE	125MG/5ML	MEDICAL UNION PHARMA .COABU-SULTAN ISMAILIA EGYPT	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2009
2464	NDA/MAL/HDP/3883	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	MYFORTIC 360	MYCOPHENOLATE SODIUM	360MG	NOVARTIS PHARMA STEIN AGSCHAFFHARVERSTRASSE CH-4332 STEIN SWITZERLAND.	SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X12.0X10.0 TABLET BLISTER	01/07/2006
2465	NDA/MAL/HDP/3886	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	DELOR	CLOBETASOL PROPIONATE	0.5 MG/G	PHARMA INTERNATIONAL COMPANYMAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE	01/07/2004

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2466	NDA/MAL/HDP/38 88	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, 1.0X1 0.0X10.0 TABLET BLISTER	01/07/2014
2467	NDA/MAL/HDP/38 91	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
2468	NDA/MAL/HDP/38 92	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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2469	NDA/MAL/HDP/3893	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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
2470	NDA/MAL/HDP/3896	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	01/07/2010
2471	NDA/MAL/HDP/3897	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	CLAVODAR	AMOXICILLIN/CLAVULANIC ACID	875MG/125MG	DAR AL DAWANA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2010

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2472	NDA/MAL/HDP/3899	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	FEDATE SYRUP	SODIUM FEREDATE + PYRIDOXINE + CYANOCOBALAMIN + 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
2473	NDA/MAL/HDP/3906	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS 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
2474	NDA/MAL/HDP/3913	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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2475	NDA/MAL/HDP/3914	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
2476	NDA/MAL/HDP/3916	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	METOCLOPRAMIDE HYDROCHLORIDE INJECTION	METOCLOPRAMIDE 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, 1.0X10.0X10.0X2.0 ML AMPOULE	01/07/2016
2477	NDA/MAL/HDP/3922	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS 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

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2478	NDA/MAL/HDP/3924	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLUFED	PARACETAMOL+P SEUDOEPHEDRINE HYDROCHLORIDE+ TRIPOLIDINE HYDROCHLORIDE	300MG+36MG+1.5MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER,1.0X250.0 TABLET CONTAINER,1.0X500.0 TABLET CONTAINER,1.0X10.0 TABLET BLISTER	01/07/1997
2479	NDA/MAL/HDP/3927	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/SYRUPS/DROPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2008
2480	NDA/MAL/HDP/3928	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,1.0X10.0 X10.0 TABLET BLISTER,1.0X50.0 X3.0 TABLET BLISTER	01/07/2004

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2481	NDA/MAL/HDP/3932	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIRAX TABLETS	CLIDINIUM BROMIDE + CHLORDIAZEPOXIDE	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
2482	NDA/MAL/HDP/3933	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	TOZAAR-50	LOSARTAN POTASSIUM	50MG	TORRENT PHARMACEUTICAL LTD AHMEDABAD-MEHSANA HIGHWAY, TALUKA-KADI, DIST. MEHSANA, INDIA-382721	INDIA	ORAL SOLID ORDINARY TABLETS	5.0X10.0 TABLET BLISTER	01/07/2001
2483	NDA/MAL/HDP/3938	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	ADRENALINE INJECTION	ADRENALINE	1MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD N-118, MIDC TARPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X1.0 ML AMPOULE	01/07/2013

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2484	NDA/MAL/HDP/3945	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS 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
2485	NDA/MAL/HDP/3947	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(BIOPHARMA DIVISION)CAMP ROAD SELAQUI-248197, DEHRADUN	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2008
2486	NDA/MAL/HDP/3948	: ALKEM LABORATORIES LIMITEDv	ABACUS PHARMA (AFRICA) LIMITED	TAXIM-O	CEFIXIME	50MG/5ML	ALKEM LABORATORIES LIMITED.-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2009

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2487	NDA/MAL/HDP/3949	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	MAGNOMINT SUSPENSION	COMPOUND MAGNESIUM TRISILICATE	N/A	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/1997
2488	NDA/MAL/HDP/3951	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
2489	NDA/MAL/HDP/3954	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	POWERCEF 1GM INJECTION	CEFTRIAZONE SODIUM	1GM	ZEISS PHARMACEUTICALS PVT. LIMITED PLOT NO. 72, EPIP I, JHARMAJIRI, BADDI (HP), INDIA WOCKHARDT LIMITED B-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

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2490	NDA/MAL/HDP/3960	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	IBUPAR	PARACETAMOL/IBUPROFEN	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
2491	NDA/MAL/HDP/3963	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	COARTEM DISPERSIBLE TABLETS	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	NOVARTIS URUNLERI TURKEYEYENISEHIR 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
2492	NDA/MAL/HDP/3965	EMCURE PHARMACEUTICALS 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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2493	NDA/MAL/HDP/3966	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,10.0X10.0 TABLET BLISTER	01/07/2008
2494	NDA/MAL/HDP/3967	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2011
2495	NDA/MAL/HDP/3969	PHARCO PHARMACEUTICALS	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/GRANULES	1.0X6.5 G SACHET	01/07/2002

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2496	NDA/MAL/HDP/3970	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
2497	NDA/MAL/HDP/3971	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 WFII	01/07/2013
2498	NDA/MAL/HDP/3983	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,1.0X50.0 X2.0 TABLET BLISTER	01/07/2008

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2499	NDA/MAL/HDP/3985	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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
2500	NDA/MAL/HDP/3987	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	ROHISOL SYRUP	LEVAMISOLE HYDROCHLORIDE	40MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X500.0 ML BOTTLE,1.0X15.0 ML BOTTLE	01/07/1997
2501	NDA/MAL/HDP/3989	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

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2502	NDA/MAL/HDP/3990	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNIXIL SYRUP	AMOXYCILLIN TRIHYDRATE	125MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X1.0X100.0 ML BOTTLE	01/07/1997
2503	NDA/MAL/HDP/3991	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008
2504	NDA/MAL/HDP/3993	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	NEM SCAB	MULTI-INGREDIENT	MULTI-INGREDIENT	NEM LABORATORIES PVT LTD 133 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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2505	NDA/MAL/HDP/3996	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOTOIN TABLETS	NITROFURANTOIN BP	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	1.0X100.0X10.0 TABLET BLISTER, 1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER	01/07/2007
2506	NDA/MAL/HDP/3998	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOKOFF SYRUP	TERBUTALINE SULPHATE +GUAIFENESIN+BROMHEXINE HYDROCHLORIDE +LEVOMENTHOL	1.25MG/5ML+50MG//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. THANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE, 1.0X1.0X60.0 ML BOTTLE	01/07/2008
2507	NDA/MAL/HDP/4000	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APIDONE SYRUP	CHLORPHENIRAMINE MALEATE/DEXAMETHASONE	2MG/5ML + 0.5MG/5ML	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL BOUR CITY, CAIRO EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X125.0 ML BOTTLE	01/07/2008

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2508	NDA/MAL/HDP/4001	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCOLD PLUS SYRUP	PARACETAMOL+PHENYLEPHRINE+CHLORPHENIRAMINE+SODIUM CITRATE	125MG/5ML+2.5MG/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.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60.0 ML BOTTLE	01/07/2008
2509	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
2510	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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2511	NDA/MAL/HDP/4007	SANOPI 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	600 + 300 +300 +300 + 600 ELISA UNITS(EU) OF LIPOPOLYSACCHARIDE (LPS)	SANOPI 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
2512	NDA/MAL/HDP/4010	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,1.0X1000.0 TABLET CONTAINER,1.0X500.0 TABLET CONTAINER,1.0X250.0 TABLET CONTAINER,1.0X10.0 TABLET BLISTER	01/07/1997
2513	NDA/MAL/HDP/4012	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

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2514	NDA/MAL/HDP/4015	CADILA PHARMACEUTICALS 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/SYRUPS/DROPS	1.0X60.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE	01/07/2005
2515	NDA/MAL/HDP/4016	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
2516	NDA/MAL/HDP/4023	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	SINAREST LINCTUS	CHLORPHENAMINE MALEATE+DEXTR OMEPHORPHAN 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

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2517	NDA/MAL/HDP/4030	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
2518	NDA/MAL/HDP/4033	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (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
2519	NDA/MAL/HDP/4035	BAYER SCHERING PHARMA	SURGIPHARM (U) LIMITED	YASMIN	DROSPIRENONE + ETHINYLESTRADIOL	3MG+0.3MG	BAYER PHARMA A.G. MULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X21.0 TABLET BLISTER	01/07/2010

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2520	NDA/MAL/HDP/4038	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
2521	NDA/MAL/HDP/4042	SWISS PARENTERALS PVT. LTD.	SHREEJI PHARMACEUTICALS LIMITED	S-CHLOR	CHLORAMPHENIC OL	1G	SWISS PARENTERALS LTD 809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2011
2522	NDA/MAL/HDP/4047	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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2523	NDA/MAL/HDP/4055	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
2524	NDA/MAL/HDP/4060	NORVATIS PHARMA AG-SWITZERLAND	LABOREX UGANDA LIMITED	TOBRADEX	TOBRAMYCIN/DEXAMETHASONE	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
2525	NDA/MAL/HDP/4062	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,1.0X3.0X10.0 TABLET BLISTER	01/07/2006

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2526	NDA/MAL/HDP/4063	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS LTD	AVOCOMB TABLET	LAMIVUDINE/ZIDOVUDINE	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
2527	NDA/MAL/HDP/4064	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	TERAFINE	TERBINAFINE	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 TABLETS	1.0X1.0X14.0 TABLET BLISTER	01/07/2010
2528	NDA/MAL/HDP/4075	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICALS LTD	CHERICOF COUGH FORMULAR	CHLORPHENIRAMINE/DEXTROMETHORPHAN HBR/PHENYLEPHRINE HCL	2MG/10MG/5MG	RANBAXY LABORATORIES LTD AT: THE MADRAS PHARMACEUTICALS 137-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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2529	NDA/MAL/HDP/4078	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	EPIGAB	PREGABALIN	75MG	DAR AI DAWANA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X14.0 CAPSULE BLISTER	01/07/2013
2530	NDA/MAL/HDP/4079	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
2531	NDA/MAL/HDP/4086	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

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2532	NDA/MAL/HDP/4091	HILTON PHARMA PVT LTD	HEALTHCARE LTD.	MYTEKA TABLETS	MONTELUKAST SODIUM	5MG	HILTON PHARMA PVT,LTD13 SECTOR 15,KORANG,IND.AREA,8TH FLOOR PROGRESSIVE PLAZA,BEAMONT RD,KARACHI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2005
2533	NDA/MAL/HDP/4093	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
2534	NDA/MAL/HDP/4095	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	IBUT-200	IBUPROFEN	200MG	LEBEN LAB PVT LTDL4 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,1.0X100.0X10.0 TABLET BLISTER	01/07/2007

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2535	NDA/MAL/HDP/4097	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
2536	NDA/MAL/HDP/4099	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS 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
2537	NDA/MAL/HDP/4100	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	NORETHISTERONE	NORETHISTERONE	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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2538	NDA/MAL/HDP/4101	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS 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
2539	NDA/MAL/HDP/4103	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 ₅₀ +10 ⁵ . ^o C CID ₅₀	GLAXO SMITHKLINE BIOLOGICALS S.ARUJE DE L'INSTITUT, 89 B-1330 RIXENSART	BELGIUM	ORAL LIQUID ORDINARY DROPS	1.0X100.0X2.0 ML VIAL (20 DOSES)	01/07/2016
2540	NDA/MAL/HDP/4104	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

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2541	NDA/MAL/HDP/41 13	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
2542	NDA/MAL/HDP/41 14	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	RINALIN SYRUP	CHLORPHENIRAMI NE MALEATE	2MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/1997
2543	NDA/MAL/HDP/41 15	REGAL PHARMACEUTICALS 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. 0X10.0 TABLET BLISTER	01/07/2007

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2544	NDA/MAL/HDP/4118	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	OCUREST-AH	PHENYLEPHRINE HYDROCHLORIDE+NAPHAZOLINE HYDROCHLORIDE+CHLORPHRENIRAMINE MALEATE+MENTHOL+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
2545	NDA/MAL/HDP/4126	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
2546	NDA/MAL/HDP/4127	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

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2547	NDA/MAL/HDP/41 28	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 LIMITED PLOT 680 KAMULI- KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE, 1.0X1.0X1 00.0 ML BOTTLE	01/07/2008
2548	NDA/MAL/HDP/41 34	INDOCO REMEDIES LTD	STAR PHARMACEUTICALS LTD	CITAL	DISODIUM HYDROGEN CITRATE	1.37G/5ML	INDOCO REMEDIES LTD B- 20, MIDC, WALUJ, AURANGABAB 431136 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2004
2549	NDA/MAL/HDP/41 38	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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2550	NDA/MAL/HDP/41 41	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
2551	NDA/MAL/HDP/41 43	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
2552	NDA/MAL/HDP/41 46	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS 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,MAHARAISTRA- 410209,INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2011

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2553	NDA/MAL/HDP/4147	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
2554	NDA/MAL/HDP/4148	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,1.0X1000.0 TABLET CONTAINER	01/07/1998
2555	NDA/MAL/HDP/4150	TORRENT PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	ANGIOPRIL-25	CAPTOPRIL	25MG	TORRENT PHARMACEUTICALS LTDINDRAD-382 721, DIST.MEHSANA,INDIA.AT: VILL.MANAKPUR,TEH.NAL AGARH,DIST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER	01/07/1997

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2556	NDA/MAL/HDP/4165	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
2557	NDA/MAL/HDP/4171	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	TOREX	MULTIINGREDIENT	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
2558	NDA/MAL/HDP/4172	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

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2559	NDA/MAL/HDP/4180	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	OSMOWIN	LACTULOSE	10G/15ML	G.S PHAMBUTOR PVT LTD.G.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
2560	NDA/MAL/HDP/4182	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS 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,1.0X50.0 X4.0 TABLET STRIP	01/07/2007
2561	NDA/MAL/HDP/4187	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	NORIGYNON	ESTRADIOL VALERATE +NORETHINDRONE 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

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2562	NDA/MAL/HDP/4188	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPRAZ	PRAZIQUANTEL	600MG	AGOG PHARMA LTD PLOT NO.33, SECTOR II, VASAI, TALUKA INDL CO-OP ESTATE LTD, GAURAI PADA, VASAI(E) DIST. THAN E 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
2563	NDA/MAL/HDP/4209	AUROBINDOM PHARMA LIMITED	GITTOES PHARMACEUTICALS 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
2564	NDA/MAL/HDP/4241	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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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2565	NDA/MAL/HDP/4275	F. HOFFMANN LA-ROCHE	LABOREX UGANDA LIMITED	AVASTIN 100MG/4ML	BEVACIZUMAB	100 MG/ 4ML	F.HOFFMANN-LA ROCHE LTD- GRENZACHERSTRASSE 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
2566	NDA/MAL/HDP/4276	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS 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
2567	NDA/MAL/HDP/4277	NABIQASIM INDUSTRIES (PVT) LIMITED	JEET PHARMACEUTICALS 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

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2568	NDA/MAL/HDP/4279	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
2569	NDA/MAL/HDP/4280	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ABACAVIR SULFATE+LAMIVUDINE	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 – MADHYA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2013
2570	NDA/MAL/HDP/4284	F. HOFFMANN LA-ROCHE	LABOREX UGANDA LIMITED	AVASTIN 400MG/4ML	BEVACIZUMAB	400MG/4ML	F.HOFFMANN-LA ROCHE LTD- GRENZACHERSTRASSE 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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2571	NDA/MAL/HDP/4287	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
2572	NDA/MAL/HDP/4291	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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
2573	NDA/MAL/HDP/4292	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

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2574	NDA/MAL/HDP/4307	ARISTO PHARMACEUTICALS 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
2575	NDA/MAL/HDP/4309	HETERO DRUGS LTD	AIVEEN (U) LIMITED	LAMIVUDINE + ZIDOVUDINE	LAMIVUDINE + ZIDOVUDINE	150MG + 300MG	HETERO LABS LTD 22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH 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	1.0X6.0 TABLET BOTTLE	01/07/2010
2576	NDA/MAL/HDP/4312	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

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2577	NDA/MAL/HDP/43 13	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
2578	NDA/MAL/HDP/43 15	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
2579	NDA/MAL/HDP/43 17	DENK PHARMA GMB H &CO. KG	BENLE CONSULT LIMITED	COLOSAR- DENK 50/12.5	LOSARTAN + HYDROCHLOROTH IAZIDE	50MG + 12.5MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER,1.0X2.0X 14.0 TABLET BLISTER	01/07/2011

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2580	NDA/MAL/HDP/43 18	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
2581	NDA/MAL/HDP/43 20	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
2582	NDA/MAL/HDP/43 24	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

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2583	NDA/MAL/HDP/43 25	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
2584	NDA/MAL/HDP/43 29	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGO-CPM	CHLORPHENIRAMI NE MALEATE	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	1.0X1.0X100.0 ML BOTTLE, 1.0X1.0X6 0.0 ML BOTTLE	01/07/2010
2585	NDA/MAL/HDP/43 30	SPARSH BIO-TECH PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	FLUCLOXACIL LIN 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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2586	NDA/MAL/HDP/4331	STEDMAN PHARMACEUTICALS 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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2010
2587	NDA/MAL/HDP/4333	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	CARVIBERG	CARVEDILOL USP	6.25MG	THE MADRAS PHARMACEUTICALS137-B,OLD MAHABALI PURAM ROAD,KARAPAKKAM,CHE NNAL INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
2588	NDA/MAL/HDP/4334	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

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2589	NDA/MAL/HDP/4335	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
2590	NDA/MAL/HDP/4339	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
2591	NDA/MAL/HDP/4348	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	MEDICLOAMP SYRUP	CLOXACILLIN+AMPICILLIN	250MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

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2592	NDA/MAL/HDP/4350	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
2593	NDA/MAL/HDP/4352	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
2594	NDA/MAL/HDP/4356	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

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2595	NDA/MAL/HDP/43 58	A.MENARINI INDUSTRIE FARMACEUTICHE S.R.I	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	LIOTON	HEPARIN SODIUM	1000I.U/G	A. MENARINI MANUFACTURING LOGISTICS AND SERVICES VIA 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
2596	NDA/MAL/HDP/43 61	: ALKEM LABORATORIES LIMITEDv	ABACUS PHARMA (AFRICA) LIMITED	TAXIM-O	CEFIXIME	200MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA ALKEM LABORATORIES LIMITED.VILLAGE THANA, BADDI, TEHSIL- NALAGARH, DISTT- SOLAN, (HP), INDIA- 173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER, 1.0X1.0X 10.0 TABLET BLISTER	01/07/2009
2597	NDA/MAL/HDP/43 62	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, 1.0X10.0 X10.0 TABLET BLISTER	01/07/2016

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2598	NDA/MAL/HDP/43 65	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
2599	NDA/MAL/HDP/43 66	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, 1.0X1 00.0X10.0 CAPSULE BLISTER	01/07/2004
2600	NDA/MAL/HDP/43 67	ASTRA ZENECA	MACNAUGHTON LIMITED	ATACAND 8MG	CANDESARTAN	8MG	ASTRA ZENECA AB, SODERTALJEGARTUNAYE GEN, SODERTALJE	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2010

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2601	NDA/MAL/HDP/4375	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	ZITHROMAX	AZITHROMYCIN DIHYDRATE	200MG/5ML	HAUPT PHARMA LATINA S.R.L LATINA-SS 156KM 47,600-04100,BORGOSAN,MICHELE	ITALY	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X30.0 ML BOTTLE,1.0X15.0 ML BOTTLE	01/07/1997
2602	NDA/MAL/HDP/4379	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
2603	NDA/MAL/HDP/4380	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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE,1.0X50.0 ML BOTTLE	01/07/1998

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2604	NDA/MAL/HDP/4383	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	ZEEMYCIN - 150	CLINDAMYCIN HYDROCHLORIDE BP	150MG	THE MADRAS PHARMACEUTICALS137-B,OLD MAHABALI PURAM ROAD,KARAPAKKAM,CHE NNAL INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2016
2605	NDA/MAL/HDP/4388	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS LIMITED	TAZOBAC	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
2606	NDA/MAL/HDP/4389	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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2607	NDA/MAL/HDP/43 90	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
2608	NDA/MAL/HDP/43 92	IND SWIFT LTD	PLANET PHARMACEUTICALS 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
2609	NDA/MAL/HDP/43 94	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

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2610	NDA/MAL/HDP/43 96	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 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2007
2611	NDA/MAL/HDP/43 98	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	SODIUM CHLORIDE	SODIUM CHLORIDE	0.9 % W/V	ACULIFE HEALTHCARE PVT. LTD VILLAGE 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
2612	NDA/MAL/HDP/43 99	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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2613	NDA/MAL/HDP/4400	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,1.0X100.0X10.3 G SACHET	01/07/1997
2614	NDA/MAL/HDP/4401	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPICEPHIN	CEFTRIAZONE DISODIUM	2G	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
2615	NDA/MAL/HDP/4402	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICALS LIMITED	CLOTRILIN	CLOTRIMAZOLE	100MG	LINCOLN PHARMACEUTICALS LTD10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI , KHATRAJ-382721, GHANDINAGAR GUJARAT , INDIA	INDIA	VAGINAL TABLETS	1.0X6.0 TABLET STRIP	01/07/2014

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2616	NDA/MAL/HDP/4404	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
2617	NDA/MAL/HDP/4406	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	01/07/2011
2618	NDA/MAL/HDP/4408	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNISTEN CREAM	CLOTRIMAZOLE	1%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/1997

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2619	NDA/MAL/HDP/44 10	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
2620	NDA/MAL/HDP/44 11	ASTRAZENECA AG	MACNAUGHTON LIMITED	ATACAND PLUS	CANDESARTAN + HYDROCHLOROTH IAZIDE	16 MG + 12.5 MG	ASTRA ZENECA AB, SODERTALJEGARTUNAYE GEN, SODERTALIE	SWEDED	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2010
2621	NDA/MAL/HDP/44 12	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

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2622	NDA/MAL/HDP/44 13	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
2623	NDA/MAL/HDP/44 15	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,1.0X2.0X 10.0 TABLET BLISTER	01/07/1997
2624	NDA/MAL/HDP/44 17	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPICEPHIN	CEFTRIAZONE 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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2625	NDA/MAL/HDP/44 18	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
2626	NDA/MAL/HDP/44 19	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIGONAL 75	HUMAN MENOPAUSAL GONADOTROPHIN	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
2627	NDA/MAL/HDP/44 25	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

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2628	NDA/MAL/HDP/44 68	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (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 AUROBINDOPHARMA LIMITED, UNIT VII, SEZ APIIC, PLOT NO. SI SURVEY NO. 425, 434, 435 &	INDIA	ORAL SOLID ORDINARY ENTERIC- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
2629	NDA/MAL/HDP/44 80	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
2630	NDA/MAL/HDP/44 83	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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2631	NDA/MAL/HDP/45 19	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, 1.0X3.0X 1.0X3.0X10.0 TABLET BLISTER	01/07/2007
2632	NDA/MAL/HDP/45 22	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, 1.0X3.0X 1.0X3.0X10.0 TABLET BLISTER	01/07/2007
2633	NDA/MAL/HDP/45 23	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

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2634	NDA/MAL/HDP/4526	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER, 1.0X20.0X3.0 TABLET BLISTER	01/07/2011
2635	NDA/MAL/HDP/4528	ARISTO PHARMACEUTICALS 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
2636	NDA/MAL/HDP/4546	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD	TATA UGANDA LIMITED	CHLORAMPHENICOL INJECTION IG	CHLORAMPHENICOL 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

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2637	NDA/MAL/HDP/45 53	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
2638	NDA/MAL/HDP/45 56	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
2639	NDA/MAL/HDP/45 59	MSN LABORATORIES PRIVATE LIMITED,	METRO PHARMACEUTICALS 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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2640	NDA/MAL/HDP/4561	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS 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
2641	NDA/MAL/HDP/4568	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
2642	NDA/MAL/HDP/4571	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ASPICLOX	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	ASTRA LIFE CARE (INDIA) PVT.LTDPLOT 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

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2643	NDA/MAL/HDP/4575	FDC LTD	AIVEEN (U) LIMITED	PYRICORT EYE/EAR DROPS	DEXAMETHASONE +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
2644	NDA/MAL/HDP/4581	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
2645	NDA/MAL/HDP/4587	CIRON DRUGS AND PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	CIRATRO	ATROPINE	1MG/ML	CIRON DRUGS AND PHARMACEUTICALS PVT LTDN-118 M.I.D.C, TAAPUR,BOISAR,DIST.THANE MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X1.0 ML AMPOULE	01/07/2008

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2646	NDA/MAL/HDP/4588	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS 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
2647	NDA/MAL/HDP/4589	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
2648	NDA/MAL/HDP/4591	S KAGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	SILVER KANT	SILVER SULPHADIAZINE USP	1%W/W	S.KANT HEALTHCARE LTD 1802-18-5 GIDC PHASE III, VAPI-396195, GUJARAT INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2009

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2649	NDA/MAL/HDP/45 92	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICALS 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
2650	NDA/MAL/HDP/45 93	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	ERYTHROKAN T-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
2651	NDA/MAL/HDP/45 95	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICALS 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,1.0X3.0X 10.0 TABLET BLISTER	01/07/2010

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2652	NDA/MAL/HDP/4598	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 TABLETS	1.0X6.0 TABLET BLISTER	01/07/2011
2653	NDA/MAL/HDP/4602	ELI-LILLY (SUISSE) SA	LABOREX UGANDA LIMITED	HUMALOG MIX 50	INSULIN LISPRO	100 .IU(50 I.U.+50 I.U)	LILLY FRANCE SA FRANCE	FRANCE	PARENTERAL ORDINARY S C VIALS	1.0X3.0 ML VIAL, 1.0X5.0 ML VIAL	01/07/2000
2654	NDA/MAL/HDP/4603	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

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2655	NDA/MAL/HDP/4605	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGODRYL SYRUP	BROMHEXINE HCL+DEXTROMET HORPHAN HBR+AMMONIUM CHLORIDE+MENTHOL	4MG/5ML+5MG/5ML+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.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60.0 ML BOTTLE	01/07/2009
2656	NDA/MAL/HDP/4606	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	ROVAS 10	ROSUVASTATIN	10MG	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
2657	NDA/MAL/HDP/4609	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYCORT	HYDROCORTISONE	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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2658	NDA/MAL/HDP/4611	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/SYRUPS/DROPS	1.0X70.0 ML BOTTLE	01/07/2011
2659	NDA/MAL/HDP/4614	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
2660	NDA/MAL/HDP/4617	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

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2661	NDA/MAL/HDP/4619	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CHLORAMPHENICOL SODIUM SUCCINATE	CHLORAMPHENICOL 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
2662	NDA/MAL/HDP/4620	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
2663	NDA/MAL/HDP/4622	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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2664	NDA/MAL/HDP/4623	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	LOPERAREN	LOPERAMIDE HYDROCHLORIDE	2MG	RENE INDUSTRIAL LTD RENE INDUSTRIES LTD, PLOT 680, KAMULI-KIREKA KAMPALA UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2007
2665	NDA/MAL/HDP/4627	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
2666	NDA/MAL/HDP/4629	DAWA LIMITED	SUPER MEDIC LTD	ORACEF	CEFALEXIN MONOHYDRATE	125MG/5ML	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1X100 ML BOTTLE	01/07/2015

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2667	NDA/MAL/HDP/4634	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
2668	NDA/MAL/HDP/4641	YURIA PHARM LTD-UKRAINE	PHARMA VILLE LIMITED	RHEOSORBIL ACT	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
2669	NDA/MAL/HDP/4645	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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2670	NDA/MAL/HDP/4646	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,1.0X1.0X1 00.0 ML BOTTLE	01/07/2013
2671	NDA/MAL/HDP/4650	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
2672	NDA/MAL/HDP/4652	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	SII TETANUS TOXOID VACCINE	TETANUS TOXOID ADSORBED ON ALUMINIUM PHOSPHATE	≥ 5 LF (≥ 40 IU) ON ≤ 1.25 MG OF ALUMINIUM PHOSPHATE	SERUM INSTITUTE OF INDIA LTD212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0 ML AMPOULE (1 DOSE AMPOULE),1.0X1 0.0 ML VIAL (20 DOSE VIAL)	01/07/1997

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2673	NDA/MAL/HDP/4658	PT SANBE FARMA	MEDVIN PHARMA LIMITED	MEROSAN 0.5	MEROPENEM	0.5G	PT SANBE FARMAJI LEUWIGAJAH 162 CIMINDI CIMAHU WEST JAVA INDONESIA	INDONESIA	PARENTERAL ORDINARY DRY VIALS	1.0X0.5 G VIAL	01/07/2014
2674	NDA/MAL/HDP/4661	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
2675	NDA/MAL/HDP/4666	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (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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2676	NDA/MAL/HDP/4669	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
2677	NDA/MAL/HDP/4670	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
2678	NDA/MAL/HDP/4675	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (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

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2679	NDA/MAL/HDP/4677	: ALKEM LABORATORIES LIMITEDv	ABACUS PHARMA (AFRICA) LIMITED	ZOCEF	CEFUROXIME	125MG/5ML	ALKEM LABORATORIES LIMITED.-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X1.0X30.0 ML BOTTLE,1.0X70.0 ML BOTTLE	01/07/2011
2680	NDA/MAL/HDP/4678	: ALKEM LABORATORIES LIMITEDv	ABACUS PHARMA (AFRICA) LIMITED	ZOCEF-500	CEFUROXIME AXETIL	500MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA ALKEM LABORATORIES LIMITED.VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2009
2681	NDA/MAL/HDP/4680	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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2011

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2682	NDA/MAL/HDP/4690	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYPEN	PHENOXYMETHYL PENICILLIN	250MG	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
2683	NDA/MAL/HDP/4694	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
2684	NDA/MAL/HDP/4697	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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2685	NDA/MAL/HDP/4700	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
2686	NDA/MAL/HDP/4701	AFRICURE PHARMACEUTICALS (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
2687	NDA/MAL/HDP/4702	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

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2688	NDA/MAL/HDP/4703	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABGYL	METRONIDAZOLE	500MG	ABACUS PARENTERAL DRUGS LTD.PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, <input type="checkbox"/> MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	01/07/2011
2689	NDA/MAL/HDP/4704	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (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
2690	NDA/MAL/HDP/4705	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (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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2691	NDA/MAL/HDP/4706	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
2692	NDA/MAL/HDP/4707	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	DICLOMOL INJECTION	DICLOFENAC SODIUM	25MG/ML	WIN MEDICARE PVT LIMITED MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X3.0 ML AMPOULE	01/07/1998
2693	NDA/MAL/HDP/4710	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

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2694	NDA/MAL/HDP/47 12	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
2695	NDA/MAL/HDP/47 15	BLUE CROSS LABARATORIES LIMITED	STAR PHARMACEUTICALS 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
2696	NDA/MAL/HDP/47 17	BLUE CROSS LABARATORIES LIMITED	STAR PHARMACEUTICALS 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,1.0X2.0X 3.0X10.0 TABLET BLISTER,1.0X10.0 X3.0X10.0 TABLET BLISTER	01/07/2008

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2697	NDA/MAL/HDP/47 18	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
2698	NDA/MAL/HDP/47 19	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
2699	NDA/MAL/HDP/47 21	PT SAMBE FARMA	MEDVIN PHARMA LIMITED	MEGABAL	MECOBALAMIN	5000MCG	PT SANBE FARMA,UNIT 1JI INDUSTRI NO.9 LEUWIGAJAH CIMINDI CIMAHI WEST JAVA,INDONESIA	INDONESIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	01/07/2011

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2700	NDA/MAL/HDP/47 23	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	MEGYL SUSPENSION	METRONIDAZOLE BENZOATE	200MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/1997
2701	NDA/MAL/HDP/47 25	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	MEGYL TABLET	METRONIDAZOLE	200MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X250. 0 TABLET CONTAINER,1.0X1 000.0 TABLET CONTAINER	01/07/1997
2702	NDA/MAL/HDP/47 26	MACK BROWN PHARMACEUTICAL S PVT LIMITED	SHURIK LTD	ADB MIN MULTIPOWER R	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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2703	NDA/MAL/HDP/4731	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	MENAFRIVAC	MENINGOCOCCAL A CONJUGATE VACCINE	10MCG/ 0.5ML + 10-33MCG/0.5ML	SERUM INSTITUTE OF INDIA LTD212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X10.0 DOSE VIAL + 1*5ML AMPOULE OF DILUENT	01/07/2011
2704	NDA/MAL/HDP/4738	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
2705	NDA/MAL/HDP/4739	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS LIMITED	MERO	MEROPENEM	1G	SWISS PARENTERALS LIMITED (UNIT-2) PLOT NO. 402, 412-414 KERALA INDUSTRIAL ESTATE, GIDC, NEAR BAVLA, AHMEDABAD,382220, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2011

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2706	NDA/MAL/HDP/4744	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
2707	NDA/MAL/HDP/4745	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PIPZO	PIPERACILLIN + TAZOBACTAM	4.5G	ALKEM LABS LTD.- VILLAGE THANA, BADDI, THE NALAGARH, DIST SOLAN (HP) 173205	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X4.5 G VIAL + STERILIZED WATER FOR INJECTION	01/07/2014
2708	NDA/MAL/HDP/4748	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	ACICONE-S CHEWABLE TABLET	MAGALDRATE+SIMETHICONE	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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2709	NDA/MAL/HDP/4749	PT SANBE FARMA	MEDVIN PHARMA LIMITED	MEROSAN	MEROPENEM	1G	PT SANBE FARMAJI LEUWIGAJAH 162 CIMINDI CIMAHI WEST JAVA INDONESIA	INDONESIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2012
2710	NDA/MAL/HDP/4751	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THAN E INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X1 0.0X10.0 TABLET BLISTER,1.0X100. 0X10.0 TABLET BLISTER	01/07/2009
2711	NDA/MAL/HDP/4757	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,1.0X3.0X 10.0 TABLET BLISTER	01/07/1998

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2712	NDA/MAL/HDP/4758	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
2713	NDA/MAL/HDP/4759	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (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
2714	NDA/MAL/HDP/4766	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2001

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2715	NDA/MAL/HDP/4769	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOBEX	MEBENDAZOLE	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 CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER, 1.0X100.0X10.0 TABLET BLISTER	01/07/2009
2716	NDA/MAL/HDP/4774	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FERROFOL VIT-Z	FERROUS SULPHATE+FOLIC ACID+ASCORBIC ACID+THIAMINE MONONITRATE+RIBOTLAVINE+PYRIDOXINE HCL+NICOTINAMIDE+ZINC	150MG+0.5MG+50MG+2MG+2MG+1MG+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
2717	NDA/MAL/HDP/4775	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

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2718	NDA/MAL/HDP/47 81	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,1.0X1 0.0X10.0 TABLET BLISTER	01/07/2001
2719	NDA/MAL/HDP/47 84	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
2720	NDA/MAL/HDP/47 88	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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2721	NDA/MAL/HDP/4794	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
2722	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
2723	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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2724	NDA/MAL/HDP/4800	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
2725	NDA/MAL/HDP/4801	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	DAZEL KIT	FLUCONAZOLE + AZITHROMYCIN + SECNIDAZOLE	150MG + 1G + 1G	AJANTA PHARMA LIMITED PAITHANMANUFACTURING 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
2726	NDA/MAL/HDP/4804	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	CLAVODAR	AMOXICILLIN + CLAVULANIC	200MG + 28MG /5ML	DAR AL DAWANA'UR PLANT AMMAN	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X70.0 ML BOTTLE	01/07/2012

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2727	NDA/MAL/HDP/4806	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THAN E INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2009
2728	NDA/MAL/HDP/4807	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOFORMIN	METFORMIN	500MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THAN E INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2011
2729	NDA/MAL/HDP/4809	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCORT SKIN CREAM	HYDROCORTISONE	0.1%W/W	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THAN E INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2013

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2730	NDA/MAL/HDP/4811	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOGYL	METRONIDAZOLE	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	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER	01/07/2009
2731	NDA/MAL/HDP/4812	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2001
2732	NDA/MAL/HDP/4813	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER,10.0X10.0 TABLET BLISTER	01/07/1998

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2733	NDA/MAL/HDP/4815	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
2734	NDA/MAL/HDP/4817	CYANO PHARMA(P) LTD	RENE PHARMACY LTD	METOCLOPRAMIDE TABLETS	METOCLOPRAMIDE	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
2735	NDA/MAL/HDP/4818	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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2736	NDA/MAL/HDP/4819	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
2737	NDA/MAL/HDP/4821	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
2738	NDA/MAL/HDP/4823	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

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2739	NDA/MAL/HDP/4826	UNIQUE PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS 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
2740	NDA/MAL/HDP/4828	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS 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
2741	NDA/MAL/HDP/4830	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS 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 LTD)-	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/1997

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2742	NDA/MAL/HDP/4832	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS 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
2743	NDA/MAL/HDP/4834	AUROBINDO PHARMA LTD UNIT VII	GITTOES PHARMACEUTICALS LIMITED	FINAGEN	FINASTERIDE	5MG	AUROBINDO PHARMA LIMITED, UNIT II SURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELEGANA (STATE)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2004
2744	NDA/MAL/HDP/4836	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	METRON	METRONIDAZOLE	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 FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X100.0X10.0 TABLET BLISTER, 1.0X1000.0 TABLET CONTAINER	01/07/2009

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2745	NDA/MAL/HDP/4838	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
2746	NDA/MAL/HDP/4839	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	ANOMEX	ZINC OXIDE+LIDOCAINE +HYDROCORTISONE+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,1.0X2.0X 5.0 SUPPOSITORY BLISTER	01/07/2007
2747	NDA/MAL/HDP/4841	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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2748	NDA/MAL/HDP/4854	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
2749	NDA/MAL/HDP/4855	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS 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
2750	NDA/MAL/HDP/4856	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,1.0X20.0 X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2001

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2751	NDA/MAL/HDP/48 58	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
2752	NDA/MAL/HDP/48 63	MEDICAL UNION PHARMACUITICALS	KARURI PHARMACEUTICALS 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
2753	NDA/MAL/HDP/48 65	MEDICAL UNION PHARMACUITICALS	KARURI PHARMACEUTICALS 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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2754	NDA/MAL/HDP/4867	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS 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
2755	NDA/MAL/HDP/4868	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
2756	NDA/MAL/HDP/4872	DAWA LIMITED	SUPER MEDIC LTD	MICLOCIN CREAM	MICONAZOLE NITRATE + CLOBETASOL PROPRIONATE + GENTAMICIN	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

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2757	NDA/MAL/HDP/4873	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
2758	NDA/MAL/HDP/4874	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
2759	NDA/MAL/HDP/4875	MARIE STOPES UGANDA LIMITED	MARIE STOPES 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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2760	NDA/MAL/HDP/4876	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
2761	NDA/MAL/HDP/4877	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
2762	NDA/MAL/HDP/4880	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

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2763	NDA/MAL/HDP/4891	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	ASPEC TABLET	ASPIRIN+PARACETAMOL+CAFFEINE ANHYDROUS	150MG+250MG+300MG	REGAL PHARMACEUTICALS LTD OFF BABA DOGO RD, RUARAKA, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER, 1.0X500.0 TABLET CONTAINER, 1.0X100.0 TABLET CONTAINER	01/07/1997
2764	NDA/MAL/HDP/4895	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (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
2765	NDA/MAL/HDP/4903	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CMT-TABLETS	MAGNESIUM TRISILICATE+DRIED ALUMINIUM HYDROXIDE+PEPPERMINT 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. THANE 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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2766	NDA/MAL/HDP/4904	NOVO NORDISK	PHILLIPS PHARMACEUTICALS (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
2767	NDA/MAL/HDP/4905	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
2768	NDA/MAL/HDP/4906	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

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2769	NDA/MAL/HDP/4907	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
2770	NDA/MAL/HDP/4908	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
2771	NDA/MAL/HDP/4909	AXA PARENTERALS LTD	VITACARE LIMITED	AXAGYL	METRONIDAZOLE	0.5%W/V	AXA PARENTERAL LIMITED PLOT 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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2772	NDA/MAL/HDP/49 10	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
2773	NDA/MAL/HDP/49 11	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	MOFILET-500	MYCOPHENOLATE 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
2774	NDA/MAL/HDP/49 15	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

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2775	NDA/MAL/HDP/49 17	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL EVILINE FORTE SUSPENSION	MAGNESSIUM HYDROXIDE +ALUMINIUM HYDROXIDE+SIME THICONE	400MG/5ML+400 MG/5ML+40MG/ 5ML	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
2776	NDA/MAL/HDP/49 18	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
2777	NDA/MAL/HDP/49 20	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,1.0X1 0.0X10.0 TABLET BLISTER	01/07/2011

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2778	NDA/MAL/HDP/4922	KOPRAN LIMITED	TATA UGANDA LIMITED	CIPROQUIN-500	CIPROFLOXACIN	500MG	KOPRAN LIMITED VILLAGE-SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	10.0X10.0 TABLET BLISTER	01/07/1999
2779	NDA/MAL/HDP/4924	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2001
2780	NDA/MAL/HDP/4926	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

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2781	NDA/MAL/HDP/49 27	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
2782	NDA/MAL/HDP/49 29	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
2783	NDA/MAL/HDP/49 32	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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2784	NDA/MAL/HDP/4933	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,1.0X250.0 CAPSULE CONTAINER,1.0X1000.0 CAPSULE CONTAINER	01/07/1997
2785	NDA/MAL/HDP/4936	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
2786	NDA/MAL/HDP/4937	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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2787	NDA/MAL/HDP/49 39	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
2788	NDA/MAL/HDP/49 40	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THAN E INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X1 0.0X10.0 TABLET BLISTER	01/07/2006
2789	NDA/MAL/HDP/49 43	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

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2790	NDA/MAL/HDP/4944	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
2791	NDA/MAL/HDP/4946	ESAPHARM SRL	BYAMAKA PHARMACEUTICAL COMPANY LTD	MOVATE	CLOBETASOL	0.05%W/W	ESAPHARMA SRLVIA DE GASPERI, 13-20066 MELZO (MILAN) ITALY	ITALY	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	01/07/1999
2792	NDA/MAL/HDP/4949	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN DRY COUGH DM	DEXTROMETHORPHAN HYDROBROMIDE	15MG/ML	JOHNSON&JOHNSON 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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2793	NDA/MAL/HDP/4951	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN ORIGINAL	DIPHENHYDRAMINE HYDROCHLORIDE + AMMONIUM CHLORIDE	12.5 MG/5ML + 125 MG/5ML	JOHNSON&JOHNSON 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
2794	NDA/MAL/HDP/4952	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN WITH CODEINE	DIPHENHYDRAMINE HCL + AMMONIUM CHLORIDE + CODEINE PHOSPHATE	12.5MG/5ML +125MG/5ML +10MG/5ML	JOHNSON&JOHNSON 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
2795	NDA/MAL/HDP/4953	MEGA LIFESCIENCES (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

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2796	NDA/MAL/HDP/4955	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
2797	NDA/MAL/HDP/4956	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS 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
2798	NDA/MAL/HDP/4957	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS 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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2799	NDA/MAL/HDP/4958	TROIKAA PHARMACEUTICALS 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
2800	NDA/MAL/HDP/4959	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	CONTUS PAEDIATRIC LINCTUS	CHLORPHENIRAMINE / PHENYLEPHRINE / DEXTROMETHORPHAN	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
2801	NDA/MAL/HDP/4962	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

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2802	NDA/MAL/HDP/4964	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	CONTUS PLUS PAEDIATRIC SUSPENSION	CHLORPHENAMINE + PHENYLEPHRINE + PARACETAMOL	1MG+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
2803	NDA/MAL/HDP/4965	BETA HEALTHCARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	BETAFEN SYRUP	IBUPROFEN	100MG/5ML	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	1.0X60.0 ML BOTTLE, 1.0X100.0 ML BOTTLE	01/07/2001
2804	NDA/MAL/HDP/4966	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	CONTUS-650	CHLORPHENIRAMINE + PHENYLEPHRINE + PARACETAMOL	2MG + 5MG + 650MG	STEDMAN PHARMACEUTICALS PVT LIMITED NO. 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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2805	NDA/MAL/HDP/4968	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	FRUSEMIDE INJECTION	FUROSEMIDE	10MG/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	01/07/2008
2806	NDA/MAL/HDP/4969	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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
2807	NDA/MAL/HDP/4971	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE 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

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2808	NDA/MAL/HDP/4972	JOHNSON & JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (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,1.0X500.0 ML CONTAINER	01/07/2001
2809	NDA/MAL/HDP/4973	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
2810	NDA/MAL/HDP/4974	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,1.0X1000.0 TABLET CONTAINER	01/07/1998

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2811	NDA/MAL/HDP/4976	MEGA LIFESCIENCES (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
2812	NDA/MAL/HDP/4979	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	FUROSEMIDE	FUROSEMIDE	10MG/ML	CIRON DRUGS AND PHARMACEUTICALS PVT LTDN-118 M.I.D.C, TAAPUR,BOISAR,DIST.THANE MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE	01/07/2010
2813	NDA/MAL/HDP/4982	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,1.0X1000.0 TABLET CONTAINER	01/07/1998

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2814	NDA/MAL/HDP/4983	PT SAMBE FARMA	MEDVIN PHARMA LIMITED	PELASTIN	IMIPENEM + CILASTATIN	500MG + 500MG	PT SANBE FARMAJI LEUWIGAJAH I62 CIMINDI CIMAHI WEST JAVA INDONESIA	INDONESIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2011
2815	NDA/MAL/HDP/4998	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	HYAN	LEVONORGESTREL	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, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM TAL-	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X28.0 TABLET BLISTER	01/07/2006
2816	NDA/MAL/HDP/4999	UNIQUE PHARMACEUTICAL LABORATORIES	PLANET PHARMACEUTICALS 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

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2817	NDA/MAL/HDP/5002	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
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,MOGADISHU 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/5008	UNIMED INDIA	ASTRA PHARMA (U) LIMITED	COLDAFEX	MULTI-INGREDIENT	MULTI-INGREDIENT	UNIMED INDIA86,MAROL COOPERATIVE ESTATE, M.V ROAD ANDHERE(E)MUMBAI 400059	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2005
2821	NDA/MAL/HDP/5010	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
2822	NDA/MAL/HDP/5011	UNIMED INDIA	ASTRA PHARMA (U) LIMITED	COLDAFEX TABLETS	MULTI-INGREDIENT	MULTI-INGREDIENT	UNIMED INDIA86,MAROL COOPERATIVE ESTATE, M.V ROAD ANDHERE(E)MUMBAI 400059	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X4.0 TABLET STRIP,1.0X10.0X10.0 TABLET BLISTER	01/07/1997

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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
2824	NDA/MAL/HDP/5015	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	COLD CAP 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	COLD CAP 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/5018	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/5019	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	COLOSPASMIN FORTE	MEBEVERINE	135MG	EGYPTIAN INT.PHARMACEUTICAL INDUSTRIES CO (E.I.P.C.O)- EGYPTIAN INT.PHARMACEUTICAL INDUSTRIES CO (E.I.P.C.O)	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X20.0 TABLET BLISTER	01/07/2011
2828	NDA/MAL/HDP/5021	BAYER SCHERING PHARMA FRANCE	SURGIPHARM (U) LIMITED	COMBINATION 3	ETHINYL ESTRADIOL+ LEVONORGESTREL +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

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2829	NDA/MAL/HDP/5028	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
2830	NDA/MAL/HDP/5031	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
2831	NDA/MAL/HDP/5032	REGAL PHARMACEUCIALS LTD	REGAL PHARMA (U) LTD	DELAISED DRY COUGH SYRUP (NON DROWSY)	DEXTROMETHORP HAN	7.5MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2004

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2832	NDA/MAL/HDP/5033	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	MEBFIL TABLETS	MEBENDAZOLE	100MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/1997
2833	NDA/MAL/HDP/5035	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
2834	NDA/MAL/HDP/5038	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	M-CAM TABLETS	MELOXICAM	15MG	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	1.0X4.0X5.0X10.0 TABLET BLISTER	01/07/2002

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2835	NDA/MAL/HDP/5041	NORVATIS PHARMA AG-SWITZERLAND	LABOREX UGANDA LIMITED	MAXITROL	DEXAMETHASONE /NEOMYCIN/POLYMYXIN 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
2836	NDA/MAL/HDP/5042	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,1.0X500.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER	01/07/1998
2837	NDA/MAL/HDP/5043	NORVATIS PHARMA AG-SWITZERLAND	LABOREX UGANDA LIMITED	MAXITROL	DEXAMETHASONE /NEOMYCIN/POLYMYXIN B	0.1%W/W+3500I.U/ML+6000I.U/ML	ALCON COUVREUR NVRIJKSWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/1997

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2838	NDA/MAL/HDP/5049	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	GIZLAN PLUS 300/12.5	IRBESARTAN/HYDROCHLOROTHIAZIDE	300MG/12.5MG	DAR AL DAWANA UR PLANT, AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013
2839	NDA/MAL/HDP/5050	NORVATIS PHARMA AG-SWITZERLAND	LABOREX UGANDA LIMITED	MAXIDEX	DEXAMETHASONE	0.1%W/V	ALCON COUVREUR NVRIJKSWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/1997
2840	NDA/MAL/HDP/5053	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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2841	NDA/MAL/HDP/5055	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
2842	NDA/MAL/HDP/5064	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
2843	NDA/MAL/HDP/5065	N.V. ORGANON	SURGIPHARM (U) LIMITED	MARVELON	DESOGESTREL/ETHINYLESTRADIOL	150MG/30MG	N.V. ORGANONKLOOSTERSTRAAT 6, 5349 AB OSS, THE NETHERLAND	NETHERLANDS	ORAL SOLID ORDINARY TABLETS	1.0X100.0X1.0X28 .0 TABLET BLISTER	01/07/2015

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2844	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
2845	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
2846	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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2847	NDA/MAL/HDP/5073	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	DEXONA EYE/EAR DROP	DEXAMATHASONE SODIUM PHOSPHATE+NEOMYCIN 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
2848	NDA/MAL/HDP/5074	ZYDUS LIFESCIENCES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DEXONA INJECTION	DEXAMETHASONE 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
2849	NDA/MAL/HDP/5076	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	DEXTRACIN EYE DROPS	DEXAMETHASONE + 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

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2850	NDA/MAL/HDP/5078	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS 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
2851	NDA/MAL/HDP/5079	GLENMARK PHARMACEUTICAL 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
2852	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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2853	NDA/MAL/HDP/5086	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	GLIFIL M FORT	GLIBENCLAMIDE + METFORMIN HYDROCHLORIDE	5MG+500MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
2854	NDA/MAL/HDP/5092	MICRO LABS LTD 92 SIPCOT	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DIAPRIDE	GLIMEPIRIDE	2MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSUR R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
2855	NDA/MAL/HDP/5095	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

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2856	NDA/MAL/HDP/5096	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
2857	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
2858	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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2859	NDA/MAL/HDP/5102	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,1.0X6.0X15.0 TABLET BLISTER,1.0X30.0 TABLET BLISTER	01/07/2010
2860	NDA/MAL/HDP/5103	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
2861	NDA/MAL/HDP/5104	NOVO NORDISK PHARMA GULF FZ-LC	PHILLIPS PHARMACEUTICALS (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	DENMARK BRAZIL FRANCE	PARENTERAL ORDINARY PRE-FILLED PENS	1.0X5.0X3.0 ML PREFILLED PEN	01/07/2014

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2862	NDA/MAL/HDP/5106	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
2863	NDA/MAL/HDP/5107	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
2864	NDA/MAL/HDP/5109	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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2865	NDA/MAL/HDP/5110	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
2866	NDA/MAL/HDP/5112	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
2867	NDA/MAL/HDP/5115	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	INDOS-25	INDOMETHACIN	25MG	AGOG PHARMA LTDPLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THAN E INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1000.0 CAPSULE CONTAINER,20.0X 5.0 CAPSULE BLISTER,1.0X10.0 X10.0 CAPSULE BLISTER	01/07/2000

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2868	NDA/MAL/HDP/5117	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
2869	NDA/MAL/HDP/5119	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
2870	NDA/MAL/HDP/5120	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	GLYFORMIN 500 TABLETS	METFORMIN	500MG	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER	01/07/1999

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2871	NDA/MAL/HDP/5121	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	DICLORAN GEL	DICLOFENAC DIETHYLAMMONIUM	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
2872	NDA/MAL/HDP/5122	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	KOFAREST SYRUP	SALBUTAMOL SULPHATE/AMBR OXOL SULPHATE/GUAFFENESIN/MENTHOL	2MG+30MG+100MG+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
2873	NDA/MAL/HDP/5124	GLAXOSMITHKLINE LTD BELGIUM	UNITED HEALTHCARE DISTRIBUTORS LTD	INFANRIX-HEXA	DIPHTHERIA TOXOID+TETANUS TOXOID+PERTUSSIS TOXOID(PT)+FILAMENTOUS HAEMAGGLUTININ(FHA)+PERTACTIN(69KDA OMP)+HBSAG PURIFIED,INACTIVATED POLIO VIRUS TYPE	MIN 30 I.U+MIN 40 I.U+25MG+25MG+8MG+10MG,40DU+8DU+32DU+10MG	GLAXOSMITHKLINE BOIOLOGICALSS.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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2874	NDA/MAL/HDP/5125	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
2875	NDA/MAL/HDP/5128	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
2876	NDA/MAL/HDP/5129	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS 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

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2877	NDA/MAL/HDP/5130	UNIQUE PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	DICLORAN MS GEL	DICLOFENAC+METHYL SALICYLATE+METHOL	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
2878	NDA/MAL/HDP/5131	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
2879	NDA/MAL/HDP/5133	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GONAL-F PEN 900IU/1.5ML(66MCG/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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2880	NDA/MAL/HDP/5134	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	GOODMORNING COUGH TABLETS	MULTIINGREDIENT	N/A	BETA HEALTHCARE INTERNATIONAL LTD - PLOT NO.209/6554,MOGADISHU 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
2881	NDA/MAL/HDP/5135	SK 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
2882	NDA/MAL/HDP/5136	BETA HEALTHCARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	GOODMORNING LUNG TONIC	MULTIINGREDIENT	N/A	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	1.0X60.0 ML BOTTLE,1.0X50.0 ML BOTTLE	01/07/1997

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2883	NDA/MAL/HDP/51 39	NOVO NORDISK	PHILLIPS PHARMACEUTICALS (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	DENMARK BRAZIL FRANCE	PARENTERAL ORDINARY CARTRIDGES	1.0X5.0X3.0 ML PREFILLED PEN,1.0X5.0X1.5 ML PREFILLED PEN	01/07/1997
2884	NDA/MAL/HDP/51 42	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	INTAMINE CREAM	MEPYRAMINE MALEATE	2%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE,1.0X400.0 G TUBE	01/07/1997
2885	NDA/MAL/HDP/51 43	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

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2886	NDA/MAL/HDP/51 46	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
2887	NDA/MAL/HDP/51 47	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
2888	NDA/MAL/HDP/51 49	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	GRAVINATE SYRUP	DIMENHYDRINATE	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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2889	NDA/MAL/HDP/5150	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS 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
2890	NDA/MAL/HDP/5153	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	GRAVINATE TABLETS	DIMENHYDRINATE	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
2891	NDA/MAL/HDP/5154	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	BETASIL PAEDIATRIC SYRUP	IPECACUANHA TINCTURE	0.5ML	BETA HEALTHCARE INTERNATIONAL LTD - PLOT NO.209/6554,MOGADISH U 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

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2892	NDA/MAL/HDP/5155	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
2893	NDA/MAL/HDP/5157	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
2894	NDA/MAL/HDP/5161	AFRICURE PHARMACEUTICALS (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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2895	NDA/MAL/HDP/5164	COSMOS LTD	ASTRA PHARMA (U) LIMITED	BROMSAL EXPECTORANT	SALBUTAMOL SULPHATE+BROMHEXINE HYDROCHLORIDE+GUAIFENESIN+MENTHOL	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
2896	NDA/MAL/HDP/5165	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	GRISEOFULVIN 500 TABLETS	GRISEOFULVIN	500MG	REMEDICA LIMITED LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X100.0 TABLET CONTAINER	01/07/2003
2897	NDA/MAL/HDP/5167	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS 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

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2898	NDA/MAL/HDP/5169	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
2899	NDA/MAL/HDP/5170	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS 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
2900	NDA/MAL/HDP/5171	TROIKAA PHARMACEUTICALS 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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2901	NDA/MAL/HDP/5176	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
2902	NDA/MAL/HDP/5177	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
2903	NDA/MAL/HDP/5179	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

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2904	NDA/MAL/HDP/5180	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	ISORYN DROPS (PAEDIATRIC)	EPHEDRINE HYDROCHLORIDE	5MG/ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	NASAL TOPICAL DROPS	1.0X15.0 ML BOTTLE	01/07/1997
2905	NDA/MAL/HDP/5182	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	ISORYN DROPS (ADULT)	EPHEDRINE HYDROCHLORIDE	10MG/ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	NASAL TOPICAL DROPS	1.0X15.0 ML BOTTLE	01/07/1997
2906	NDA/MAL/HDP/5183	PHARCO B PHARMACEUTICALS	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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2907	NDA/MAL/HDP/5184	PHARCO PHARMACEUTICALS	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
2908	NDA/MAL/HDP/5186	TROIKAA PHARMACEUTICALS 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
2909	NDA/MAL/HDP/5187	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	HEALIT SKIN OINTMENT	BACITRACIN+POLYMYXIN B SO4+NEOMYCIN+LIDOCAINE	500UNITS+5000UNITS+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

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2910	NDA/MAL/HDP/5188	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X5.0 CAPSULE BLISTER, 1.0X6.0X10.0 CAPSULE BLISTER	01/07/2009
2911	NDA/MAL/HDP/5200	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, 1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER	01/07/1998
2912	NDA/MAL/HDP/5201	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM BENDAZOLE	MEBENDAZOLE	100MG	KAMPALA PHARMACEUTICALS 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, 1.0X500.0 TABLET CONTAINER, 1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER	01/07/1997

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2913	NDA/MAL/HDP/5205	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
2914	NDA/MAL/HDP/5207	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
2915	NDA/MAL/HDP/5211	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	DINAC GEL	DICLOFENAC	1%W/W	S KANT HEALTHCARE LTD 1802-1805 GIDC PHASE III VAPI 396 195 GUJARAT	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE	01/07/2009

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2916	NDA/MAL/HDP/5214	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
2917	NDA/MAL/HDP/5215	J.B CHEMICALS & PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS 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,1.0X20.0 X5.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X5.0X2.0X10.0 TABLET BLISTER	01/07/2001
2918	NDA/MAL/HDP/5221	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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,1.0X10.0X3.0 ML AMPOULE	01/07/2006

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2919	NDA/MAL/HDP/5222	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	EMTRICITABINE+TENOFVIR DF	EMTRICITABINE/TENOFOVIR	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 – MADHYA PRADESH	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET CONTAINER	07/07/2008
2920	NDA/MAL/HDP/5224	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	EMTRICITABINE+TENOFVIR DISOPROXIL FUMERATE	EMTRICITABINE/TENOFOVIR 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
2921	NDA/MAL/HDP/5226	HETERO DRUGS LTD	AIVEEN (U) LIMITED	EMTRICITABINE+TENOFVIR DISOPROXIL FUMERATE	EMTRICITABINE+TENOFOVIR DISOPROXIL FUMERATE	200MG/300MG	HETERO LABS LTD (UNIT-V)SY.NO.438,439,440 & 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

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2922	NDA/MAL/HDP/5228	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	DICLOGENTA	DICLOFENAC SODIUM+GENTAMICIN 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
2923	NDA/MAL/HDP/5231	INTAS, PHARMACEUTICALS 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(BIOPHARMA DIVISION)CAMP ROAD SELAQUI-248197	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
2924	NDA/MAL/HDP/5232	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	ENAPRIL-5	ENALAPRIL MALEATE	5MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA 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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2925	NDA/MAL/HDP/5233	CADILA PHARMACEUTICALS LIMITED	PLANET PHARMACEUTICALS 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
2926	NDA/MAL/HDP/5234	CADILA PHARMACEUTICALS LIMITED	PLANET PHARMACEUTICALS 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
2927	NDA/MAL/HDP/5235	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS 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,5.0X2.0X10.0 TABLET BLISTER	01/07/1997

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2928	NDA/MAL/HDP/5243	IND SWIFT LTD	PLANET PHARMACEUTICALS 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
2929	NDA/MAL/HDP/5245	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	FABUTAS-40	FEBUXOSTAT	40MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
2930	NDA/MAL/HDP/5248	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,1.0X100.0 CAPSULE CONTAINER,1.0X1000.0 CAPSULE CONTAINER,1.0X500.0 CAPSULE CONTAINER,1.0X250.0 CAPSULE CONTAINER	01/07/1997

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2931	NDA/MAL/HDP/5249	EMCURE PHARMACEUTICALS 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
2932	NDA/MAL/HDP/5250	PHARCO PHARMACEUTICALS	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
2933	NDA/MAL/HDP/5255	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/GRANULES	1.0X8.0X4.5 G SACHET,1.0X10.0 X4.5 G SACHET,1.0X48.0 X4.5 G SACHET,1.0X4.0X4.5 G SACHET,1.0X24.0 X4.5 G SACHET	01/07/1997

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2934	NDA/MAL/HDP/5260	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
2935	NDA/MAL/HDP/5269	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	DIVAA OD 500	DIVALPROEX	500MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2010
2936	NDA/MAL/HDP/5271	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	ERYTHYL SYRUP	ERYTHROMYCIN ETHYL SUCCINATE	125MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

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2937	NDA/MAL/HDP/5272	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X1000.0 TABLET CONTAINER	01/07/2011
2938	NDA/MAL/HDP/5279	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
2939	NDA/MAL/HDP/5281	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	EFAVIRENZ+EMTRICITABINE+TENOFVIR DISOPROXIL	EFAVIRENZ + EMTRICITABINE + TENOFVIR DISOPROXIL FUMARATE	600MG +200MG +300MG	AUROBINDO PHARMA LTD UNIT VIIEZ 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

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2940	NDA/MAL/HDP/5282	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
2941	NDA/MAL/HDP/5283	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	IBUMEX GEL	IBUPROFEN	5%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL EMULSION GELS	1.0X25.0 G TUBE	01/07/2001
2942	NDA/MAL/HDP/5284	HETERO LABS LTD	AIVEEN (U) LIMITED	EFAVIRENZ+EMTRICITABINE+TENOFVIR	EFAVIRENZ + EMTRICITABINE + TENOFVIR	600MG + 200MG + 300MG	HETERO LABS LTD(UNIT V).JADCHERLA (M),MAHABOBNAGAR DIST, ANDHRA PRADESH,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2012

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2943	NDA/MAL/HDP/52 87	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	EFAVIRENZ + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMERATE	EFAVIRENZ + LAMIVUDINE + TENOFOVIR 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
2944	NDA/MAL/HDP/52 88	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	IBUMEX SUSPENSION	IBUPROFEN	100MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	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
2945	NDA/MAL/HDP/52 91	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	IBUMEX TABLET	IBUPROFEN	200MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	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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2946	NDA/MAL/HDP/5292	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	DOMI 10	DOMPERIDONE	10MG	LINCOLN PHARMACEUTICAL LIMITED TRIMAL ESTATE KHATRAJ KOLOL, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2011
2947	NDA/MAL/HDP/5295	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
2948	NDA/MAL/HDP/5297	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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2949	NDA/MAL/HDP/5298	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
2950	NDA/MAL/HDP/5299	PHARMA INTERNATIONAL.CO	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
2951	NDA/MAL/HDP/5300	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS 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

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2952	NDA/MAL/HDP/5302	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER, 1.0X10.0X10.0 CAPSULE BLISTER, 1.0X100.0X10.0 CAPSULE BLISTER	01/07/2014
2953	NDA/MAL/HDP/5305	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE 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
2954	NDA/MAL/HDP/5311	ABBOTT HEALTHCARE PRODUCTS B.V.	HARLEYS UGANDA LIMITED	DUPHASTON TABLETS	DYDROGESTERONE	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

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2955	NDA/MAL/HDP/5312	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
2956	NDA/MAL/HDP/5316	TROIKAA PHARMACEUTICALS 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
2957	NDA/MAL/HDP/5317	MACK BROWN	SHURIK LTD	DR MAC'S COUGH FORMULA	TERBUTALINE SULPHATE+BROM HEXINE HYDROCHLORIDE+ GUAIFENESIN+MENTHOL	2.5MG+8.0MG+100MG+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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2958	NDA/MAL/HDP/5318	TROIKAA PHARMACEUTICALS 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
2959	NDA/MAL/HDP/5320	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,1.0X100.0X10.0 CAPSULE BLISTER	01/07/2010
2960	NDA/MAL/HDP/5321	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	IBUGESIC COLD & SINUS	IBUPROFEN/PSEUDOEPHEDRINE	200MG/30MG	DAR AL DAWANA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY GELATIN-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2012

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2961	NDA/MAL/HDP/53 23	STEDMAN PHARMACEUTICAL S 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,1.0X3 0.0 ML CONTAINER,1.0X1 00.0 ML CONTAINER,1.0X5 00.0 ML CONTAINER	01/07/2010
2962	NDA/MAL/HDP/53 24	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAN ENTERPRISES LIMITED	IBUFIL 400	IBUPROFEN	400MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDALUR ROAD,KELAMBAKKAM- 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
2963	NDA/MAL/HDP/53 26	UNIQUE PHARMACEUTICAL S LABORATORIES	PLANET PHARMACEUTICALS 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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2964	NDA/MAL/HDP/53 27	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAN ENTERPRISES LIMITED	IBUFIL 200	IBUPROFEN	200MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDALUR ROAD,KELAMBAKKAM- 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
2965	NDA/MAL/HDP/53 29	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
2966	NDA/MAL/HDP/53 30	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, THIRUPURUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/2011

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2967	NDA/MAL/HDP/5333	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
2968	NDA/MAL/HDP/5338	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	HYDROSIL TABLETS	ALUMINIUM HYDROXIDE+MAGNESIUM HYDROXIDE+SIME THICONE	200MG+200MG+20MG	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
2969	NDA/MAL/HDP/5341	LABORATORY&ALLIED 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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2970	NDA/MAL/HDP/53 46	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
2971	NDA/MAL/HDP/53 47	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
2972	NDA/MAL/HDP/53 48	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	CELEPID 20	INTRAVENOUS FAT EMULSION	20%W/V	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X250.0 ML BOTTLE, 1.0X500.0 ML BOTTLE	01/07/2005

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2973	NDA/MAL/HDP/5352	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS LTD	MUMFER	IRON(111) POLYMALTOSE COMPLEX	50MG/5ML	GLENMARK PHARMACEUTICALS LTD PLOT EPLT NO. E-37, 39, MIDC AREA, SATPUR, NASIK - 422 007, MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X150.0 ML BOTTLE	01/07/2005
2974	NDA/MAL/HDP/5356	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
2975	NDA/MAL/HDP/5358	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	CADISTIN EXPECTORANT	CHLORPHENIRAMINE 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 LTDSAKAR 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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2976	NDA/MAL/HDP/53 61	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
2977	NDA/MAL/HDP/53 62	ASTRA ZENECA	MACNAUGHTON LIMITED	CASODEX 150MG	BICALUTAMIDE	150MG	ASTRAZENECA MACCLESFIELDCHESHIRE	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	2.0X14.0 TABLET STRIP	01/07/2001
2978	NDA/MAL/HDP/53 63	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,CHESHIRE SK 10 2NA,	UNITED KINGDOM GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/1997

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2979	NDA/MAL/HDP/53 66	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
2980	NDA/MAL/HDP/53 67	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
2981	NDA/MAL/HDP/53 68	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/SYRU PS/DROPS	1.0X60.0 ML BOTTLE, 1.0X30.0 ML BOTTLE	01/07/2007

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2982	NDA/MAL/HDP/5370	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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2010
2983	NDA/MAL/HDP/5377	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (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
2984	NDA/MAL/HDP/5379	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,1.0X10.0 X10.0 CAPSULE BLISTER	01/07/2008

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2985	NDA/MAL/HDP/5380	CIRON DRUGS & PHARMACEUTICALS 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,INDIA.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE	01/07/2013
2986	NDA/MAL/HDP/5381	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
2987	NDA/MAL/HDP/5386	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	UDIHEP TABLETS	URSODEOXYCHOLIC ACID	150MG	WIN- MEDICARE LTD MODIPURAM -250 110,UTTAR PRAADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2001

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2988	NDA/MAL/HDP/5388	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
2989	NDA/MAL/HDP/5389	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,1.0X30.0 X6.0 TABLET BLISTER,1.0X1.0X12.0 TABLET BLISTER,1.0X1.0X18.0 TABLET BLISTER,1.0X30.0 X12.0 TABLET BLISTER 1.0X30.0	01/07/2011
2990	NDA/MAL/HDP/5391	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	NITROFURANTOIN	NITROFURANTOIN	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

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2991	NDA/MAL/HDP/53 92	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
2992	NDA/MAL/HDP/53 93	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
2993	NDA/MAL/HDP/53 94	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	FINAZOL	ALBENDAZOLE	400MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDALUR ROAD,KELAMBAKKAM- 603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X1 000.0 TABLET CONTAINER	01/07/2007

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2994	NDA/MAL/HDP/5395	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
2995	NDA/MAL/HDP/5400	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	ALBEN SUSPENSION	ALBENDAZOLE	400MG/10ML	PANACEA BIOTEC LTDMALPUR, BADDI, TEHSIL, NALAGARH, DIST. SOLAN (H.P) – 173 205	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	01/07/1999
2996	NDA/MAL/HDP/5404	INTAS, PHARMACEUTICALS 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

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2997	NDA/MAL/HDP/5406	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	HIFENAC SR	ACECLOFENAC	200 MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2007
2998	NDA/MAL/HDP/5407	THEMIS PHARMACEUTICALS	STAR PHARMACEUTICALS LTD	E MAL-75	ALPHA-BETA ARTEETHER	75MG/ML	THEMIS MEDICARE LTDSECTOR 6A, PLOT NO. 16 TO18, IIE, BHEL HARIDWA, UTTARAKHAND	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X3.0X1.0 ML AMPOULE	01/07/2013
2999	NDA/MAL/HDP/5410	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	UNICTAM 1500	AMPICILLIN + SULBACTAM	1000 MG + 500 MG	MEDICAL UNION PHARMACEUTICALS LTD - ABU SULTAN, CR 13363 ISMAILLIA, EGYPT	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	01/07/2009

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3000	NDA/MAL/HDP/54 14	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
3001	NDA/MAL/HDP/54 15	CENTAUR PHARMACEUTICAL S PVT. LTD	GITTOES PHARMACEUTICALS 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
3002	NDA/MAL/HDP/54 16	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

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3003	NDA/MAL/HDP/54 17	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
3004	NDA/MAL/HDP/54 18	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	PAEDIATRIC CO- TRIMOXAZOL E	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
3005	NDA/MAL/HDP/54 19	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGO-CPM	CHLORPHENIRAMI NE	4MG	AGOG PHARMA LTDPLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO- OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THAN E INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000 .0 TABLET CONTAINER,1.0X1 00.0X10.0 TABLET BLISTER	01/07/2005

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3006	NDA/MAL/HDP/54 23	HETERO LABS LTD	AIVEEN (U) LIMITED	EFAVIRENZ+L AMIVUDINE+ TENOFVIR	EFAVIRENZ+LAMI VUDINE+TENOF VIR	600MG/300MG/3 00MG	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 JEEEDIMETTA HYDRABAD 500055	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER,1.0X9 0.0 TABLET JAR,1.0X100.0 TABLET JAR	01/07/2013
3007	NDA/MAL/HDP/54 25	ROYAL GROUP	HARLEYS UGANDA LIMITED	PARACETAM OL	PARACETAMOL	500MG	HEBEI (JIHENG GRP) PHARMACEUTICALS CO.LTD-INDIA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
3008	NDA/MAL/HDP/54 27	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

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3009	NDA/MAL/HDP/5428	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	CIPFIL 500	CIPROFLOXACIN	500MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007
3010	NDA/MAL/HDP/5429	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THAN E INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X100.0 TABLET CARTON	01/07/2006
3011	NDA/MAL/HDP/5434	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,UGANDA AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THAN E 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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3012	NDA/MAL/HDP/5435	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	PIC	PARACETAMOL+IBUPROFEN+CAFFEINE	500MG+200MG+30MG	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	1.0X25.0X4.0 TABLET STRIP	01/07/2015
3013	NDA/MAL/HDP/5439	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
3014	NDA/MAL/HDP/5441	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL NASATAB TABLETS	PARACETAMOL+CHLORPHENIRAMINE+PSEUDOEPHEDRINE	500MG+4MG+60MG	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,1.0X10.0X10.0 TABLET BLISTER	01/07/2008

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3015	NDA/MAL/HDP/54 42	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	CHLORAMPH ENICOL 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
3016	NDA/MAL/HDP/54 47	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	DICLOFENAC	DICLOFENAC SODIUM	50MG	TRIVENI FORMULATION LTD PLOT NO.52,53,54,63,62,64, ALEAP INDUSTRIAL ESTATE SURAMPALI, AP-INDIA – 521212	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CARTON,1.0X10.0 X10.0 TABLET BLISTER	01/07/2012
3017	NDA/MAL/HDP/54 49	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DICLOFENAC 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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3018	NDA/MAL/HDP/54 57	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,1.0X25.0 X3.0 TABLET BLISTER,1.0X25.0 X6.0 TABLET BLISTER	01/07/2014
3019	NDA/MAL/HDP/54 58	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,1.0X25.0 X3.0 TABLET BLISTER	01/07/2014
3020	NDA/MAL/HDP/54 60	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,1.0X25.0 X3.0 TABLET BLISTER,1.0X25.0 X6.0 TABLET BLISTER	01/07/2011

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3021	NDA/MAL/HDP/5464	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CO-METHER	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	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	1.0X3.0X4.0 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 1.0X1.0X	01/07/2007
3022	NDA/MAL/HDP/5467	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMSIDAR	SULFADOXINE/PYRIMETHAMINE	525MG	KAMPALA PHARMACEUTICALS 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, 1.0X500.0 TABLET CONTAINER, 1.0X1000.0 TABLET CONTAINER	01/07/1997
3023	NDA/MAL/HDP/5469	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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3024	NDA/MAL/HDP/5471	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
3025	NDA/MAL/HDP/5472	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
3026	NDA/MAL/HDP/5473	TROIKAA PHARMACEUTICALS 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

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3027	NDA/MAL/HDP/5474	PHARMA INTERNATIONAL.CO	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
3028	NDA/MAL/HDP/5476	ACINO PHARMA AG	LABOREX UGANDA LIMITED	MESPORIN 1000MG I.V	CEFTRIAZONE	1000MG	LABESFAL LABORATORIESALMIRO S.A ZONA INDUSTRIAL DO LAGEDO, 3465-157, SANTIAGO DE BESTEIRO ROS PORTUGAL	PORTUGAL	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL + 10 ML WFI	01/07/2002
3029	NDA/MAL/HDP/5478	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	BECORT 50	BECLMETHASON E DIPROPIONATE	50MCG/ACTUATION	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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3030	NDA/MAL/HDP/5479	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS 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
3031	NDA/MAL/HDP/5482	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE, 1.0X60.0 ML BOTTLE	01/07/2010
3032	NDA/MAL/HDP/5483	GUILIN PHARMACEUTICALS CO. LTD	TRIDEM PHARMA UGANDA LIMITED	ASAQ GPSC	ARTESUNATE + AMODIAQUINE	25 MG + 67.5 MG	GUILIN PHARMACEUTICALS CO. LTD NO 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

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3033	NDA/MAL/HDP/5486	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	FOSEAL 400	SEVELAMER HCL	400MG	EMCURE PHARMACEUTICALS LIMITED PLOT 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
3034	NDA/MAL/HDP/5489	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	CORBIS-5	BISOPROLOL	5MG	UNICHEM LABORATORIES LIMITED UNIT II VILLAGE 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
3035	NDA/MAL/HDP/5495	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS 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. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER	01/07/2001

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3036	NDA/MAL/HDP/54 96	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
3037	NDA/MAL/HDP/54 97	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
3038	NDA/MAL/HDP/55 91	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS 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

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3039	NDA/MAL/HDP/5619	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	RABELOX 20	RABEPRAZOLE SODIUM	20MG	CADILA PHARMACEUTICALS LIMITED 1389, 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
3040	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
3041	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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3042	NDA/MAL/HDP/6032	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	MET XL 100	METOPROLOL SUCCINATE	100MG	AJANTA PHARMA LIMITED AJANTA 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
3043	NDA/MAL/HDP/6034	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOXIN -250 DT	AMOXICILLIN TRIHYDRATE	250 MG	MILAN LABS PVT LTD 63-67 JAWAHAR CO.OP. INDUSTRIAL ESTATE KAMOTHE,NAVI MUMBAI	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER	01/07/2016
3044	NDA/MAL/HDP/6036	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	OFLOTECH-O	OFLOXACIN + ORNIDAZOLE	200MG + 500MG	AKUMS DRUGS & PHARMACEUTICALS LTD 19-20,21, SECTOR 6-4, SIDCUL, IIE, RANIPUR HARIDWAR-249403	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER	27/03/2019

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3045	NDA/MAL/HDP/6037	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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,1.0X10.0 X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE JAR	01/07/2017
3046	NDA/MAL/HDP/6040	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
3047	NDA/MAL/HDP/6041	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CANDIZOL	CLOTRIMAZOLE	100MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	VAGINAL TABLETS	1.0X6.0 PESSARY STRIP	01/07/2017

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3048	NDA/MAL/HDP/6050	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
3049	NDA/MAL/HDP/6057	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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2009
3050	NDA/MAL/HDP/6059	RESONANT PHARMACEUTICALS PVT LTD	SHREEJI PHARMACEUTICALS 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

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3051	NDA/MAL/HDP/6065	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
3052	NDA/MAL/HDP/6067	RENE PHARMACY(R) LTD..	RENE PHARMACY LTD	DIAZEPAM	DIAZEPAM	5MG	NEM LABORATORIES PVT LTD 133 KRISHNA INDUSTRIAL ESTATE VASAI (E) DIST THANE 401 210 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017
3053	NDA/MAL/HDP/6070	DEVA HOLDING A.S	SHREEJI PHARMACEUTICALS LIMITED	VAZKOR	AMLODIPINE BESILATE	10MG	DEVA HOLDING A.S CERKEZKOY ORGANIZASYONU 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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3054	NDA/MAL/HDP/6071	DEVA HOLDING A.S	SHREEJI PHARMACEUTICALS LIMITED	VAZKOR	AMLODIPINE BESILATE	5MG	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
3055	NDA/MAL/HDP/6075	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
3056	NDA/MAL/HDP/6076	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS 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 NAACL AMPOULE + 1*1 ML OF 5%W/V NAHCO3 AMPOULE	01/07/2017

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3057	NDA/MAL/HDP/6078	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
3058	NDA/MAL/HDP/6079	ADCOCK INGRAM LIMITED	SURGIPHARM (U) LIMITED	ALLERGEX	CHLORPHENIRAMINE 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
3059	NDA/MAL/HDP/6080	EXPHAR SA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	FEBRILEX JUNIOR	PARACETAMOL+CHLORPHENIRAMINE 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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3060	NDA/MAL/HDP/6081	TIANJIN MNCHIP TECHNOLOGIES CO.,LTD	PHILLIPS PHARMACEUTICALS (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
3061	NDA/MAL/HDP/6082	EXPHAR SA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CROMSOL	SODIUM CROMOGLYCATE	2%W/V	AHLCONPARENTERALS (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
3062	NDA/MAL/HDP/6086	UNOSOURCE PHARMA LTD	MEDVIN PHARMA LIMITED	ACEWEL-P	ACECLOFENAC+PARACETAMOL	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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2017

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3063	NDA/MAL/HDP/6092	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPOTCLAV 1000	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	875 MG + 125 MG	SPARSH BIO-TECH PVT. LIMITED PLOT NO. 1; SURVEY NO. 242/243/244, LAKHABAVA D, JAMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017
3064	NDA/MAL/HDP/6093	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, LAKHABAVA D, JAMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2017
3065	NDA/MAL/HDP/6094	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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3066	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
3067	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
3068	NDA/MAL/HDP/6101	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TELPRESS-H 40/12.5	TELMISARTAN + HYDROCHLOROTHIAZIDE	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

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3069	NDA/MAL/HDP/6102	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
3070	NDA/MAL/HDP/6103	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
3071	NDA/MAL/HDP/6105	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	AZOPIIL 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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3072	NDA/MAL/HDP/6106	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (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
3073	NDA/MAL/HDP/6107	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	SULPREX	IPRATROPIUM BROMIDE+SALBUTAMOL 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
3074	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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3075	NDA/MAL/HDP/61 15	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 TABLET STRIP	01/07/1997
3076	NDA/MAL/HDP/61 17	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, 1.0X5.0 X3.0 ML AMPOULE	01/07/2017
3077	NDA/MAL/HDP/61 18	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	L-TRIM DS	SULPHAMETHOXA ZOLE + 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

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3078	NDA/MAL/HDP/6121	İLKO İLAÇ SANAYI VE TİCARET A. Ş.	CORE ACCESS LTD	DEXİREN	DEKİETOPROFEN TROMETAMOL	25MG	İLKO İLAÇ SANAYI 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	01/07/2017
3079	NDA/MAL/HDP/6126	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS 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
3080	NDA/MAL/HDP/6127	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	İNTELENCE	ETRAVİRİNE	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

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3081	NDA/MAL/HDP/6129	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)PRIORITY STREET, WARE HERTFORDSHIRE SG12 0DJ, UK	UNITED KINGDOM POLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2016
3082	NDA/MAL/HDP/6132	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
3083	NDA/MAL/HDP/6134	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	ZAMADOL P	TRAMADOL HYDROCHLORIDE+ ACETAMINOPHEN	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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3084	NDA/MAL/HDP/61 35	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
3085	NDA/MAL/HDP/61 37	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
3086	NDA/MAL/HDP/61 41	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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2016

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3087	NDA/MAL/HDP/6142	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET BOTTLE, 1.0X10.0X10.0 TABLET BLISTER	01/07/2016
3088	NDA/MAL/HDP/6143	IESUS GROUP	SHREEJI PHARMACEUTICALS LIMITED	CONTRACTUBEX	EXTRACT CEPAE FLUID + HEPARIN SODIUM + ALLANTOIN	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
3089	NDA/MAL/HDP/6158	DEVA HOLDING A.S	SHREEJI PHARMACEUTICALS LIMITED	DESEFIN	CEFTRIAZONE SODIUM	1G	DEVA HOLDING A.S. CERKEZKOY ORGANIZASYONU 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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3090	NDA/MAL/HDP/6167	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
3091	NDA/MAL/HDP/6169	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
3092	NDA/MAL/HDP/6170	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (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

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3093	NDA/MAL/HDP/6176	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	G-GLUTAMIN	VITAMIN B1 +B6+B12 WITH L-GLUTAMIC ACID	100MG+50MG+100MCG+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
3094	NDA/MAL/HDP/6179	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
3095	NDA/MAL/HDP/6181	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	AZINOWEL-500	AZITHROMYCIN	500MG	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	1.0X3.0 TABLET BLISTER	01/07/2016

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3096	NDA/MAL/HDP/6182	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (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
3097	NDA/MAL/HDP/6184	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ATOXIA 60MG	ETORICOXIB	60MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD.P.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
3098	NDA/MAL/HDP/6185	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

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3099	NDA/MAL/HDP/61 86	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
3100	NDA/MAL/HDP/61 87	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
3101	NDA/MAL/HDP/61 88	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	GIZLAN 150	IRBESARTAN	150MG	DAR AI DAWANA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016

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3102	NDA/MAL/HDP/6189	UNEED 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
3103	NDA/MAL/HDP/6190	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	D-LYTE	ANHYDROUS GLUCOSE+SODIUM CHLORIDE+TRISODIUM CITRATE+POTASSIUM CHLORIDE, ANHYDROUS GLUCOSE+SODIUM CHLORIDE+TRISODIUM	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. THANE 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
3104	NDA/MAL/HDP/6191	AMOUN PHARMACEUTICALS 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-BOUR CITY, KALYUBIA CAIRO EGYPT	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X6.0X5.0 ML AMPOULE	01/07/2016

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3105	NDA/MAL/HDP/6201	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, LAKHABAVA D, JAMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE STRIP	01/07/2016
3106	NDA/MAL/HDP/6207	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	GOIGEL	DICLOFENAC DIETHYLAMINE+M ETHYL 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
3107	NDA/MAL/HDP/6211	EXPHAR SA.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CLOFAINS	PARACETAMOL/DI CLOFENAC SODIUM	500MG/50MG	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 TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016

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3108	NDA/MAL/HDP/62 17	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
3109	NDA/MAL/HDP/62 18	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
3110	NDA/MAL/HDP/62 20	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	METHYLDOP A	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

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3111	NDA/MAL/HDP/6223	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROPROST-RT	LATANOPROST	0.005%W/V	AUROLAB.SIVAGANGAI MAIN ROAD, VEERAPANJAN, MADURAI 625 020 TAMIL INDIA	INDIA	OPHTHALMIC DROPS	1.0X2.5 ML BOTTLE	01/07/2016
3112	NDA/MAL/HDP/6227	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
3113	NDA/MAL/HDP/6228	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,1.0X2.0X 7.0 TABLET BLISTER	01/07/2016

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3114	NDA/MAL/HDP/62 29	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, LAKHABA VA D, JAMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE STRIP	01/07/2016
3115	NDA/MAL/HDP/62 30	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
3116	NDA/MAL/HDP/62 31	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP DISPERSIBLE	DIHYDROARTEMIS ININ/PIPERAQUIN E	20MG/160MG	GUILIN PHARMACEUTICAL CO LTD NO.43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X2.0X3.0 TABLET BLISTER, 1.0X3.0X 35.0 TABLET BLISTER	01/07/2016

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3117	NDA/MAL/HDP/6234	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP DISPERSIBLE	DIHYDROARTEME SININE/ PIPERAQUINE PHOSPHATE	40MG/320MG	GUILIN PHARMACEUTICAL CO.,LTDNO 43 QILIDIAN 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
3118	NDA/MAL/HDP/6235	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ANGINET 160MG	VALSARTAN	160MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD.P.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
3119	NDA/MAL/HDP/6237	HETERO LABS LTD	AIVEEN (U) LIMITED	LOPINAVIR/RITONAVIR	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

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3120	NDA/MAL/HDP/6238	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (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
3121	NDA/MAL/HDP/6239	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
3122	NDA/MAL/HDP/6242	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP	DIHYDROARTEMESININ/PIPERAQUINE PHOSPHATE	80MG/640MG	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	01/07/2016

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3123	NDA/MAL/HDP/62 43	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
3124	NDA/MAL/HDP/62 44	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,1.0X3.0X 10.0 CAPSULE BLISTER	01/07/2016
3125	NDA/MAL/HDP/62 45	BIOLOGICAL E. LTD	ABACUS PHARMA (AFRICA) LIMITED	COSCOPIN LINCTUS	NOSCAPINE + CHLORPHENIRAMI NE 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,INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2016

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3126	NDA/MAL/HDP/6246	CIRON DRUGS & PHARMACEUTICALS 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
3127	NDA/MAL/HDP/6247	MILAN LABORATORIES LTD (INDIA) PVT LTD	GITTOES PHARMACEUTICALS 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
3128	NDA/MAL/HDP/6249	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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3129	NDA/MAL/HDP/6250	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
3130	NDA/MAL/HDP/6256	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
3131	NDA/MAL/HDP/6257	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

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3132	NDA/MAL/HDP/6264	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
3133	NDA/MAL/HDP/6267	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
3134	NDA/MAL/HDP/6270	MACLEODS PHARMACEUTICALS 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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3135	NDA/MAL/HDP/6275	SEV PHARMACEUTICALS LIMITED	SEV PHARMACEUTICALS 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
3136	NDA/MAL/HDP/6279	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
3137	NDA/MAL/HDP/6281	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	HOMAGON	CHLORPHENAMINE MALEATE + CAFFEINE ANHYDROUS + PSEUDOEPHEDRINE 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,1.0X10.0 X10.0 CAPSULE BLISTER	07/11/2018

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3138	NDA/MAL/HDP/6282	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (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
3139	NDA/MAL/HDP/6283	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
3140	NDA/MAL/HDP/6288	THEON PHARMACEUTICALS LTD	AIVEEN (U) LIMITED	THEOFIX-100DS	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/SYRUPS/DROPS	1X1X60 ML BOTTLE	17/12/2018

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3141	NDA/MAL/HDP/6292	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
3142	NDA/MAL/HDP/6293	MACLEODS PHARMACEUTICALS 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
3143	NDA/MAL/HDP/6294	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

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3144	NDA/MAL/HDP/6300	GUILIN PHARMACEUTICAL (SHANGHAI) CO., LTD	TRIDEM PHARMA UGANDA LIMITED	AMOXICILLIN	AMOXICILLIN	250MG	SINOPHARM WEIQJDA 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,1.0X2.0X10.0 CAPSULE BLISTER, 1.0X10.0X10.0 CAPSULE BLISTER	31/01/2018
3145	NDA/MAL/HDP/6302	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
3146	NDA/MAL/HDP/6304	UNOSOURCE PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	UNOSURE 72	LEVONORGESTREL	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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3147	NDA/MAL/HDP/63 14	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,1.0X2.0X 10.0 TABLET BLISTER	30/05/2018
3148	NDA/MAL/HDP/63 27	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
3149	NDA/MAL/HDP/63 32	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

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3150	NDA/MAL/HDP/6334	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
3151	NDA/MAL/HDP/6338	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.A. MACIERZYSZ, 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
3152	NDA/MAL/HDP/6339	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OXY-POL	OXYTETRACYCLINE HCL + POLYMYXIN B SULPHATE	5MG+10000IU/G	EGYPTIAN INT. PHARMACEUTICAL 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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3153	NDA/MAL/HDP/6340	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
3154	NDA/MAL/HDP/6341	MACLEODS PHARMACEUTICALS LTD 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
3155	NDA/MAL/HDP/6342	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

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3156	NDA/MAL/HDP/63 43	BIOTON S.A.	BHL HEALTHCARE LIMITED	GENSULIN N	ISOPHANE HUMAN HUMAN OF RECOMBINANT DNA ORIGIN	100 IU/ML	BIOTON S.A.MACIERZYSZ, 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
3157	NDA/MAL/HDP/63 44	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
3158	NDA/MAL/HDP/63 46	BIOTON S.A.	BHL HEALTHCARE LIMITED	GENSULIN R	SOLUBLE HUMAN INSULIN OF RECOMBINANT DNA ORIGIN	100 IU/ML	BIOTON S.A.MACIERZYSZ, 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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3159	NDA/MAL/HDP/6348	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
3160	NDA/MAL/HDP/6349	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
3161	NDA/MAL/HDP/6350	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,PALGHAR, MAHARASHTRA 401404,INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X7.0 SUPPOSITORY STRIP	27/03/2019

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3162	NDA/MAL/HDP/6352	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
3163	NDA/MAL/HDP/6353	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	DOLUTEGRAVIR/LAMIVUDINE/TENOFOVIR	DOLUTEGRAVIR+LAMIVUDINE+TENOFVIR	50MG+300MG+300MG	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
3164	NDA/MAL/HDP/6354	EXPHAR SA.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TIMOSOL ®	TIMOLOL MALEATE	0.5%W/V	AHLCONPARENTERALS (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

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3165	NDA/MAL/HDP/6360	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS 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
3166	NDA/MAL/HDP/6361	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
3167	NDA/MAL/HDP/6365	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	EASY PILL	LEVONORGESTREL	1.5MG	CORONA REMEDIES PVT LTD CORONA 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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3168	NDA/MAL/HDP/63 68	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS 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
3169	NDA/MAL/HDP/63 69	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/SYRU PS/DROPS	1.0X60.0 ML BOTTLE	31/01/2018
3170	NDA/MAL/HDP/63 74	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,1.0X10.0 X10.0 TABLET BLISTER	28/03/2018

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3171	NDA/MAL/HDP/6375	MACLEODS PHARMACEUTICALS 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
3172	NDA/MAL/HDP/6377	REGAL PHARMA U LIMITED	REGAL PHARMA U LIMITED	EPHICOL CAPSULES	CHLORPHENIRAMINE MALEATE+ PARACETAMOL+ CAFFEINE ANHYDROUS+ PHENYLEPHRINE HCL	2MG+500 MG+30MG+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
3173	NDA/MAL/HDP/6381	MANKIND PHARM LTD	TATA UGANDA LIMITED	SERTAKIND	SERTACONAZOLE NITRATE	2.0%W/W	CURETECH SKINCARE PLOT 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

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3174	NDA/MAL/HDP/63 83	EXPHAR SA.	PHILLIPS PHARMACEUTICALS (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
3175	NDA/MAL/HDP/63 85	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
3176	NDA/MAL/HDP/63 86	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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3177	NDA/MAL/HDP/63 89	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	METRONIDAZ OLE 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
3178	NDA/MAL/HDP/63 90	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
3179	NDA/MAL/HDP/63 92	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

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3180	NDA/MAL/HDP/6395	EXPHAR SA.	PHILLIPS PHARMACEUTICALS (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
3181	NDA/MAL/HDP/6400	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
3182	NDA/MAL/HDP/6401	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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3183	NDA/MAL/HDP/6404	STEDMAN PHARMACEUTICALS 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
3184	NDA/MAL/HDP/6405	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
3185	NDA/MAL/HDP/6407	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

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3186	NDA/MAL/HDP/64 08	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
3187	NDA/MAL/HDP/64 14	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
3188	NDA/MAL/HDP/64 15	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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3189	NDA/MAL/HDP/64 16	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
3190	NDA/MAL/HDP/64 19	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
3191	NDA/MAL/HDP/64 22	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

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3192	NDA/MAL/HDP/64 23	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
3193	NDA/MAL/HDP/64 24	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICALS 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
3194	NDA/MAL/HDP/64 25	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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3195	NDA/MAL/HDP/64 26	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
3196	NDA/MAL/HDP/64 30	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,1.0X30.0 X1.0X12.0 TABLET BLISTER	27/03/2019
3197	NDA/MAL/HDP/64 31	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/SYRUPS/ DROPS	1.0X100.0 ML BOTTLE	01/07/2017

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3198	NDA/MAL/HDP/64 32	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	UMBI-GEL	CHLORHEXIDINE GLUCONATE	4 % W/W	KAMPALA PHARMACEUTICALS INDUSTRIES (1996)LTDSTRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X50.0X1.0X5.0 G TUBE	27/03/2019
3199	NDA/MAL/HDP/64 33	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
3200	NDA/MAL/HDP/64 35	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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2017

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3201	NDA/MAL/HDP/64 37	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
3202	NDA/MAL/HDP/64 38	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMADOL PLUS	PARACETAMOL + CAFFEINE	500 MG + 65 MG	KAMPALA PHARMACEUTICALS INDUSTRIES (1996) LTD STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	27/03/2019
3203	NDA/MAL/HDP/64 39	MACLEODS PHARMACEUTICALS 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

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3204	NDA/MAL/HDP/64 40	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
3205	NDA/MAL/HDP/64 41	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
3206	NDA/MAL/HDP/64 42	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/SYRU PS/DROPS	1.0X30.0 ML BOTTLE, 1.0X15.0 ML BOTTLE	31/01/2018

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3207	NDA/MAL/HDP/64 43	MICRO LABS	MALIX PHARMA (U) LIMITED	SINURHON SUSPENSION	CHLORPHENIRAMI NE + 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
3208	NDA/MAL/HDP/64 47	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
3209	NDA/MAL/HDP/64 48	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIZOLONE- DEPOT 40 MG/ 1 ML VIAL	METHYLPREDNISO LONE 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

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3210	NDA/MAL/HDP/64 49	EVA PHARMA FOR PHARMACEUTICAL S & MEDICAL APPLIANCES	GAMA PHARMACEUTICALS (U) LIMITED	DESORAT SYRUP	DESORATIDINE	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
3211	NDA/MAL/HDP/64 54	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
3212	NDA/MAL/HDP/64 55	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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3213	NDA/MAL/HDP/64 56	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
3214	NDA/MAL/HDP/64 59	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,1.0X25.0 X3.0 TABLET BLISTER,1.0X25.0 X6.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER	27/03/2019
3215	NDA/MAL/HDP/64 60	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

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3216	NDA/MAL/HDP/64 62	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
3217	NDA/MAL/HDP/64 65	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
3218	NDA/MAL/HDP/64 68	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,1.0X5.0 X1.0 ML AMPOULE	30/05/2018

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3219	NDA/MAL/HDP/64 72	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
3220	NDA/MAL/HDP/64 76	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIZOLONE- DEPOT	METHYLPREDNISOLONE	80MG/2ML	EGYPTIAN INT.PHARMACEUTICAL 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
3221	NDA/MAL/HDP/64 77	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,1.0X10.0 X10.0 TABLET BLISTER	27/03/2019

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3222	NDA/MAL/HDP/64 82	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
3223	NDA/MAL/HDP/64 91	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
3224	NDA/MAL/HDP/64 95	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- TEKIRDAĞ/ TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	29/11/2017

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3225	NDA/MAL/HDP/6498	MICRO LABS LIMITED	PHARMA VILLE 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
3226	NDA/MAL/HDP/6499	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS 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
3227	NDA/MAL/HDP/6500	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS 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

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3228	NDA/MAL/HDP/6501	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS 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
3229	NDA/MAL/HDP/6504	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	CAPXCEL	CAPECITABINE	500MG	KHANDELWAL LABORATORIES PVT. LTDB-1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1X1X10 TABLET BLISTER	29/05/2019
3230	NDA/MAL/HDP/6506	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICALS 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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3231	NDA/MAL/HDP/6507	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
3232	NDA/MAL/HDP/6508	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICALS 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
3233	NDA/MAL/HDP/6510	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS 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

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3234	NDA/MAL/HDP/6512	AXA PARENTERALS LTD	VITACARE LIMITED	AXACIP	CIPROFLOXACIN	200MG/100ML	AXA PARENTERAL LIMITED PLOT 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
3235	NDA/MAL/HDP/6513	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
3236	NDA/MAL/HDP/6514	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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3237	NDA/MAL/HDP/65 15	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICALS 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
3238	NDA/MAL/HDP/65 16	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICALS 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
3239	NDA/MAL/HDP/65 20	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

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3240	NDA/MAL/HDP/65 21	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
3241	NDA/MAL/HDP/65 22	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
3242	NDA/MAL/HDP/65 23	EXPHAR SA.	PHILLIPS PHARMACEUTICALS (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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3243	NDA/MAL/HDP/65 24	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS 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
3244	NDA/MAL/HDP/65 25	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS 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
3245	NDA/MAL/HDP/65 26	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS 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

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3246	NDA/MAL/HDP/65 27	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PULMOFIRST 62.5	BOSENTAN MONOHYDRATE	62.5MG	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
3247	NDA/MAL/HDP/65 28	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
3248	NDA/MAL/HDP/65 32	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	BUNASE 200	BUDESONIDE	200MCG / ACTUATION	OXALIS LABS-VILLAGE THEDA,P.O.LODHIMAJRA ,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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3249	NDA/MAL/HDP/65 36	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
3250	NDA/MAL/HDP/65 37	EXPHAR LTD.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CARBOSOL	CARMELLOSE SODIUM	0.5%W/V	AHLCONPARENTERALS (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
3251	NDA/MAL/HDP/65 38	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

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3252	NDA/MAL/HDP/6545	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
3253	NDA/MAL/HDP/6546	RAPTAKOS, BRETT & CO. LTD.	EUROPA HEALTHCARE (U) LTD	NEOPEPTINE	ALPHA AMYLASE + PAPAINE	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
3254	NDA/MAL/HDP/6549	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	28/03/2019

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3255	NDA/MAL/HDP/6550	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
3256	NDA/MAL/HDP/6551	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICALS LIMITED	NUROFEN FOR CHILDREN SUGAR FREE	IBUPROFEN	100MG/5ML	RECKITT BENCKISER HEALTHCARE -DAMSON LANE,HULL, HUB H08 7DS	UNITED KINGDOM	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	27/03/2019
3257	NDA/MAL/HDP/6552	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICALS LIMITED	NUROFEN	IBUPROFEN + LYSINE	342MG	RECKITT BENCKISER HEALTHCARE -DAMSON LANE,HULL, HUB H08 7DS	UNITED KINGDOM	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X12.0 TABLET BLISTER	27/03/2019

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3258	NDA/MAL/HDP/65 53	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
3259	NDA/MAL/HDP/65 54	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
3260	NDA/MAL/HDP/65 56	SAVA HEALTHCARE LIMITED	PHILLIPS PHARMACEUTICALS (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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3261	NDA/MAL/HDP/65 62	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS 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
3262	NDA/MAL/HDP/65 63	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ANATAX [®] 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
3263	NDA/MAL/HDP/65 65	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	IBUPROFEN	IBUPROFEN	200MG	TRIVENI FORMULATIONS LTD PLOT NO. 52,53,54,63,62,64 ALEAP INDUSTRIUAL ESTATE SARAMPALLI VIJAYWADA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	28/03/2019

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3264	NDA/MAL/HDP/65 68	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	PINNADIP 50 TABLET	DICLOFENAC	50MG	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
3265	NDA/MAL/HDP/65 69	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
3266	NDA/MAL/HDP/65 72	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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3267	NDA/MAL/HDP/6573	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
3268	NDA/MAL/HDP/6577	UNOSOURCE PHARMA LTD	MEDVIN PHARMA LIMITED	CEFIWEL-200	CEFIXIME	200MG	MALIK LIFESCIENCES PRIVATE LIMITED PLOT NO. 16, NH 58, VARDHMAN INDUSTRIAL ESTATE, VILLAGE BAHADARPUR SAINI HARIDWAR, UTTARAKHAND-247667	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	21/11/2019
3269	NDA/MAL/HDP/6578	CACHET PHARMACEUTICALS 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. LTD VILLAGE-THANA, BADDI, DIST. SOLAN, HIMACHAL PRADESH-173205.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	27/08/2019

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3270	NDA/MAL/HDP/6579	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	PLENCOXIB 200	CELECOXIB	200 MG	AKUMS DRUGS AND PHARMACEUTICALS19,20, 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
3271	NDA/MAL/HDP/6587	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SEDALAM	MIDAZOLAM	1MG/ML	MS PHARMA - JORDANPLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH-WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY VIALS	1X10X5 ML VIAL	29/05/2019
3272	NDA/MAL/HDP/6588	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SEDALAM	MIDAZOLAM	5MG/ML	MS PHARMA - JORDANPLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH-WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY VIALS	1X5X3 ML VIAL	29/05/2019

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3273	NDA/MAL/HDP/65 89	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS 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
3274	NDA/MAL/HDP/65 90	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS 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
3275	NDA/MAL/HDP/65 93	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS 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

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3276	NDA/MAL/HDP/6598	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	BREATHEZY-L (10/5)	MONTELUKAST SODIUM + LEVOCETIRIZINE DIHYDROCHLORIDE	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
3277	NDA/MAL/HDP/6600	EXPHAR SA.	PHILLIPS PHARMACEUTICALS (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
3278	NDA/MAL/HDP/6602	EXPHAR SA.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CARDIURINE	CAPTOPRIL + HYDROCHLOROTHIAZIDE	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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3279	NDA/MAL/HDP/6608	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
3280	NDA/MAL/HDP/6610	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,1.0X4.0 X4.0 ML AMPOULE	01/07/2014
3281	NDA/MAL/HDP/6611	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

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3282	NDA/MAL/HDP/6612	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	APRAZOLE PLUS-20	OMEPRAZOLE + SODIUM BICARBONATE	20MG/6G + 1680MG/6G	AJANTA PHARMA LIMITED PAITHANMANUFACTURING 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
3283	NDA/MAL/HDP/6613	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (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
3284	NDA/MAL/HDP/6614	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	AXETINE	CEFUROXIME SODIUM	1.5MG	MEDOCHEMIE 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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3285	NDA/MAL/HDP/6616	SHIN POONG PHARMACEUTICALS CO.LTD	AAFIYA (A) LIMITED	PYRAMAX	PYRONARIDINE TETRAPHOSPHATE + 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
3286	NDA/MAL/HDP/6617	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	APFLU	CHLOROPHENERAMINE + 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
3287	NDA/MAL/HDP/6619	ESAPHARM SRL	BYAMAKA PHARMACEUTICAL COMPANY LTD	ORANVATE	CLOBETASOL PROPIONATE	0.05G/100G	ESAPHARMA SRLVIA DE GASPERI, 13-20066 MELZO (MILAN) ITALY	ITALY	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/2016

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3288	NDA/MAL/HDP/6620	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILET 5MG	NEBIVOLOL HYDROCHLORIDE	5MG	BERLIN-CHEMIE AGBERLIN-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
3289	NDA/MAL/HDP/6621	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
3290	NDA/MAL/HDP/6622	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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3291	NDA/MAL/HDP/6624	SQUARE PHARMACEUTICALS LTD.PABNA UNIT	GAMA PHARMACEUTICALS (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
3292	NDA/MAL/HDP/6625	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILET PLUS 5/12.5	NEBIVOLOL HYDROCHLORIDE + HYDROCHLOROTHIAZIDE	5MG + 12.5MG	BERLIN-CHEMIE AG/MENARINI, GLIENICKE R WEG 125, D-12489 BERLIN GERMANY BERLIN-CHEMIE AG, SITE BRITZ (BULK PRODUCTION,) BERLIN-CHEMIE AG, SITE BRITZ (BULK PRODUCTION, BATCH CONTROL) TEMPELHOFER 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
3293	NDA/MAL/HDP/6627	RECKITT BENCKISER HEALTHCARE INTERNATIONAL	GITTOES PHARMACEUTICALS LIMITED	STREPSILS HONEY & LEMON	MULTI-INGREDIENT	MULTI-INGREDIENT	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED65 MOO 12,LARD KRABANG-BANGPLEE ROAD, BANGPLEE SAMUTPRAKARAN 10 540, THAILAND	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

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3294	NDA/MAL/HDP/6628	RECKITT BENCKISER HEALTHCARE INTERNATIONAL	GITTOES PHARMACEUTICALS LIMITED	STREPSILS ORIGINAL	MULTI-INGREDIENT	MULTI-INGREDIENT	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED RECKITT BENCKISER HEALTHCARE INTERNATIONAL-65 MOO 12,LARD KRABANG-BANGPLEE ROAD, BANGPLEE SAMUTPRAKARAN 10 540, THAILAND	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
3295	NDA/MAL/HDP/6629	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILET PLUS 5/25	NEBIVOLOL+HYDROCHLOROTHIAZIDE	5MG+25MG	BERLIN-CHEMIE AG/MENARINIGLIENICKER WEG 125, D-12489 BERLIN GERMANY(BATCH RELEASE) BERLIN-CHEMIE AG, SITE BRITZ (BULK PRODUCTION)TEMPELHOFER 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
3296	NDA/MAL/HDP/6630	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TOPRAZ 20	PANTOPRAZOLE	20MG	AUROBINDO PHARMA LIMITED (SEZ, UNIT "A" VII), SURVEY NO.411, 425, 434, 435 & 458, APIIC, PLOT NO. SI GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHERLA MANDAL, MAHABOON 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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3297	NDA/MAL/HDP/6631	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X500.0 G JAR	01/07/2016
3298	NDA/MAL/HDP/6633	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	COLDRIIL	PARACETAMOL + CHLORPHENIRAMINE MALEATE + PSEUDOEPHEDRINE HCL	500MG + 30MG + 2MG	BETA HEALTHCARE INTERNATIONAL LTD - - PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X12.0 X1.0X2.0X10.0 CAPSULE BLISTER	01/07/2017
3299	NDA/MAL/HDP/6636	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS 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

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3300	NDA/MAL/HDP/6638	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	COSAMIDE 50	LACOSAMIDE	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	1.0X10.0 TABLET BLISTER	01/07/2016
3301	NDA/MAL/HDP/6640	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SAFETELMI H (40/ 12.5)	TELMISARTAN + HYDROCHLOROTHIAZIDE	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
3302	NDA/MAL/HDP/6641	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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3303	NDA/MAL/HDP/6645	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SAFETELMI H (80/ 12.5)	TELMISARTAN + HYDROCHLOROTHIAZIDE	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
3304	NDA/MAL/HDP/6650	INDUS LIFE SCIENCES PVT LIMITED	NORVIK ENTERPRISES LIMITED	INTRIAX-S-1	CEFTRIAZONE SODIUM+SULBACTAM 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
3305	NDA/MAL/HDP/6653	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

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3306	NDA/MAL/HDP/6654	PANACEA BIOTEC PHARMA LTD	VITACARE LIMITED	LIVOLUK FIBRE	LACTULOSE + ISPAGHULA HUSK	10G + 3.5G/ 15G	PANACEA BIOTEC PHARMA LIMITEDMALPURI BADDI, DISTRICT SOLAN, HIMACHAL PRADESH-173205 - INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X90.0 G CONTAINER	01/07/2016
3307	NDA/MAL/HDP/6658	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
3308	NDA/MAL/HDP/6662	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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3309	NDA/MAL/HDP/6663	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
3310	NDA/MAL/HDP/6664	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,LAKHABAVA D,JAMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
3311	NDA/MAL/HDP/6665	REGAL PHARMACEUCIALS LTD	REGAL PHARMA (U) LTD	SALBUMOL SYRUP	SALBUTAMOL	2MG/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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3312	NDA/MAL/HDP/6666	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	NEBIEM 5	NEBIVOLOL HYDROCHLORIDE	5MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISION PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325-TELENGANA,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3313	NDA/MAL/HDP/6667	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, LAKHABAVA D, JAMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2016
3314	NDA/MAL/HDP/6669	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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3315	NDA/MAL/HDP/6670	AFRICURE PHARMACEUTICALS (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
3316	NDA/MAL/HDP/6675	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
3317	NDA/MAL/HDP/6679	BLUE CROSS LABORATORIES LIMITED	STAR PHARMACEUTICALS 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

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3318	NDA/MAL/HDP/6681	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
3319	NDA/MAL/HDP/6685	NEON LABORATORIES 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
3320	NDA/MAL/HDP/6686	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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3321	NDA/MAL/HDP/6689	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
3322	NDA/MAL/HDP/6693	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
3323	NDA/MAL/HDP/6694	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

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3324	NDA/MAL/HDP/6695	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
3325	NDA/MAL/HDP/6699	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
3326	NDA/MAL/HDP/6713	CACHET PHARMACEUTICALS PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	CAMET	METOCLOPRAMIDE 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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3327	NDA/MAL/HDP/67 15	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
3328	NDA/MAL/HDP/67 17	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
3329	NDA/MAL/HDP/67 22	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	CILZEC 40	TELMISARTAN	40MG	MSN LABORATORIES PVT. LIMITED PLOT 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

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3330	NDA/MAL/HDP/67 24	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	CILZEC 80	TELMISARTAN	80MG	MSN LABORATORIES PVT. LIMITED PLOT 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
3331	NDA/MAL/HDP/67 28	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
3332	NDA/MAL/HDP/67 29	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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3333	NDA/MAL/HDP/6732	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
3334	NDA/MAL/HDP/6734	CACHET PHARMACEUTICALS 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
3335	NDA/MAL/HDP/6736	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

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3336	NDA/MAL/HDP/6750	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
3337	NDA/MAL/HDP/6752	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
3338	NDA/MAL/HDP/6754	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) .KOZHIPPANNAI PUDUMUND P.O DR. BASAVAIAH NAGAR UDHAGAMANDALAM 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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3339	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
3340	NDA/MAL/HDP/6759	ADCOCK INGRAM LIMITED	SURGIPHARM (U) LIMITED	BETAPYN	PARACETAMOL+C ODEINE 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
3341	NDA/MAL/HDP/6763	ADCOCK INGRAM LIMITED	SURGIPHARM (U) LIMITED	COMPRAL HEADACHE TABLETS	PARACETAMOL+ASPIRIN+CAFFEINE ANHYDROUS	100MG+400MG+130MG	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

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3342	NDA/MAL/HDP/67 64	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	IZRA 40	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40MG	UNICHEM LABORATORIES LTD UNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205	INDIA	ORAL SOLID ORDINARY ENTERIC- COATED TABLETS	1.0X10.0 TABLET STRIP	01/07/2006
3343	NDA/MAL/HDP/67 67	ADCOCK INGRAM LIMITED	SURGI PHARM (U) LIMITED	MEDI-KEEL A	BENZOCAINE+CET YL PYRIDINIUM CHLORIDE	12MG+1.5MG	UNIQUE PHARMACEUTICALS LABORATORIES SURVEY 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
3344	NDA/MAL/HDP/67 69	ADCOCK INGRAM LIMITED	SURGI PHARM (U) LIMITED	MEDI-KEEL A HONEY & LEMON	BENZOCAINE+CET YL PYRIDINIUM CHLORIDE	12MG+1.5MG	UNIQUE PHARMACEUTICALS LABORATORIES SURVEY 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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3345	NDA/MAL/HDP/6771	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
3346	NDA/MAL/HDP/6772	ARISTO PHARMACEUTICALS 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
3347	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

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3348	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
3349	NDA/MAL/HDP/6781	IND SWIFT LIMITED	PLANET PHARMACEUTICALS 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
3350	NDA/MAL/HDP/6785	IND SWIFT LIMITED	PLANET PHARMACEUTICALS 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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3351	NDA/MAL/HDP/6787	IND SWIFT LIMITED	PLANET PHARMACEUTICALS 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/SYRUPS/DROPS	1.0X30.0 ML BOTTLE	01/07/2008
3352	NDA/MAL/HDP/6788	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
3353	NDA/MAL/HDP/6789	AFRICURE PHARMACEUTICALS (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

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3354	NDA/MAL/HDP/6790	MEGA LIFESCIENCES (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
3355	NDA/MAL/HDP/6792	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
3356	NDA/MAL/HDP/6794	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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2017

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3357	NDA/MAL/HDP/6797	MARTINDALE PHARMACEUTICALS 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
3358	NDA/MAL/HDP/6808	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
3359	NDA/MAL/HDP/6810	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CERVARIX	HUMAN PAPILLOMA VIRUS VACCINE (RDNA)	TYPE 16 L1 PROTEIN + TYPE 18 L1 PROTEIN + 3 0-DESACYL-4'MONOPHOSPHORYL LIPID A(MPL)	GLAXOSMITHKLINE BOILOGICALSS.A RUE DE L'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

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3360	NDA/MAL/HDP/68 12	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	NOFLOX	NORFLOXACIN	0.3%W/V	ABACUS PARENTERAL DRUGS LIMITED PLOT 114, BLOCK 191	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE, 1.0X5.0 ML BOTTLE	01/07/2016
3361	NDA/MAL/HDP/68 15	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
3362	NDA/MAL/HDP/68 17	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	LETROZOLE DENK 2.5	LETROZOLE	2.5MG	HAUPT PHARMA MÜNSTER GMBH SCHLEEBRÜGGEN AMP 15 48159 MÜNSTER GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016

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3363	NDA/MAL/HDP/6818	SANOFI 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	SANOFI PASTEURMÉRIEUX 69280 MARCY L'ETOILE	FRANCE	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL	01/07/2016
3364	NDA/MAL/HDP/6820	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
3365	NDA/MAL/HDP/6821	LABOREX UGANDA LIMITED	LABOREX UGANDA LIMITED	MAGNESIUM SULPHATE INJECTION	MAGNESIUM SULPHATE	50%W/V	MARTINDALE PHARMACEUTICAL LIMITED BAMPTON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X10.0 ML AMPOULE	01/07/2016

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3366	NDA/MAL/HDP/6823	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
3367	NDA/MAL/HDP/6833	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
3368	NDA/MAL/HDP/6837	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	ZEEL KIT	CLARITHROMYCIN + METRONIDAZOLE + PANTOPRAZOLE SODIUM SESQUIHYDRATE	250MG + 400MG +40MG	THE MADRAS PHARMACEUTICALS137-B,OLD MAHABALI PURAM ROAD,KARAPAKKAM,CHE NNAL INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X7.0 TABLET STRIP	01/07/2016

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3369	NDA/MAL/HDP/6843	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS 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
3370	NDA/MAL/HDP/6845	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS 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
3371	NDA/MAL/HDP/6857	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

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3372	NDA/MAL/HDP/6859	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
3373	NDA/MAL/HDP/6862	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
3374	NDA/MAL/HDP/6865	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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3375	NDA/MAL/HDP/6870	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	HYDROSONE 100MG	HYDROCORTISONE 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
3376	NDA/MAL/HDP/6871	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
3377	NDA/MAL/HDP/6872	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	NETRACORTIL EYE/EAR SUSPENSION	OXYTETRACYCLINE HYDROCHLORIDE +HYDROCORTISONE ACETATE+POLYMYXIN B SULPHATE	10MG+5MG+100 00I.U	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML BOTTLE	01/07/2017

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3378	NDA/MAL/HDP/6873	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
3379	NDA/MAL/HDP/6874	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
3380	NDA/MAL/HDP/6875	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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3381	NDA/MAL/HDP/6879	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
3382	NDA/MAL/HDP/6882	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
3383	NDA/MAL/HDP/6887	RAVIAN LIFE SCIENCE PVT. LTD	ROYAL PHARMA 2011 LIMITED	WELBEEN-L	LEVOCETIRIZINE DIHYDROCHLORIDE	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

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3384	NDA/MAL/HDP/6897	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
3385	NDA/MAL/HDP/6898	F. HOFFMANN LA-ROCHE	LABOREX UGANDA LIMITED	RECORMON	EPOETIN BETA	5000I.U/0.3ML	ROCHE DIAGNOSTICS GMBH MANNHEIMSANDHOFER STRASSE 116, 68305 MANNHEIM - GERMANY	GERMANY	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X6.0X1.0X0.3 ML PRE- FILLED SYRINGE	28/05/2019
3386	NDA/MAL/HDP/6901	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/GRANULES	1.0X2.0X20.5 G SACHET + 1*10 TABLET BLISTER	28/05/2019

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3387	NDA/MAL/HDP/6905	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICALS LIMITED	NUROFEN	IBUPROFEN	400MG	ASTRA ZENCA TURKEYNOTTINGHAM SITE, THANE ROAD, NOTTINGHAM, NOTTINGHAMSHIRE, NG90 2DB, UNITED KINGDOM	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X1.0X12.0 TABLET BLISTER	28/05/2019
3388	NDA/MAL/HDP/6907	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICALS LIMITED	NUROFEN EXPRESS	IBUPROFEN	400MG	ASTRA ZENCA TURKEYNOTTINGHAM 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
3389	NDA/MAL/HDP/6911	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

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3390	NDA/MAL/HDP/6919	MACLEODS PHARMACEUTICALS 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,1.0X25.0 X3.0 TABLET BLISTER	27/03/2019
3391	NDA/MAL/HDP/6921	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
3392	NDA/MAL/HDP/6922	EXPHAR S.A. ZONING INDUSTRIEL DE NIVELLES SUD	PHILLIPS PHARMACEUTICALS (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/SYRUPS/DROPS	1.0X60.0 ML BOTTLE	27/11/2018

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3393	NDA/MAL/HDP/6923	MACLEODS PHARMACEUTICALS 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,1.0X25.0 X3.0 TABLET BLISTER	27/03/2019
3394	NDA/MAL/HDP/6924	CARE PHARMA LIMITED	AIVEEN (U) LIMITED	NAC MR	DICLOFENAC POTASSIUM+PARACETAMOL+CHLOROXYLOXAZONE	50MG+325MG+250MG	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
3395	NDA/MAL/HDP/6926	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

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3396	NDA/MAL/HDP/69 27	SEGURA PHARMA PRIVATE LTD	ABACUS PHARMA (AFRICA) LIMITED	GOPAYN MR	ACECLOFENAC BP+TIZANIDINE HYDROCHLORIDE USP+PARACETAM OL BP	100MG+2MG+50 0MG	SAI MIRRA INNOPHARM PVT LIMITED 288&299, SIDCO ESTATE AMBTTUR, CHENNAI 600098	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	28/05/2019
3397	NDA/MAL/HDP/69 28	SAVA HEALTHCARE LIMITED	PHILLIPS PHARMACEUTICALS (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
3398	NDA/MAL/HDP/69 29	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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3399	NDA/MAL/HDP/6930	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS 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
3400	NDA/MAL/HDP/6931	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
3401	NDA/MAL/HDP/6932	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

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3402	NDA/MAL/HDP/6933	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
3403	NDA/MAL/HDP/6936	SAVA HEALTHCARE LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	RANKOF	PARACETAMOL+C AFFEINE, PHENYLEPHRINE + CHLORPHENAMINE MALEATE	500MG+30MG+10MG+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
3404	NDA/MAL/HDP/6937	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	1X10 ML VIAL	29/05/2019

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3405	NDA/MAL/HDP/69 39	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
3406	NDA/MAL/HDP/69 41	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
3407	NDA/MAL/HDP/69 42	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

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3408	NDA/MAL/HDP/6946	PHARMACTIV FZCO	JEET PHARMACEUTICALS 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
3409	NDA/MAL/HDP/6948	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	D3 MUST 60K	CHOLECALCIFEROL	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
3410	NDA/MAL/HDP/6949	PHARMACTIV FZCO	JEET PHARMACEUTICALS LIMITED	MEGAFER	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

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3411	NDA/MAL/HDP/6953	SYNOKEM PHARMACEUTICALS 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
3412	NDA/MAL/HDP/6955	TROIKAA PHARMACEUTICALS 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
3413	NDA/MAL/HDP/6956	TROIKAA PHARMACEUTICALS 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

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3414	NDA/MAL/HDP/6961	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS 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
3415	NDA/MAL/HDP/6962	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROXONE- S	CEFTRIAXONE 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
3416	NDA/MAL/HDP/6963	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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3417	NDA/MAL/HDP/69 64	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
3418	NDA/MAL/HDP/69 67	EVA PHARMA FOR PHARMACEUTICAL S & MEDICAL APPLIANCES -	GAMA PHARMACEUTICALS (U) LIMITED	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
3419	NDA/MAL/HDP/69 70	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

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3420	NDA/MAL/HDP/6971	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
3421	NDA/MAL/HDP/6973	THE UNITED PHARMACEUTICALS MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIFED DM SYRUP 120ML	TRIPROLDINE HYDROCHLORIDE + PSEUDOEPHEDRINE HYDROCHLORIDE + DEXTROMETHORPHAN	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
3422	NDA/MAL/HDP/6974	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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3423	NDA/MAL/HDP/6976	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	KETORIV SOAP	KETOCONAZOLE	2.0%W/V	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN Å€ 248011 (U.K), INDIA	INDIA	TOPICAL EXTERNAL SOLID SOAPS/BARS	1.0X75.0 G SACHET	28/08/2019
3424	NDA/MAL/HDP/6977	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CLINDARIV	CLINDAMYCIN PHOSPHATE	1.0%W/W	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN Å€ 248011 (U.K), INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	28/08/2019
3425	NDA/MAL/HDP/6978	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	DEXARIV	DEXAMETHASONE 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

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3426	NDA/MAL/HDP/69 80	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
3427	NDA/MAL/HDP/69 82	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	DEXARIV	DEXAMETHASONE 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
3428	NDA/MAL/HDP/69 83	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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3429	NDA/MAL/HDP/69 84	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	VIREXIM-400	CEFIXIME TRIHYDRATE	400 MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X5.0 CAPSULE BLISTER, 1.0X10.0 X10.0 CAPSULE BLISTER	27/08/2019
3430	NDA/MAL/HDP/69 85	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
3431	NDA/MAL/HDP/69 86	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

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3432	NDA/MAL/HDP/6989	THE UNITED PHARMACEUTICALS MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIFED EXPECTORANT SYRUP 120ML	TRIPROLIDINE HYDROCHLORIDE + PSEUDOEPHEDRINE HYDROCHLORIDE + GUAIFENESIN	1.25MG+30MG+100MG/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
3433	NDA/MAL/HDP/6990	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ESORIV-40	ESOMEPRAZOLE MAGNESIUM	40MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	28/05/2019
3434	NDA/MAL/HDP/6991	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ESORIV-20	ESOMEPRAZOLE MAGNESIUM	20MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	28/05/2019

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3435	NDA/MAL/HDP/6992	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
3436	NDA/MAL/HDP/6993	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
3437	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/SYRUPS/DROPS	1X30 ML BOTTLE	31/01/2018

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3438	NDA/MAL/HDP/7003	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	NAC-SP	DICLOFENAC POTASSIUM + SERRATIOPEPTIDASE	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
3439	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
3440	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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3441	NDA/MAL/HDP/7006	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
3442	NDA/MAL/HDP/7007	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EPNONE 50	EPLERENONE	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	1.0X3.0X10.0 TABLET BLISTER	27/11/2018
3443	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

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3444	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
3445	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
3446	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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3447	NDA/MAL/HDP/70 13	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
3448	NDA/MAL/HDP/70 14	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
3449	NDA/MAL/HDP/70 15	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

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3450	NDA/MAL/HDP/7018	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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	27/08/2019
3451	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
3452	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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3453	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
3454	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
3455	NDA/MAL/HDP/7023	EXPHAR SA.	PHILLIPS PHARMACEUTICALS (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,1.0X20.0X10.0 ML BOTTLE	28/03/2018

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3456	NDA/MAL/HDP/7024	EXPHAR SA.	PHILLIPS PHARMACEUTICALS (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
3457	NDA/MAL/HDP/7027	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	CELCOXX	CELECOXIB	200MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	25/11/2021
3458	NDA/MAL/HDP/7029	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

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3459	NDA/MAL/HDP/7037	MEDLEY PHARMACEUTICALS LTD	EUROPA HEALTHCARE (U) LTD	O2	OFLOXACIN + ORNIDAZOLE	50MG + 125MG	MEDLEY PHARMACEUTICALS LTD LANE 03, PHASE 1, SIDCO INDUSTRIAL COMPLEX, BARI BRAHMANA JAMMU 181133	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X30.0 ML BOTTLE	27/08/2019
3460	NDA/MAL/HDP/7039	MEDLEY PHARMACEUTICALS LTD	EUROPA HEALTHCARE (U) LTD	O2	OFLOXACIN + ORNIDAZOLE	200MG + 500MG	MEDLEY PHARMACEUTICALS LTD LANE 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
3461	NDA/MAL/HDP/7053	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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3462	NDA/MAL/HDP/7057	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
3463	NDA/MAL/HDP/7058	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
3464	NDA/MAL/HDP/7063	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	GRISEOFULVIN 500MG FILM-COATED TABLET	GRISEOFULVIN	500MG	HOVID BHD LOT 56442, 7.5 MILE JALAN IPOH/CHEMOR 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	31/01/2018

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3465	NDA/MAL/HDP/7064	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
3466	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
3467	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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3468	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
3469	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
3470	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

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3471	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, APIC 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
3472	NDA/MAL/HDP/7083	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
3473	NDA/MAL/HDP/7084	PHARMACTIV FZCO	JEET PHARMACEUTICALS 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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3474	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
3475	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
3476	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% NACL)	27/08/2019

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3477	NDA/MAL/HDP/7091	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	AARLEFLOX 500 TABLETS	LEVOFLOXACIN HEMIHYDRATE	500MG	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	29/11/2017
3478	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% NACL)	27/08/2019
3479	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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3480	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
3481	NDA/MAL/HDP/7098	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	ACEFORCE SP	ACECLOFENAC+PARACETAMOL+SERATIOPEPTIDASE	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
3482	NDA/MAL/HDP/7101	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

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3483	NDA/MAL/HDP/7102	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REPRAZINE	CHLORPROMAZINE HYDROCHLORIDE	100MG	RENE INDUSTRIES LIMITED PLOT 680 KAMULI- KIREKA	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
3484	NDA/MAL/HDP/7103	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
3485	NDA/MAL/HDP/7104	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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3486	NDA/MAL/HDP/7105	CACHET PHARMACEUTICALS 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
3487	NDA/MAL/HDP/7106	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
3488	NDA/MAL/HDP/7107	MACLEODS PHARMACEUTICALS 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,1.0X10.0 X10.0 TABLET BLISTER	27/03/2019

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3489	NDA/MAL/HDP/7109	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
3490	NDA/MAL/HDP/7110	THE UNITED PHARMACEUTICALS MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIFED EXTRA SYRUP 120ML	TRIPROLDINE HYDROCHLORIDE + PSEUDOEPHEDRINE HYDROCHLORIDE + DEXTROMETHORPHAN + 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
3491	NDA/MAL/HDP/7112	HETERO DRUGS LTD	AIVEEN (U) LIMITED	ETROBAX 60	ETORICOXIB	60MG	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

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3492	NDA/MAL/HDP/7115	INTAS, PHARMACEUTICALS LTD	STAR BIOTECH UGANDA LTD	SARTEL 40H	TELMISARTAN +HYDROCHLOROTHIAZIDE	(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
3493	NDA/MAL/HDP/7116	THE UNITED PHARMACEUTICALS MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIFED SYRUP 120ML	TRIPROLIDINE HYDROCHLORIDE + PSEUDOEPHEDRINE 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
3494	NDA/MAL/HDP/7117	THE UNITED PHARMACEUTICALS MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIFED TABLETS	TRIPROLIDINE HYDROCHLORIDE + PSEUDOEPHEDRINE 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

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3495	NDA/MAL/HDP/71 18	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
3496	NDA/MAL/HDP/71 19	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	OLMAT-40 H	OLMESARTAN MEDOXOMIL + HYDROCHLOROTH IAZIDE	40MG + 12.5MG	MICRO LABS LIMITED .92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
3497	NDA/MAL/HDP/71 20	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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3498	NDA/MAL/HDP/7122	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
3499	NDA/MAL/HDP/7123	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
3500	NDA/MAL/HDP/7124	PHARCO PHARMACEUTICALS	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

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3501	NDA/MAL/HDP/7125	SYNOKEM PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	I-FREE 72	LEVONORGESTREL	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
3502	NDA/MAL/HDP/7127	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
3503	NDA/MAL/HDP/7128	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	COTRIKANT-960	TRIMETHOPRIM+SULFAMETHOXAZOLE	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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3504	NDA/MAL/HDP/7131	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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	26/09/2018
3505	NDA/MAL/HDP/7132	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
3506	NDA/MAL/HDP/7133	LIPTIS EGYPT FOR PHARMACEUTICALS AND MEDICAL PRODUCTS	HARLEYS UGANDA LIMITED	WELLNESS	DAY TABLET: PARACETAMOL + PSEUDOEPHEDRINE HYDROCHLORIDE + DEXTROMETHORPHAN HYDROBROMIDE NIGHT TABLET: PARACETAMOL + PSEUDOEPHEDRINE	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

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3507	NDA/MAL/HDP/7135	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
3508	NDA/MAL/HDP/7136	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	AMIKACIN 100 MG / 2ML	AMIKACIN SULPHATE	100MG/2ML	EGYPTIAN INT.PHARMACEUTICAL 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
3509	NDA/MAL/HDP/7145	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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3510	NDA/MAL/HDP/7147	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
3511	NDA/MAL/HDP/7148	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,1.0X10.0 X10.0 TABLET STRIP	25/07/2018
3512	NDA/MAL/HDP/7149	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

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3513	NDA/MAL/HDP/71 50	SAKAR HEALTHCARE LIMITED	ROYAL PHARMA 2011 LIMITED	SEFIXI - SB 1500	CEFTRIAZONE 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
3514	NDA/MAL/HDP/71 51	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	APDROPS DX	MOXIFLOXACIN HYDROCHLORIDE + DEXAMETHASONE 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
3515	NDA/MAL/HDP/71 52	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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3516	NDA/MAL/HDP/71 54	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CIPROFLOXA CIN HYDROCHLO RIDE	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
3517	NDA/MAL/HDP/71 62	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
3518	NDA/MAL/HDP/71 63	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

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3519	NDA/MAL/HDP/71 67	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
3520	NDA/MAL/HDP/71 72	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
3521	NDA/MAL/HDP/71 75	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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3522	NDA/MAL/HDP/7179	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	AVONZA	TENOFOVIR DISOPROXIL FUMARATE+LAMI VUDINE+EFAVIRE NZ	300MG+300MG+ 400MG	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,1.0X9 0.0 TABLET CONTAINER	07/11/2018
3523	NDA/MAL/HDP/7180	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (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
3524	NDA/MAL/HDP/7181	PHARMACTIV FZCO	JEET PHARMACEUTICALS 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

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3525	NDA/MAL/HDP/71 82	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
3526	NDA/MAL/HDP/71 83	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
3527	NDA/MAL/HDP/71 87	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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3528	NDA/MAL/HDP/71 91	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
3529	NDA/MAL/HDP/71 92	EXPHAR SA.	PHILLIPS PHARMACEUTICALS (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
3530	NDA/MAL/HDP/71 93	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

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3531	NDA/MAL/HDP/7194	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
3532	NDA/MAL/HDP/7197	SERUM INSTITUTE OF INDIA PVT LTD	NORVIK ENTERPRISES LIMITED	RABIVAX-S	PURIFIED RABIES ANTIGEN (RABIES VIRUS PITMAN-MOORE STRAIN 3218)	NOT LESS THAN 2.5 I.U / DOSE	SERUM INSTITUTE OF INDIA PVT LTD .212/2, HADAPSAR, PUNE-411028, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0X1.0 DOSE VIAL + IML DILUENT AMPOULE	27/08/2019
3533	NDA/MAL/HDP/7198	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICAL S LTD)	PLANET PHARMACEUTICALS 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

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3534	NDA/MAL/HDP/7201	SERUM INSTITUTE OF INDIA PVT LTD	NORVIK ENTERPRISES LIMITED	MEASLES AND RUBELLA VACCINE	LIVE, ATTENUATED MEASLES VIRUS + LIVE ATTENUATED RUBELLA VIRUS	NLT 1000 CCID50 + 1000 CCID50 / DOSE	SERUM INSTITUTE OF INDIA PVT LTD .212/2, HADAPSAR, PUNE-411028, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0X10.0 DOSE VIAL + 5ML DILUENT,1.0X50.0X1.0 DOSE VIAL + 1ML DILUENT	27/08/2019
3535	NDA/MAL/HDP/7206	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
3536	NDA/MAL/HDP/7207	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/SYRUPS/DROPS	1.0X30.0 ML BOTTLE	29/08/2019

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3537	NDA/MAL/HDP/72 11	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
3538	NDA/MAL/HDP/72 15	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	CELCOXX	CELECOXIB	100MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	10/01/2022
3539	NDA/MAL/HDP/72 16	SHIN POONG PHARMACEUTICAL S CO.LTD	AAFIYA (A) LIMITED	PYRAMAX	PYRONARIDINE TETRAPHOSPHATE + 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/GRANUL ES	1.0X90.0 SACHET CARTON	27/08/2019

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3540	NDA/MAL/HDP/72 17	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS 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
3541	NDA/MAL/HDP/72 18	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS 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
3542	NDA/MAL/HDP/72 19	THEON PHARMACEUTICALS LTD	AIVEEN (U) LIMITED	THEOXONE -1 G	CEFTRIAZONE	1G	THEON PHARMACEUTICALS LTD.VILLAG SAINI MAJRA, TEHSIL NALAGARH DIST, SOLAN- 174101,	INDIA	PARENTERAL ORDINARY DRY VIALS	1X1 G VIAL	29/11/2017

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3543	NDA/MAL/HDP/7220	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
3544	NDA/MAL/HDP/7222	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
3545	NDA/MAL/HDP/7223	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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3546	NDA/MAL/HDP/72 25	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
3547	NDA/MAL/HDP/72 26	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
3548	NDA/MAL/HDP/72 29	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS 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

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3549	NDA/MAL/HDP/7234	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
3550	NDA/MAL/HDP/7235	JAMJOOM PHARMACEUTICALS COMPANY	MU PHARMA CO - SMC LIMITED	OPTIDEX-T	DEXAMETHASONE + 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
3551	NDA/MAL/HDP/7237	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	CONTUS PAEDIATRIC	CHLORPHENAMINE 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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3552	NDA/MAL/HDP/72 38	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
3553	NDA/MAL/HDP/72 39	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
3554	NDA/MAL/HDP/72 40	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED	GITTOES PHARMACEUTICALS 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

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3555	NDA/MAL/HDP/7241	EXPHAR SA.	PHILLIPS PHARMACEUTICALS (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
3556	NDA/MAL/HDP/7242	STEDMAN PHARMACEUTICALS 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
3557	NDA/MAL/HDP/7243	BAL PHARMA LIMITED -	PLANET PHARMACEUTICALS UGANDA LTD	EMTRIM	TRIMETHOPRIM + SULPHAMETHOXAZOLE	80MG+ 400MG	BAL PHARMA LTD1, 2, 3 & SECTOR 69, SECTOR 4, IIE-PANTNAGAR UDHAM SINGH NAGAR, RUDRAPUR-263153 UTTARAKHAND-INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	31/01/2018

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3558	NDA/MAL/HDP/72 45	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
3559	NDA/MAL/HDP/72 46	EVA PHARMA FOR PHARMACEUTICAL S & MEDICAL APPLIANCES	GAMA PHARMACEUTICALS (U) LIMITED	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
3560	NDA/MAL/HDP/72 47	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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3561	NDA/MAL/HDP/7248	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES	GAMA PHARMACEUTICALS (U) LIMITED	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
3562	NDA/MAL/HDP/7249	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES	GAMA PHARMACEUTICALS (U) LIMITED	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
3563	NDA/MAL/HDP/7250	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	DOLUTEGRAVIR SODIUM, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE	DOLUTEGRAVIR SODIUM +LAMIVUDINE +TENFOVIR 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

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3564	NDA/MAL/HDP/7251	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	HYDROXYUREA	HYDROXYCARBAMIDE	500MG	HAUPT PHARMA AMAREG GMBHDONAUSTAUFER STRASSE 378, 93055 REGENSBURG	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	21/11/2019
3565	NDA/MAL/HDP/7253	MANKIND PHARM LTD	TATA UGANDA LIMITED	MONTICOPE	MONTELUKAST SODIUM + LEVOCETIRIZINE DIHYDROCHLORIDE	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
3566	NDA/MAL/HDP/7257	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS 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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3567	NDA/MAL/HDP/7258	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	DESCOVY 200MG/10MG	EMTRICITABINE + TENOFOVIR 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
3568	NDA/MAL/HDP/7259	FERRER INTERNATIONAL, S.A.	PHILLIPS PHARMACEUTICALS (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
3569	NDA/MAL/HDP/7260	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

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3570	NDA/MAL/HDP/7264	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MIOPAN PLUS SUSPENSION	MAGALDRATE+SIMETHICONE	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
3571	NDA/MAL/HDP/7267	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
3572	NDA/MAL/HDP/7269	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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3573	NDA/MAL/HDP/7271	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
3574	NDA/MAL/HDP/7272	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
3575	NDA/MAL/HDP/7275	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (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

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3576	NDA/MAL/HDP/7284	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LTD	LIVERCOL 10	ROSUVASTATIN 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
3577	NDA/MAL/HDP/7286	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TOBRIN OPTHALMIC 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
3578	NDA/MAL/HDP/7287	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPISTIGMIN 0.05%	NEOSTIGMINE METHYLSULPHATE	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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3579	NDA/MAL/HDP/7288	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	KETESSE FILM COATED TABLETS	DEXKETOPROFEN 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
3580	NDA/MAL/HDP/7292	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
3581	NDA/MAL/HDP/7293	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LTD	ALRINAST	DESLORATADINE	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	1.0X2.0X10.0 TABLET BLISTER	29/11/2017

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3582	NDA/MAL/HDP/72 95	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
3583	NDA/MAL/HDP/72 96	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MEDAXONU M 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
3584	NDA/MAL/HDP/72 98	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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3585	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
3586	NDA/MAL/HDP/7302	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
3587	NDA/MAL/HDP/7304	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,1.0X3.0X 10.0 CAPSULE BLISTER	26/09/2018

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3588	NDA/MAL/HDP/7305	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
3589	NDA/MAL/HDP/7306	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
3590	NDA/MAL/HDP/7307	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

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3591	NDA/MAL/HDP/73 10	JAMJOOM PHARMACEUTICAL S 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
3592	NDA/MAL/HDP/73 11	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	FLUCA OPHTHALMIC SUSPENSION	FLUOROMETHOLO N + 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
3593	NDA/MAL/HDP/73 12	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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3594	NDA/MAL/HDP/73 17	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
3595	NDA/MAL/HDP/73 18	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MOXICLAV 625	AMOXICILLIN TRIHYDRATE + CLAVULINIC ACID	500MG + 125MG	MEDOCHEMIE 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
3596	NDA/MAL/HDP/73 19	DROGSAN İLAÇLARI SAN. VE TIC. A.Ş.	BUFFALO HEALTH CARE LTD	SIPROSAN 500	CIPROFLOXACIN HYDROCHLORIDE	500MG	DROGSAN İLAÇLARI SAN. VE TIC. A.Ş.ESENBOGA 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

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3597	NDA/MAL/HDP/73 21	GLENMARK PHARMACEUTICAL S LTD	ABACUS PHARMA (AFRICA) LIMITED	ASCORIL-D	DEXTROMETHORP HAN HYDROBROMIDE + TRIPROLDINE HYDROCHLORIDE + PSEUDOEPHEDRIN E 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
3598	NDA/MAL/HDP/73 25	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
3599	NDA/MAL/HDP/73 29	DAWA LIMITED	SUPER MEDIC LTD	ACEPAR- MR	PARACETAMOL +ACECLOFENAC+C HLORZOAZONE	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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3600	NDA/MAL/HDP/73 30	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	FAMY-POP	LEVONORGESTREL	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
3601	NDA/MAL/HDP/73 35	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
3602	NDA/MAL/HDP/73 36	MODI NUNDIPHARMA PVT LTD	SURGIPHARM (U) LIMITED	BETADINE GERMICIDE GARGLE 2% MINT	POVIDONE IODINE	2%W/V	G.S PHAMBUTOR PVT LTD G.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

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3603	NDA/MAL/HDP/73 37	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
3604	NDA/MAL/HDP/73 38	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
3605	NDA/MAL/HDP/73 39	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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3606	NDA/MAL/HDP/7340	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 BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	21/11/2019
3607	NDA/MAL/HDP/7341	M/S.MAXHEAL PHARMACEUTICALS(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
3608	NDA/MAL/HDP/7342	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS 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

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3609	NDA/MAL/HDP/73 45	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
3610	NDA/MAL/HDP/73 46	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
3611	NDA/MAL/HDP/73 48	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

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3612	NDA/MAL/HDP/7350	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
3613	NDA/MAL/HDP/7351	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYFIX CV DS	CEFIXIME+CLAVULANIC ACID	50MG+31.25MG	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD-ROORKEE DISTT HARIDWAR	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
3614	NDA/MAL/HDP/7353	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

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3615	NDA/MAL/HDP/7355	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,INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X60.0 ML BOTTLE	31/01/2018
3616	NDA/MAL/HDP/7357	CACHET PHARMACEUTICALS PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	PAMAGIN-C SYRUP	CETIRIZINE HYDROCHLORIDE+ DEXTROMETHORPHAN HYDROBROMIDE+ ACETAMINOPHEN +PHENYLEPHRINE HYDROCHLORIDE+ ZINC GLUCONATE+MENTHOL	2.5MG+7.5MG+125MG+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
3617	NDA/MAL/HDP/7359	INDCHEMIE HEALTH SPECIALITIES PVT. LTD.	NUMED STORES SMC LIMITED	INDCLAV 625	AMOXICILLIN+CLAVULANATE POTASSIUM	500MG+125MG	INDCHEMIE HEALTH SPECIALITIES PVT LTDVILLAGE THANA TEHSIL BADDI DIST SOLAN HIMACHAL PRADESH 173205	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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3618	NDA/MAL/HDP/73 60	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICALS 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,1.0X12.0X 10.0 ML SACHET	21/11/2019
3619	NDA/MAL/HDP/73 61	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
3620	NDA/MAL/HDP/73 63	INDCHEMIE HEALTH SPECIALITIES PVT. LTD.	NUMED STORES SMC LIMITED	INDCLAV 228	AMOXICILLIN+CLA VULANATE POTASSIUM	200MG+28MG/5 ML	INDCHEMIE HEALTH SPECIALITIES PVT. LTD.VILLAGE & P.O – THANA, TEHSIL – BADDI, DIST- SOLAN, HIMACHAL	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRU PS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017

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3621	NDA/MAL/HDP/73 64	İLKO İLAÇ SANAYI VE TİCARET A. Ş.	CORE ACCESS LIMITED	MOKSEFEN 400 MG	MOXIFLOXACIN HYDROCHLORIDE	400MG	İLKO İLAÇ SANAYI VE TİCARET A. Ş. 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
3622	NDA/MAL/HDP/73 65	OCHOA LABORATORIES LIMITED -	SUPER MEDIC LTD	DOLOACT MR	PARACETAMOL+ DICLOFENAC POTASSIUM+CHL ORZOXAZONE	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
3623	NDA/MAL/HDP/73 66	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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3624	NDA/MAL/HDP/7367	TWENTY FIRST CENTURY PHARMACEUTICALS 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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
3625	NDA/MAL/HDP/7369	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	XOMOX CV DS	AMOXICILLIN TRIHYDRATE+POTASSIUM CLAVULANATE	200MG+28.5MG/5ML	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTDUNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
3626	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

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3627	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
3628	NDA/MAL/HDP/7381	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
3629	NDA/MAL/HDP/7384	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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3630	NDA/MAL/HDP/7386	TWENTY FIRST CENTURY PHARMACEUTICALS 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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
3631	NDA/MAL/HDP/7388	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYFIX CV 200	CEFIXIME+CLAVULANIC 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
3632	NDA/MAL/HDP/7389	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES -	GAMA PHARMACEUTICALS (U) LIMITED	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

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3633	NDA/MAL/HDP/7391	EMCURE PHARMACEUTICALS 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
3634	NDA/MAL/HDP/7407	HETERO LABS LTD	AIVEEN (U) LIMITED	MONAST 5	MONTELUKAST SODIUM	5MG	HETERO LABS LIMITED (UNIT V)SY NO. 436,440, 441 & 458, APIC 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
3635	NDA/MAL/HDP/7408	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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3636	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
3637	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, 1.0X50.0 X10.0 TABLET BLISTER, 1.0X100.0X10.0 TABLET BLISTER, 1.0X1000.0 TABLET CONTAINER	26/09/2018
3638	NDA/MAL/HDP/7411	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/SYRUPS/DROPS	1.0X60.0 ML BOTTLE	28/11/2019

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3639	NDA/MAL/HDP/74 13	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
3640	NDA/MAL/HDP/74 14	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICALS 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
3641	NDA/MAL/HDP/74 15	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICALS 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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3642	NDA/MAL/HDP/74 17	INTAS PHARMACUTICALS 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
3643	NDA/MAL/HDP/74 18	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
3644	NDA/MAL/HDP/74 19	INTAS PHARMACEUTICAL S 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

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3645	NDA/MAL/HDP/74 21	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
3646	NDA/MAL/HDP/74 24	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
3647	NDA/MAL/HDP/74 25	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,1.0X1.0X 10.0 TABLET BLISTER	21/11/2019

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3648	NDA/MAL/HDP/74 26	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MEDOFED	GUAIFENESIN + DEXTROMETHORP HAN HYDROBROMIDE + PSEUDOEPHEDRIN E HYDROCHLORIDE AND + TRIPROLDINE HYDROCHLORIDE	100MG + 15MG + 20MG + 1.25MG/5ML	MEDOCHEMIE ACTORY).....1-10 CONSTANTINOPOLEOS STREET, 3011, LIMASSOL	CYPRUS	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE	21/11/2019
3649	NDA/MAL/HDP/74 29	SAKAR HEALTHCARE LIMITED	ROYAL PHARMA 2011 LIMITED	SEFIXI 1000	CEFTRIAXONE SODIUM	1G	SAKAR HEALTHCARE PVT LTDBLOCK NO. 10-13, NR. M.N DESAI PETRO PUMP, SARKHEJ-BAVLA ROAD, CHANGODAR, DIST: AHMEDABAD-382213, GUJARAT	INDIA	PARENTERAL ORDINARY DRY VIALS	1X50X1 G VIAL	28/11/2019
3650	NDA/MAL/HDP/74 31	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	MOVICOL	MACROGOL 3350 (POLYETHYLENE GLYCOL)+SODIUM CHLORIDE+SODIU M BICARBONATE+ POTASSIUM CHLORIDE	13.125G+350.7M G+178.5MG+46.6 MG	WIN-MEDICARE PVT. LTDMODIPURAM-250 110, UTTAR PRADESH,INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X10.0X13.81 G SACHET	26/09/2018

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3651	NDA/MAL/HDP/7432	SERUM INSTITUTE OF INDIA PVT LTD	NORVIK ENTERPRISES LIMITED	MENAFRIVAC	MENINGOCOCCAL A POLYSACCHARIDE + TETANUS TOXOID	5µG + 5µG /0.5ML	SERUM INSTITUTE OF INDIA PVT LTD .212/2, HADAPSAR, PUNE-411028, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X5.0 ML VIAL + 1*5ML AMPOULE FOR DILUENT	21/11/2019
3652	NDA/MAL/HDP/7435	SQUARE FORMULATIONS LTD	GAMA PHARMACEUTICALS (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
3653	NDA/MAL/HDP/7436	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (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

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3654	NDA/MAL/HDP/74 39	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
3655	NDA/MAL/HDP/74 40	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
3656	NDA/MAL/HDP/74 41	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	HYORTH XL	SODIUM HYALURONATE	8MG/ML	VIRCHOW BIOTECH PVT LTDSURVEY NO. 172, PART GAGILLAPUR(P) QUTHBULLAPUR(MANDA L), 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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3657	NDA/MAL/HDP/74 42	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
3658	NDA/MAL/HDP/74 47	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
3659	NDA/MAL/HDP/74 48	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

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3660	NDA/MAL/HDP/74 50	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
3661	NDA/MAL/HDP/74 54	MEDISEL(K) LTD	AIVEEN (U) LIMITED	GIT	ITOPRIDE HYDROCHLORIDE	150MG	CORONA REMEDIES PVT. LTDVILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	OPHTHALMIC DROPS	1.0X1.0X10.0 CAPSULE BLISTER	28/11/2019
3662	NDA/MAL/HDP/74 56	INFUGEN PHARMA PVT. LTD.	TATA UGANDA LIMITED	INFUTRAX	CEFTRIAZONE 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 CAPTAB PVT	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	21/11/2019

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3663	NDA/MAL/HDP/74 60	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
3664	NDA/MAL/HDP/74 61	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
3665	NDA/MAL/HDP/74 63	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

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3666	NDA/MAL/HDP/74 64	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
3667	NDA/MAL/HDP/74 65	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	P-ALAXIN TS	DIHYDROARTEMIS ININ + 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
3668	NDA/MAL/HDP/74 67	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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3669	NDA/MAL/HDP/74 68	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
3670	NDA/MAL/HDP/74 69	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
3671	NDA/MAL/HDP/74 70	AKRITI PHARMACEUTICAL S PVT LTD	PHARMA VILLE LIMITED	AKSONE	CEFTRIAXONE 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

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3672	NDA/MAL/HDP/7473	INVENTIA HEALTHCARE PVT LTD	EUROPA HEALTHCARE (U) LTD	AFLODOR 16	ACECLOFENAC + THIOCOLCHICOSIDE	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
3673	NDA/MAL/HDP/7474	INVENTIA HEALTHCARE PVT LTD	EUROPA HEALTHCARE (U) LTD	AFLODOR 8	ACECLOFENAC + THIOCOLCHICOSIDE	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
3674	NDA/MAL/HDP/7475	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	UMOCLOX 500	AMPICILLIN TRIHYDRATE+CLOXACILLIN 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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3675	NDA/MAL/HDP/7477	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
3676	NDA/MAL/HDP/7480	DEVA HOLDING A.S	SHREEJI PHARMACEUTICALS 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/SYRUPS/DROPS	1.0X70.0 ML BOTTLE	21/11/2019
3677	NDA/MAL/HDP/7481	INTAS PHARMACEUTICALS 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

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3678	NDA/MAL/HDP/7483	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
3679	NDA/MAL/HDP/7487	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
3680	NDA/MAL/HDP/7488	INTAS PHARMACEUTICALS 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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3681	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
3682	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
3683	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

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3684	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
3685	NDA/MAL/HDP/7493	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
3686	NDA/MAL/HDP/7503	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (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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3687	NDA/MAL/HDP/7504	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICALS 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
3688	NDA/MAL/HDP/7505	DEV LIFE CORPORATION	PLANET PHARMACEUTICALS UGANDA LTD	EPIRYTE 300	SODIUM VALPOATE	300 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1X10X10 TABLET STRIP	27/11/2019
3689	NDA/MAL/HDP/7506	DEV LIFE CORPORATION	PLANET PHARMACEUTICALS UGANDA LTD	EPIRYTE 500	SODIUM VALPOATE	500 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1X3X10 TABLET BLISTER	27/11/2019

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3690	NDA/MAL/HDP/7507	ZIM LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	FINEVIT-D3 2000	CHOLECALCIFEROL (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
3691	NDA/MAL/HDP/7510	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
3692	NDA/MAL/HDP/7514	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	İLFLX 500	LEVOFLOXACIN HEMIHYDRATE	500 MG	İLKO İLAÇ SANAYİ VE TİCARET A.Ş.ORGANIZİ SANAYİ BOLGESİ, BÜYÜK 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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3693	NDA/MAL/HDP/7515	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
3694	NDA/MAL/HDP/7516	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	İLFLÖX 750	LEVOFLOXACIN HEMIHYDRATE	750 MG	İLKO İLAÇ SANAYİ VE TİCARET A.Ş. ORGANİZE SANAYİ BÖLGESİ, BÜYÜK 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
3695	NDA/MAL/HDP/7517	RESONANT PHARMACEUTICALS PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	LEVOCET-M	LEVOCETIRIZINE DIHYDROCHLORIDE + 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

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3696	NDA/MAL/HDP/7518	RESONANT PHARMACEUTICALS	SHREEJI PHARMACEUTICALS LIMITED	LEVOCET-M SUSPENSION	LEVOCETIRIZINE DIHYDROCHLORIDE + 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
3697	NDA/MAL/HDP/7519	MACLEODS PHARMACEUTICALS 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
3698	NDA/MAL/HDP/7520	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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3699	NDA/MAL/HDP/7523	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
3700	NDA/MAL/HDP/7524	AMMAN PHARMACEUTICALS 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
3701	NDA/MAL/HDP/7525	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

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3702	NDA/MAL/HDP/75 26	I-CARE PHARMA LTD	AIVEEN (U) LIMITED	MANIGRA 100	SILDENAFIL CITRATE	100 MG	CORONA REMEDIES PVT. LTD VILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	27/11/2019
3703	NDA/MAL/HDP/75 29	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
3704	NDA/MAL/HDP/75 30	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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3705	NDA/MAL/HDP/7535	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
3706	NDA/MAL/HDP/7536	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS UGANDA LTD	SPINESIA-D	BUPIVACAINE HYDROCHLORIDE + DEXTROSE	5MG + 80MG /ML	UNIQUE PHARMACEUTICAL LABORATORIES PLOT 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, 1.0X10.0X4.0 ML AMPOULE, 1.0X1.0X5.0X5.0X4.0 ML AMPOULE, 1.0X5.0X4.0 ML AMPOULE	01/07/2017
3707	NDA/MAL/HDP/7539	SEV PHARMACEUTICALS LIMITED	SEV PHARMACEUTICALS LIMITED	COUGH LINCTUS	CHLORPHENIRAMINE	2MG/5ML	SEV PHARMACEUTICALS LIMITED PLOT 100 NALUKOLONGO	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X1000.0 ML JERRYCAN, 1.0X200.0 ML BOTTLE	01/07/2011

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3708	NDA/MAL/HDP/7541	SEV PHARMACEUTICALS LIMITED	SEV PHARMACEUTICALS LIMITED	CHLORHEXIDINE SCRUB	CHLORHEXIDINE GLUCONATE	4%W/V	SEV PHARMACEUTICALS LIMITED PLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X1000.0 ML JERRYCAN	01/07/2012
3709	NDA/MAL/HDP/7544	SEV PHARMACEUTICALS LIMITED	SEV PHARMACEUTICALS LIMITED	GLYCERIN OF BORAX	GLYCERINE+BORAX	12%W/V	SEV PHARMACEUTICALS LIMITED PLOT 100 NALUKOLONGO	UGANDA	ORAL LIQUID ORDINARY LIQUIDS	1.0X22.0 ML BOTTLE	01/07/2013
3710	NDA/MAL/HDP/7546	SEV PHARMACEUTICALS LIMITED	SEV PHARMACEUTICALS LIMITED	HYDROGEN PEROXIDE	HYDROGEN PEROXIDE	6%W/V	SEV PHARMACEUTICALS LIMITED PLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X200.0 ML BOTTLE, 1.0X1.0 L JERRYCAN	01/07/2012

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3711	NDA/MAL/HDP/7548	SEV PHARMACEUTICALS LIMITED	SEV PHARMACEUTICALS LIMITED	IODINE TINCTURE	IODINE + POTASSIUM IODIDE	2.5%W/V+2.5%W/V	SEV PHARMACEUTICALS LIMITED PLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X22.0 ML BOTTLE	01/07/2013
3712	NDA/MAL/HDP/7552	SEV PHARMACEUTICALS LIMITED	SEV PHARMACEUTICALS LIMITED	MAGNESIUM TRISILICATE MIXTURE	MAGNESIUM TRISILICATE + LIGHT MAGNESIUM CARBONATE + SODIUM BICARBONATE	250MG + 250MG + 250MG/5ML	SEV PHARMACEUTICALS LIMITED PLOT 100 NALUKOLONGO	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	01/07/2010
3713	NDA/MAL/HDP/7554	SEV PHARMACEUTICALS LIMITED	SEV PHARMACEUTICALS LIMITED	POVIDONE IODINE BP	POVIDONE IODINE	10%W/V	SEV PHARMACEUTICALS LIMITED PLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X200.0 ML BOTTLE, 1.0X1000.0 ML JERRYCAN	01/07/2013

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3714	NDA/MAL/HDP/7556	SEV PHARMACEUTICALS LIMITED	SEV PHARMACEUTICALS LIMITED	SEVASTAT	CETRIMIDE + CHLORHEXIDINE	3%W/V+0.3%W/V	SEV PHARMACEUTICALS LIMITED PLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X1.0 L BOTTLE	01/07/2012
3715	NDA/MAL/HDP/7559	SEV PHARMACEUTICALS LIMITED	SEV PHARMACEUTICALS LIMITED	SURGICAL SPIRIT	METHYL SALICYLATE	0.5%V/V	SEV PHARMACEUTICALS LIMITED PLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL SPIRITS	1.0X100.0 ML BOTTLE	01/07/2011
3716	NDA/MAL/HDP/7560	SEV PHARMACEUTICALS LIMITED	SEV PHARMACEUTICALS LIMITED	VIOLGENT	CRYSTAL VIOLET	0.5%W/V	SEV PHARMACEUTICALS LIMITED PLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X25.0 ML BOTTLE	01/07/2014

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3717	NDA/MAL/HDP/75 71	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
3718	NDA/MAL/HDP/75 86	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
3719	NDA/MAL/HDP/75 87	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

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3720	NDA/MAL/HDP/7588	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
3721	NDA/MAL/HDP/7589	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
3722	NDA/MAL/HDP/7590	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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3723	NDA/MAL/HDP/7595	AMMAN PHARMACEUTICALS 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
3724	NDA/MAL/HDP/7598	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	RABEFLEX-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
3725	NDA/MAL/HDP/7605	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

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3726	NDA/MAL/HDP/7607	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
3727	NDA/MAL/HDP/7610	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
3728	NDA/MAL/HDP/7611	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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3729	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
3730	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
3731	NDA/MAL/HDP/7622	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	MONTELAIR 5	MONTELUKAST SODIUM	5MG	HOVID BHDLOT 56442,71/2 MILES JALAN IPOH,PERAK,MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2018

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3732	NDA/MAL/HDP/7652	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
3733	NDA/MAL/HDP/7653	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
3734	NDA/MAL/HDP/7656	A.MENARINI INDUSTRIE FARMACEUTICHE RIUNITE	PHILLIPS PHARMACEUTICALS (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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3735	NDA/MAL/HDP/7674	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABLEVOX	LEVOFLOXACIN HEMIHYDRATE	5G/L	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	01/07/2017
3736	NDA/MAL/HDP/7681	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS 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
3737	NDA/MAL/HDP/7683	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DELAREX	DESLORATADINE	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

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3738	NDA/MAL/HDP/7686	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
3739	NDA/MAL/HDP/7687	ABACUS PHARMA (AFRICA) LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DI - QUIN	DIHYDROARTEMISININ+PIPERAQUINE 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
3740	NDA/MAL/HDP/7688	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE 850MG TABLET	METFORMIN HYDROCHLORIDE	850MG	NKUNZI PHARMACEUTICALS259 DAVIDSON ROAD, WADEVILLEGERMISTON, 1428 SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X300.0 TABLET CONTAINER,1.0X60.0 TABLET CONTAINER,1.0X4.0X15.0 TABLET BLISTER	01/07/2017

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3741	NDA/MAL/HDP/7695	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	CORTUM 500	CEFUROXIME AXETIL	500MG	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	1.0X10.0 TABLET BLISTER	01/07/2017
3742	NDA/MAL/HDP/7706	CACHET PHARMACEUTICALS 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.) ALKEM LABORATORIES LIMITED VILLAGE- THANA BADDI, YEH NALAGAR, DISTRICT SOLAN, HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER, 1.0X10.0 TABLET BLISTER	01/07/2017
3743	NDA/MAL/HDP/7714	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROXONE 1GM	CEFTRIAXONE 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 LIMITED HILLTOP, INDUSTRIAL AREA, BHATOLI KALAN, BADDI, DISTT. SOLAN (HP) -	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	07/11/2018

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3744	NDA/MAL/HDP/77 15	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
3745	NDA/MAL/HDP/77 16	CORE ACCESS LIMITED	CORE ACCESS LTD	ALRINAST 2.5 MG / 5 ML SYRUP	DESLORATIDINE	2.5 MG / 5 ML	NOBEL İLAÇ SAN. VE TIC. A.ŞŞANCAKLAR, DÜZCE, 81100	TURKEY	ORAL LIQUID ORDINARY SYRUPS	1.0X150.0 ML BOTTLE	29/11/2017
3746	NDA/MAL/HDP/77 26	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

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3747	NDA/MAL/HDP/77 35	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	IBUMOL 400	PARACETAMOL + IBUPROFEN	325MG + 400MG	AJANTA PHARMA LIMITED PAITHANMANUFACTURIN G 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
3748	NDA/MAL/HDP/77 45	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
3749	NDA/MAL/HDP/77 47	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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3750	NDA/MAL/HDP/7751	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	UNODEX COUGH SYRUP	BROMHEXINE HYDROCHLORIDE + DEXTROMETHORPHAN HYDROBROMIDE + AMMONIUM CHLORIDE	8MG + 10MG + 100MG	AKUMS DRUGS & PHARMACEUTICALS LTD- PLANT IIPLOT 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
3751	NDA/MAL/HDP/7760	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
3752	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

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3753	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
3754	NDA/MAL/HDP/7905	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	ACEFYL	ACEFYLINE PIPRAZINE + 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
3755	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 NACL AMBER GLASS AMPOULE	01/07/2017

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3756	NDA/MAL/HDP/8015	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS 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,1.0X10.0X1.0X10.0X3.0 ML AMPOULE	01/07/2011
3757	NDA/MAL/HDP/8023	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 GMBHBRTENBACHSTR ASSE 13 D-13509 BERLIN	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X8.0 TABLET BLISTER	01/07/2011
3758	NDA/MAL/HDP/8043	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	RABEZOL	RABEPRAZOLE SODIUM	20MG	BİLİM PHARMACEUTICALSGOSB 41480 GEBZE-KOCAELI/TURKE	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X14.0 TABLET BLISTER	01/07/2017

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3759	NDA/MAL/HDP/8073	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
3760	NDA/MAL/HDP/8085	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
3761	NDA/MAL/HDP/8089	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,1.0X100.0X10.0 CAPSULE BLISTER,1.0X500.0 CAPSULE CONTAINER,1.0X250.0 CAPSULE CONTAINER	01/07/1997

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3762	NDA/MAL/HDP/8091	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEGEL SUSPENSION	ALUMINIUM HYDROXIDE+MAGNESIUM 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
3763	NDA/MAL/HDP/8092	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
3764	NDA/MAL/HDP/8095	DENK PHARMA GMB H & CO. KG	BENLE CONSULT LIMITED	COLOSAR-DENK 100/12.5	LOSARTAN POTASSIUM + HYDROCHLOROTHIAZIDE	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

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3765	NDA/MAL/HDP/8096	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	BENZALIN	BENZATHINE BENZYL PENICILLIN SODIUM	2.4MEGA/ VIAL	REYOUNG PHARMACEUTICAL CO. LIMITED NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0 VIAL CARTON, 1.0X100.0X2.4 VIAL CARTON, 1.0X10.0X2.4 VIAL CARTON	01/07/2011
3766	NDA/MAL/HDP/8097	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	REPOITIN 5000	ERYTHROPOIETIN	5000IU/ 0.5ML	SERUM INSTITUTE OF INDIA LTD 212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X6.0X0.5 ML PRE-FILLED SYRINGE	01/07/2016
3767	NDA/MAL/HDP/8103	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

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3768	NDA/MAL/HDP/8104	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
3769	NDA/MAL/HDP/8105	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
3770	NDA/MAL/HDP/8107	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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3771	NDA/MAL/HDP/8108	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	ORS	GLUCOSE ANHYDROUS+TRISODIUM CITRATE+SODIUM CHLORIDE+POTASSIUM 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
3772	NDA/MAL/HDP/8109	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
3773	NDA/MAL/HDP/8110	MEDLEY PHARMACEUTICALS 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,1.0X1.0X100.0 ML BOTTLE	01/07/2017

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3774	NDA/MAL/HDP/81 12	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MOXICLAV	AMOXICILLIN + CLAVULANIC ACID	156.25MG/5ML	MEDOCHEMIE 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
3775	NDA/MAL/HDP/81 13	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MOXICLAV FORTE	AMOXICILLIN + CLAVULANIC ACID	312.5MG/5ML	MEDOCHEMIE 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
3776	NDA/MAL/HDP/81 14	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	RUPAN	IBUPROFEN	400MG	MEDOCHEMIE 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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3777	NDA/MAL/HDP/81 15	MACLEODS PHARMACEUTICALS 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
3778	NDA/MAL/HDP/81 18	MACLEODS PHARMACEUTICALS 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
3779	NDA/MAL/HDP/81 19	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS 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. 0X1.0 ML AMPOULE	01/07/2017

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3780	NDA/MAL/HDP/81 21	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS 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
3781	NDA/MAL/HDP/81 27	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS LIMITED	LIDOCAINE HYDROCHLO RIDE	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
3782	NDA/MAL/HDP/81 30	DEVA HOLDING A.S	SHREEJI PHARMACEUTICALS 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

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3783	NDA/MAL/HDP/8131	DEVA HOLDING A.S	SHREEJI PHARMACEUTICALS LIMITED	DEGRA	SILDENAFIL CITRATE	50MG	DEVA HOLDING A. S.ÇERKEZKÖY ORGANIZE SANAYI BOLGESI. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKİRDAĞ/ TURKEY	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	01/07/2017
3784	NDA/MAL/HDP/8133	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	MYHEP	SOFOBUVIR	400MG	MYLAN LABORATORIES LIMITEDD ,F-4 & F-12,MIDC, MALEGAON,SIRRRRAR, NASHIK -422113 MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X28.0 TABLET BOTTLE	01/07/2017
3785	NDA/MAL/HDP/8135	BAL PHARMA LIMITED -	PLANET PHARMACEUTICALS UGANDA LTD	REGAMOL	PARACETAMOL	500MG	BAL PHARMA LTD1, 2, 3 & SECTOR 69, SECTOR 4, IIE-PANTNAGAR UDHAM SINGH NAGAR, RUDRAPUR-263153 UTTARAKHAND-INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017

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3786	NDA/MAL/HDP/81 42	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,1.0X2.0X 14.0 TABLET BLISTER	01/07/2017
3787	NDA/MAL/HDP/81 43	NAARI LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	LYDIA POSTPIL	LEVONORGESTREL	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
3788	NDA/MAL/HDP/81 44	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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3789	NDA/MAL/HDP/81 45	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
3790	NDA/MAL/HDP/81 46	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
3791	NDA/MAL/HDP/81 47	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

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3792	NDA/MAL/HDP/8148	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	FLUCLOXACILIN	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
3793	NDA/MAL/HDP/8150	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
3794	NDA/MAL/HDP/8151	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THAN E 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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3795	NDA/MAL/HDP/8152	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
3796	NDA/MAL/HDP/8154	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2013
3797	NDA/MAL/HDP/8155	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

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3798	NDA/MAL/HDP/8156	TATA UGANDA LIMITED	GITTOES PHARMACEUTICALS 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+11 MCG	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
3799	NDA/MAL/HDP/8157	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THAN E INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X20.5 G SACHET	01/07/2016
3800	NDA/MAL/HDP/8159	AUROBINDO PHARMA LIMITED	GITTOES PHARMACEUTICALS 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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3801	NDA/MAL/HDP/8160	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ULGICID (CHERRY FLAVOUR)	ALGINIC ACID+ MAGNESIUM HYDROXIDE+ ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE +SIMETICONE	200MG+250MG+ 250MG+250MG+ 125MG/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
3802	NDA/MAL/HDP/8162	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 NACL	01/07/2017
3803	NDA/MAL/HDP/8163	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

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3804	NDA/MAL/HDP/8167	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,1.0X1.0X100.0 ML BOTTLE,1.0X500.0 ML BOTTLE	01/07/1997
3805	NDA/MAL/HDP/8170	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ULGICID (PINEAPPLE FLAVOUR)	ALGINIC + MAGNESIUM HYDROXIDE +DRIED ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE +SIMETICONE	200MG+250MG+250MG+250MG+125MG/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
3806	NDA/MAL/HDP/8177	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	CILZEC PLUS	TELMISARTAN + HYDROCHLOROTHIAZIDE	40MG + 12.5MG	MSN LABORATORIES PVT. LIMITEDPLOT 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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3807	NDA/MAL/HDP/8178	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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.THANE INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X100.0 TABLET BOTTLE,1.0X10.0X10.0 TABLET BLISTER	01/07/2005
3808	NDA/MAL/HDP/8185	AFRICURE PHARMACEUTICALS (INDIA) LTD	AFRICURE PHARMACEUTICALS 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
3809	NDA/MAL/HDP/8194	MACLEODS PHARMACEUTICALS 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

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3810	NDA/MAL/HDP/8195	MACLEODS PHARMACEUTICALS 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
3811	NDA/MAL/HDP/8197	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
3812	NDA/MAL/HDP/8198	MEDLEY PHARMACEUTICALS 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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3813	NDA/MAL/HDP/8199	MEDLEY PHARMACEUTICALS 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
3814	NDA/MAL/HDP/8200	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,UGANDA	UGANDA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X10.4 G SACHET	01/07/2017
3815	NDA/MAL/HDP/8201	CIRON DRUGS AND PHARMACEUTICALS 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

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3816	NDA/MAL/HDP/8202	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	ISONIAZID	ISONIAZID	300MG	OXALIS LABS-VILLAGE THEDA,P.O.LODHIMAJRA ,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,1.0X10.0 X10.0 TABLET BLISTER,1.0X24.0 X28.0 TABLET BLISTER	01/07/2017
3817	NDA/MAL/HDP/8206	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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2018
3818	NDA/MAL/HDP/8207	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	ZOMETA	ZOLEDRONIC ACID	4MG/5ML	NOVARTIS PHARMA STEIN AG ;SCHAFFHAUSERSTRASSE CH 4332 STEIN-SWITZERLAND	SWITZERLAND	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X5.0 ML VIAL	01/07/2017

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3819	NDA/MAL/HDP/8210	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	HYDROCORTISONE SODIUM SUCCINATE FOR INJECTION BP	HYDROCORTISONE	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
3820	NDA/MAL/HDP/8211	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	MUCO-ASTHALIN SYRUP	SALBUTAMOL + BROMHEXINE	2MG/5ML + 4MG/5ML	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	1.0X100.0 ML BOTTLE	01/07/2010
3821	NDA/MAL/HDP/8212	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

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3822	NDA/MAL/HDP/8213	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
3823	NDA/MAL/HDP/8216	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS 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
3824	NDA/MAL/HDP/8224	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

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3825	NDA/MAL/HDP/8226	DEVA HOLDING A.S	SHREEJI PHARMACEUTICALS 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
3826	NDA/MAL/HDP/8228	AFRICURE PHARMACEUTICALS (INDIA) LTD	AFRICURE PHARMACEUTICALS 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
3827	NDA/MAL/HDP/8232	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS 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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3828	NDA/MAL/HDP/82 35	DAWA LIMITED-	SUPER MEDIC LTD	ACEPAR	ACECLOFENAC + SERRATIOPEPTIDA SE + PARACETAMOL	100MG + 15MG + 500MG	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017
3829	NDA/MAL/HDP/82 43	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
3830	NDA/MAL/HDP/82 52	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED	SURGIPHARM (U) LIMITED	PARACETAM OL FRESENIUS	PARACETAMOL	10MG/ML	FRESENIUS KABI DEUTSCHLAND GMBHFRESENIUSSTRASSE 1, D-61169, FRIEDBERG	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X10.0X50.0 ML VIAL,1.0X10.0X10 0.0 ML VIAL	01/07/2017

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3831	NDA/MAL/HDP/82 53	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
3832	NDA/MAL/HDP/82 54	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
3833	NDA/MAL/HDP/82 64	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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3834	NDA/MAL/HDP/8274	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
3835	NDA/MAL/HDP/8275	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
3836	NDA/MAL/HDP/8276	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

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3837	NDA/MAL/HDP/8277	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
3838	NDA/MAL/HDP/8278	HETERO LABS LTD	AIVEEN (U) LIMITED	ANATERO	ANASTROZOLE	1MG	HETERO LABS LTD, UNIT VI, INDIAAPIIC, FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGER DISTRICT ANDHRA PRADESH-509301, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1X30 TABLET BOTTLE	01/07/2013
3839	NDA/MAL/HDP/8279	SAKAR HEALTHCARE PVT LTD	ROYAL PHARMA 2011 LIMITED	GENTACIN	GENTAMICIN SULPHATE	80MG/2ML	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	1.0X2.0X6.0X2.0 ML AMPOULE IN BLISTERS	01/07/2013

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3840	NDA/MAL/HDP/8299	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED	AFRICURE PHARMACEUTICALS 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
3841	NDA/MAL/HDP/8300	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED	AFRICURE PHARMACEUTICALS 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
3842	NDA/MAL/HDP/8307	NAME AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED	AFRICURE PHARMACEUTICALS 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

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3843	NDA/MAL/HDP/8308	NAME AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED	AFRICURE PHARMACEUTICALS 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
3844	NDA/MAL/HDP/8312	CADILA PHARMACEUTICALS LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	TRICORT 40	TRIAMCINOLONE ACETONIDE	40MG/ML	CADILA PHARMACEUTICALS LIMITED 1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL	29/11/2017
3845	NDA/MAL/HDP/8315	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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3846	NDA/MAL/HDP/83 16	AUROBINDOM PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	DOLUTEGRAVIR 50 MG/ LAMIVUDINE 300 MG/ TENOFIVIR DISOPROXIL FUMARATE 300 MG TABLETS	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFIVIR 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 LIMITED UNIT -VII, SEZ, TSIC, PLOT NO. SI,S. NO.'S 411/P, 425/P, 434/P, 435/P & 458/P GREEN INDUSTRIAL	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE	30/05/2018
3847	NDA/MAL/HDP/83 19	KOPRAN LIMITED	TATA UGANDA LIMITED	ERYKO-250	ERYTHROMYCIN STEARATE TABLETS BP	250MG	KOPRAN LTD VILLAGE SAVROLI TAL KHARAPUR DIST RAIGAD 410 202	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000 .0 TABLET CONTAINER,1.0X5 00.0 TABLET CONTAINER	29/11/2017
3848	NDA/MAL/HDP/83 21	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,1.0X3.0X 10.0 CAPSULE BLISTER	31/01/2018

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3849	NDA/MAL/HDP/83 22	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICALS 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
3850	NDA/MAL/HDP/83 24	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
3851	NDA/MAL/HDP/83 26	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,1.0X3.0X 10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER (EMBOSSSED WITH "GOU NOT FOR SALE" & NON- EMBOSSSED)	29/11/2017

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3852	NDA/MAL/HDP/83 31	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (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
3853	NDA/MAL/HDP/83 32	DEVA HOLDING A.S	SHREEJI PHARMACEUTICALS LIMITED	AZITRO 500 MG	AZITHROMYCIN	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
3854	NDA/MAL/HDP/83 33	MICRO LABS LTD 92 SIPCOT INDUSTRIAL	PHILLIPS PHARMACEUTICALS (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

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3855	NDA/MAL/HDP/8337	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
3856	NDA/MAL/HDP/8340	MACLEODS PHARMACEUTICALS 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
3857	NDA/MAL/HDP/8341	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	GENVOYA	ELVITEGRAVIR+COBICISTAT+EMTRICITABINE+TENOFIVIR 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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3858	NDA/MAL/HDP/8343	TROIKAA PHARMACEUTICALS 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
3859	NDA/MAL/HDP/8344	CACHET PHARMACEUTICALS 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/SYRUPS/DROPS	1.0X50.0 ML BOTTLE	29/11/2017
3860	NDA/MAL/HDP/8345	CACHET PHARMACEUTICALS 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

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3861	NDA/MAL/HDP/83 46	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
3862	NDA/MAL/HDP/83 47	YICHANGHUMANW ELL PHARMACEUTICAL CO., LTD.	KAIYUANTANG (U) LIMITED	FENTWELL 0.05MG/ML	FENTANYL CITRATE	0.05MG/ML	YICHANGHUMANWELL 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
3863	NDA/MAL/HDP/83 48	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	IRBECOR PLUS 300MG/12.5 MG	IRBESARTAN + HYDROCHLOROTH IAZIDE	300MG + 12.5MG	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	1.0X2.0X14.0 TABLET BLISTER	29/11/2017

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3864	NDA/MAL/HDP/8350	YICHANGHUMANWELL PHARMACEUTICAL CO., LTD.	KAIYUANTANG (U) LIMITED	FENTWELL 0.05MG/ML	FENTANYL CITRATE	0.05MG/ML	YICHANGHUMANWELL 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
3865	NDA/MAL/HDP/8352	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (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
3866	NDA/MAL/HDP/8353	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.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	29/11/2017

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3867	NDA/MAL/HDP/8354	MEGA LIFESCIENCES 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
3868	NDA/MAL/HDP/8356	UNOSOURCE PHARMA LTD	MEDVIN PHARMA LIMITED	LORFACT-D	DES Loratidine	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
3869	NDA/MAL/HDP/8392	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	IRBECOR PLUS 150MG/12.5 MG	IRBESARTAN + HYDROCHLOROTHIAZIDE	150MG + 12.5MG	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	1.0X2.0X14.0 TABLET BLISTER	29/11/2017

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3870	NDA/MAL/HDP/83 94	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	RIFAMPICIN 75 MG ISONIAZID 50 MG AND PYRAZINAMI DE 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,1.0X24.0 X28.0 TABLET BLISTER	29/11/2017
3871	NDA/MAL/HDP/83 95	MACLEODS PHARMACEUTICAL S 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
3872	NDA/MAL/HDP/83 96	MARIE STOPE INTERNATIONAL	MARIE STOPE UGANDA LIMITED	BACK-UP	LEVONORGESTREL	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

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3873	NDA/MAL/HDP/8407	INTAS PHARMACEUTICALS 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
3874	NDA/MAL/HDP/8411	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
3875	NDA/MAL/HDP/8419	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	VB COMPLEX	VIT B1+ VIT B2 +VIT B3 + NICOTINAMIDE+PANTOTHENOL	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, 1.0X10.0X2.0 ML AMPOULE	01/07/2018

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3876	NDA/MAL/HDP/84 34	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
3877	NDA/MAL/HDP/84 68	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
3878	NDA/MAL/HDP/84 77	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

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3879	NDA/MAL/HDP/84 85	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
3880	NDA/MAL/HDP/84 87	BAL PHARMA LIMITED -	PLANET PHARMACEUTICALS UGANDA LTD	EMTRIM FORTE	SULFAMETHOXAZ OLE + TRIMETHOPRIM	800MG + 160MG	BAL PHARMA LTD1, 2, 3 & SECTOR 69, SECTOR 4, IIE-PANTNAGAR UDHAM SINGH NAGAR, RUDRAPUR-263153 UTTARAKHAND-INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	31/01/2018
3881	NDA/MAL/HDP/84 89	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS 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,1.0X5.0 X2.0 ML AMPOULE	31/01/2018

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3882	NDA/MAL/HDP/84 90	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
3883	NDA/MAL/HDP/84 91	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
3884	NDA/MAL/HDP/84 93	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	DESCOVY 200MG/25M G	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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3885	NDA/MAL/HDP/8497	TWENTY FIRST CENTURY PHARMACEUTICALS 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
3886	NDA/MAL/HDP/8499	YELURI FORMULATIONS PVT LTD	SUPER MEDIC	SOLOCEF 1000 MG	CEFTRIAXONE 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
3887	NDA/MAL/HDP/8522	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS 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

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3888	NDA/MAL/HDP/8566	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	AZINOWEL	AZITHROMYCIN	200MG/5ML	AKUMS DRUGS & PHARMACEUTICALS LTD PLANT 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
3889	NDA/MAL/HDP/8569	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	TERBINOL®	TERBINAFINE HYDROCHLORIDE	1%W/W	NOBEL İLAÇ SAN. VE TIC. A.ŞSANCARLAR, DÜZCE, 81100	TURKEY	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	21/11/2019
3890	NDA/MAL/HDP/8602	KIMSY MEDS LTD	KIMSY MEDS LTD	KOFLIN COUGH FLU LINCTUS	CHLOPHENIRAMINE	2MG	MAVID PHARMACEUTICAL INDUSTRIES LIMITED PLOT 490 BIRONGO, KITIICO	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2005

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3891	NDA/MAL/HDP/8603	KIMSY MEDS LTD	KIMSY MEDS LTD	MAAGA	SODIUM BICARBONATE + LIGHT MAGNESIUM CARBONATE + MAGNESIUM	250 MG + 250 MG + 250 MG	MAVID PHARMACEUTICAL INDUSTRIES LIMITED PLOT 490 BIRONGO, KITIIKO	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	01/07/2005
3892	NDA/MAL/HDP/8637	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/SYRUPS/DROPS	1.0X1.0X15.0 ML BOTTLE	28/03/2018
3893	NDA/MAL/HDP/8639	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

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3894	NDA/MAL/HDP/8641	CADILA PHARMACEUTICALS LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	TELI H	TELMISARTAN + HYDROCHLOROTHIAZIDE	40MG + 12.5MG	CADILA PHARMACEUTICALS LIMITED 1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/03/2018
3895	NDA/MAL/HDP/8643	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
3896	NDA/MAL/HDP/8648	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	UNODEX PLUS	TERBUTALINE SULPHATE + BROMHEXINE HYDROCHLORIDE + GUAIFENESIN	2.5MG + 8MG + 100MG	AKUMS DRUGS & PHARMACEUTICALS LTD- PLANT IIPLOT 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

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3897	NDA/MAL/HDP/8649	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
3898	NDA/MAL/HDP/8650	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
3899	NDA/MAL/HDP/8655	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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3900	NDA/MAL/HDP/8660	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
3901	NDA/MAL/HDP/8661	AUROBINDO PHARMA LIMITED	GITTOES PHARMACEUTICALS 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
3902	NDA/MAL/HDP/8662	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	AMOXIRENDS	AMOXICILLIN TRIHYDRATE	250MG/5ML	RENE INDUSTRIES LTD .PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X1.0X100.0 ML BOTTLE	28/03/2018

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3903	NDA/MAL/HDP/8665	CACHET PHARMACEUTICALS PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	PAMAGIN-C	CETIRIZINE HYDROCHLORIDE + DEXTROMETHORPHAN HYDROBROMIDE + ACETAMINOPHEN + PHENYLEPHRINE HYDROCHLORIDE + ZINC GLUCONATE	5.0 MG +15 MG + 500 MG + 5 MG + 7.5 MG	CACHET PHARMACEUTICALS PVT LTD VILLAGE 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
3904	NDA/MAL/HDP/8684	TENTH OF RAMADAN FOR PHARMACEUTICALS INDUSTRIES AND DIAGNOSTICS REAGENTS (RAMEDA)	GAMA PHARMACEUTICALS (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
3905	NDA/MAL/HDP/8685	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	RANCV 500	RANOLAZINE	500 MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISION PLOT 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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3906	NDA/MAL/HDP/86 88	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	DURART 600	DARUNAVIR	600 MG	MYLAN LABORATORIES LTD -H-12 & H-13, MIDC, WALUJ,AURANGABAD- 431136 MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	30/05/2018
3907	NDA/MAL/HDP/86 89	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	DURART 800	DARUNAVIR	800 MG	MYLAN LABORATORIES LTD -H-12 & H-13, MIDC, WALUJ,AURANGABAD- 431136 MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	30/05/2018
3908	NDA/MAL/HDP/86 91	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

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3909	NDA/MAL/HDP/8694	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ERBITUX	CETUXIMAB	5MG/ML	MERCK KGAA-250 FRANKFURTERSTRASSE, D-6100 DARMSTADT	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X20.0 ML VIAL	07/11/2018
3910	NDA/MAL/HDP/8699	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
3911	NDA/MAL/HDP/8778	CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVCEF-250	CEFUROXIME AXETIL	250MG	ASSOCIATED BIOTECHKRISHANPURA, P. O GURUMAJRA, BADDI, DIST. SOLAN	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	26/11/2019

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3912	NDA/MAL/HDP/8779	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
3913	NDA/MAL/HDP/8780	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
3914	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,1.0X10.0 X10.0 TABLET BLISTER,1.0X10.0 X1.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	21/11/2019

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3915	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
3916	NDA/MAL/HDP/8784	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
3917	NDA/MAL/HDP/8785	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/SYRUPS/DROPS	1.0X60.0 ML BOTTLE	21/11/2019

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3918	NDA/MAL/HDP/8786	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVXIM	CEFIXIME TRIHYDRATE	100MG	ASSOCIATED BIOTECHKRISHANPURA, 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
3919	NDA/MAL/HDP/8787	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
3920	NDA/MAL/HDP/8788	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

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3921	NDA/MAL/HDP/87 95	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
3922	NDA/MAL/HDP/87 96	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
3923	NDA/MAL/HDP/87 97	TENTH OF RAMADAN FOR PHARMACEUTICALS INDUSTRIES AND DIAGNOSTICS REAGENTS(RAMED A)	GAMA PHARMACEUTICALS (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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3924	NDA/MAL/HDP/8803	SQUARE PHARMACEUTICALS LTD.(CHEMICALS DIVISION)	GAMA PHARMACEUTICALS (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
3925	NDA/MAL/HDP/8814	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ACRIPTEGA	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFOVIR 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
3926	NDA/MAL/HDP/8815	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

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3927	NDA/MAL/HDP/88 16	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
3928	NDA/MAL/HDP/88 17	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,UGANDA	UGANDA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X5.0 ML BOTTLE	30/05/2018
3929	NDA/MAL/HDP/88 18	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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3930	NDA/MAL/HDP/8819	UNOSOURCE PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	LORFACT-D SYRUP	DES Loratadine	5MG/5ML	AKUMS DRUGS & PHARMACEUTICALS LTD- PLANT IIPLOT 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
3931	NDA/MAL/HDP/8820	TROIKAA PHARMACEUTICALS 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
3932	NDA/MAL/HDP/8823	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	EPCLUSA	SOFOBUVIR + 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

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3933	NDA/MAL/HDP/8824	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
3934	NDA/MAL/HDP/8826	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
3935	NDA/MAL/HDP/8827	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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3936	NDA/MAL/HDP/8829	HETERO LABS LTD	AIVEEN (U) LIMITED	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE	50 MG + 300 MG + 300 MG	M/S. ANNORA PHARMA PRIVATE LIMITEDS.Y. 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 (I.D.A) JEEDIMETLA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1X90 TABLET BOTTLE	20/12/2018
3937	NDA/MAL/HDP/8830	HETERO LABS LTD	AIVEEN (U) LIMITED	IRBIS-HT	IRBESARTAN + HYDROCHLOROTHIAZIDE	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
3938	NDA/MAL/HDP/8831	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

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3939	NDA/MAL/HDP/8836	EXPHAR S.A. ZONING INDUSTRIEL DE NIVELLES SUD	PHILLIPS PHARMACEUTICALS (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, MAHARASTRA-410209, INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X4.0 TABLET STRIP	07/11/2018
3940	NDA/MAL/HDP/8839	MACK BROWN PHARMACEUTICALS 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
3941	NDA/MAL/HDP/8844	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

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3942	NDA/MAL/HDP/8845	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS 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
3943	NDA/MAL/HDP/8914	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
3944	NDA/MAL/HDP/8915	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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3945	NDA/MAL/HDP/8916	MACLEODS PHARMACEUTICALS 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
3946	NDA/MAL/HDP/8920	MERCK	UNITED HEALTHCARE DISTRIBUTORS LTD	CRINONE 8% GEL	PROGESTERONE	90MG/APPLICATOR	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
3947	NDA/MAL/HDP/8926	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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3948	NDA/MAL/HDP/8927	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	1.0X24.0X1.0X1.0 DOSE VIAL,1.0X48.0X1.0 DOSE VIAL	25/07/2018
3949	NDA/MAL/HDP/8929	OCTAPHARMA AG	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ALBUNORM	HUMAN ALBUMIN	20%W/V	OCTAPHARMA PRODUKTIONSGESELLSCH AFT DEUTSCHLAND MBH-WOLFGANG-MARGUERRE-ALLEE 1 31832 SPRINGE GERMANY	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X50.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE	25/07/2018
3950	NDA/MAL/HDP/8931	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

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3951	NDA/MAL/HDP/8933	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	Q-TIB	SULFAMETHOXAZOLE + 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
3952	NDA/MAL/HDP/8934	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
3953	NDA/MAL/HDP/8936	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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3954	NDA/MAL/HDP/8940	İLKO İLAÇ SANAYI VE TİCARET A. Ş.	CORE ACCESS LIMITED	RABIZA 20MG	RABEPRAZOLE SODIUM	20MG	İLKO İLAÇ SANAYI 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
3955	NDA/MAL/HDP/8941	İLKO İLAÇ SANAYI VE TİCARET A. Ş.	CORE ACCESS LIMITED	LIVERCOL 20MG	ROSUVASTATIN CALCIUM	20MG	İLKO İLAÇ SANAYI 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
3956	NDA/MAL/HDP/8943	HETERO LABS LTD	AIVEEN (U) LIMITED	IRBIS-HT 150/12.5	IRBESARTAN + HYDROCHLOROTHIAZIDE	150MG + 12.5MG	HETERO LABS LIMITED (UNIT V)SY NO. 436,440, 441 & 458, APIC 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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3957	NDA/MAL/HDP/89 44	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
3958	NDA/MAL/HDP/89 46	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
3959	NDA/MAL/HDP/89 47	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

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3960	NDA/MAL/HDP/8949	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
3961	NDA/MAL/HDP/8952	THEON PHARMACEUTICALS 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
3962	NDA/MAL/HDP/8953	JOHNSON & JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN CHILDREN'S WET COUGH	GUAIFENESIN	100MG PER 10ML	JOHNSON&JOHNSON 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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3963	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
3964	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
3965	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

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3966	NDA/MAL/HDP/9057	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP®	DIHYDROARTEMISININ + 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
3967	NDA/MAL/HDP/9058	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP® DISPERSIBLE	DIHYDROARTEMISININ + 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
3968	NDA/MAL/HDP/9059	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/SYRUPS/DROPS	1.0X10.0 ML BOTTLE	26/09/2018

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3969	NDA/MAL/HDP/9062	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
3970	NDA/MAL/HDP/9063	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
3971	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

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3972	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
3973	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
3974	NDA/MAL/HDP/9067	MEDISEL(K) LTD	AIVEEN (U) LIMITED	BRONCHOWIN	DOXOFYLLINE	400 MG	CORONA REMEDIES PVT LIMITED VILLAGE 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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3975	NDA/MAL/HDP/9068	MEDISEL(K) LTD	AIVEEN (U) LIMITED	MOXIDOC TABLET	MOXIFLOXACIN HYDROCHLORIDE	400 MG	CORONA REMEDIES PVT LIMITED VILLAGE 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
3976	NDA/MAL/HDP/9129	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LOXAMOX	LEVOFLOXACIN HEMIHYDRATES	250MG/50ML	MS PHARMA - JORDAN PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH-WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY INFUSION BAGS	1.0X50.0 ML BAG	21/11/2019
3977	NDA/MAL/HDP/9130	AUROLAB	SWASTIK PHARMACEUTICAL LTD	MFLOX-DM	MOXIFLOXACIN + DEXAMETHASONE SODIUM PHOSPHATE	0.5%W/V + 0.1%W/V	AUROLAB LIMITED NO 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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3978	NDA/MAL/HDP/9137	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
3979	NDA/MAL/HDP/9140	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
3980	NDA/MAL/HDP/9141	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

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3981	NDA/MAL/HDP/9142	THEON PHARMACEUTICALS 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/SYRUPS/DROPS	1X60 ML BOTTLE	26/11/2019
3982	NDA/MAL/HDP/9146	MICRO LABS LTD	PHARMA VILLE LIMITED	ISONIAZID	ISONIAZID	300MG	MICRO LABS LIMITED ,92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X24.0 X28.0 TABLET BLISTER,1.0X1000.0 TABLET BOTTLE	21/11/2019
3983	NDA/MAL/HDP/9147	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	HUMAN ROTAVIRUS REASSORTANT	LIVE ATTENUATED BOVINE - HUMAN ROTAVIRUS REASSORTANT [G1, G2, G3, G4 AND G9]	≥105.6 FFU / SEROTYPE	SERUM INSTITUTE OF INDIA PVT LTD .212/2, HADAPSAR, PUNE-411028, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X2.5 ML VIAL (1DOSE),1.0X1.0X5.0 ML VIAL (2 DOSES)	21/11/2019

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3984	NDA/MAL/HDP/9165	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
3985	NDA/MAL/HDP/9166	HETERO LABS LTD	AIVEEN (U) LIMITED	VIRDAC 30	DACLATASVIR DIHYDROCHLORIDE	30 MG	HETERO LABS LIMITED (UNIT V)SY NO. 436,440, 441 & 458, APIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X28.0 TABLET BOTTLE	27/11/2019
3986	NDA/MAL/HDP/9172	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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3987	NDA/MAL/HDP/9173	PROFARMA .SH.A	JOINT MEDICAL STORE (UPMB - UCMB)	PRODEXA-T	DEXAMETHASONE	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
3988	NDA/MAL/HDP/9174	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
3989	NDA/MAL/HDP/9175	PROFARMA .SH.A	JOINT MEDICAL STORE (UPMB - UCMB)	ERITROMICIN E	ERYTHROMYCIN ESTOLATE	250MG	PROFARMA SH.AMYSLYM KETA,TIRANA	ALBANIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	21/11/2019

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3990	NDA/MAL/HDP/9176	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
3991	NDA/MAL/HDP/9177	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
3992	NDA/MAL/HDP/9178	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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3993	NDA/MAL/HDP/9189	SAGA LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	ESOFLEX 40	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40 MG	SAGA LIFESCIENCES LIMITED SURVEY 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
3994	NDA/MAL/HDP/9190	SAKAR HEALTHCARE LIMITED	TATA UGANDA LIMITED	RABEKAR	RABEPRAZOLE SODIUM	20MG	SAKAR HEALTH CARE PVT LTD-10/13 CHONGODAR SARKHEJ BAVLA ROAD DIST AHMEDABAD 382213 GUJARATI	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 MG VIAL + 1*5ML WFI IN LDPE	15/02/2023
3995	NDA/MAL/HDP/9191	SANCE LABORATORIES PVT LTD	DELMAN ENTERPRISES LIMITED	SANDOX-DS 50	CEFPODOXIME PROXETIL	50 MG/5ML	SANCE LABORATORIES PVT LTD VI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	08/09/2020

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3996	NDA/MAL/HDP/9192	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
3997	NDA/MAL/HDP/9193	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
3998	NDA/MAL/HDP/9194	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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3999	NDA/MAL/HDP/9195	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	SOBISIS	SODIUM BICARBONATE	500 MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRIAL AREA,MEHATPUR-174 315, HIMACHAL PRADESH.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/09/2020
4000	NDA/MAL/HDP/9196	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	SOBISIS FORTE	SODIUM BICARBONATE	1000 MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRIAL AREA,MEHATPUR-174 315, HIMACHAL PRADESH.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/09/2020
4001	NDA/MAL/HDP/9197	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	SEVLAREN 400	SEVELAMER CARBONATE	400 MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRIAL 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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4002	NDA/MAL/HDP/9198	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	PBREN 75	PREGABALIN	75 MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRIAL AREA,MEHATPUR-174 315, HIMACHAL PRADESH.	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	08/09/2020
4003	NDA/MAL/HDP/9199	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	KCHEK	CALCIUM POLYSTYRENE SULPHONATE	15 MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRIAL AREA,MEHATPUR-174 315, HIMACHAL PRADESH.	INDIA	ORAL LIQUID ORDINARY OTHER POWDERS/GRANULES	1.0X15.0 G SACHET	08/09/2020
4004	NDA/MAL/HDP/9200	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	LEVIGRESS 250	LEVETIRACETAM	250 MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRIAL 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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4005	NDA/MAL/HDP/9201	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	LEVIGRESS 500	LEVETIRACETAM	500MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRIAL AREA,MEHATPUR-174 315, HIMACHAL PRADESH.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/09/2020
4006	NDA/MAL/HDP/9202	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	ESCIGRESS 5	ESCITALOPRAM OXALATE	5MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRIAL AREA,MEHATPUR-174 315, HIMACHAL PRADESH.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/09/2020
4007	NDA/MAL/HDP/9203	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	ESCIGRESS 10	ESCITALOPRAM OXALATE	10MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRIAL 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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4008	NDA/MAL/HDP/9204	SUN PHARMACEUTICAL INDUSTRIES LTD	STAR PHARMACEUTICALS LTD	CHERIFLU PLUS WITH VITAMIN C	CHLORPHENAMINE 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
4009	NDA/MAL/HDP/9205	SYNOKEM PHARMACEUTICALS 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
4010	NDA/MAL/HDP/9210	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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4011	NDA/MAL/HDP/9211	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HI DEE 10000 IU	CHOLECALCIFEROL	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
4012	NDA/MAL/HDP/9212	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HI DEE 50000 IU	CHOLECALCIFEROL	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
4013	NDA/MAL/HDP/9213	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/SYRUPS/DROPS	1.0X60.0 ML BOTTLE	08/09/2020

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4014	NDA/MAL/HDP/9214	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HI DEE 2000 IU	CHOLECALCIFEROL	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
4015	NDA/MAL/HDP/9215	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HI DEE 2000 IU/5 DROPS	CHOLECALCIFEROL	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
4016	NDA/MAL/HDP/9217	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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4017	NDA/MAL/HDP/9219	TROIKAA PHARMACEUTICALS 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
4018	NDA/MAL/HDP/9222	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
4019	NDA/MAL/HDP/9223	WALLACE PHARMACEUTICALS PVT. LTD	STAR PHARMACEUTICALS 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,1.0X1.0X200.0 ML BOTTLE	08/09/2020

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4020	NDA/MAL/HDP/92 25	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
4021	NDA/MAL/HDP/92 28	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
4022	NDA/MAL/HDP/92 29	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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4023	NDA/MAL/HDP/9237	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
4024	NDA/MAL/HDP/9238	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
4025	NDA/MAL/HDP/9241	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

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4026	NDA/MAL/HDP/92 46	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	CLAMOXIN	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500 MG + 125 MG	MEDOPHARM PVT LIMITED NO. 50 KAYARAMBEDU VILLAGE, GUDUVANCHERY-603202	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER, 1.0X2.0X 10.0 TABLET BLISTER	19/02/2021
4027	NDA/MAL/HDP/92 48	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
4028	NDA/MAL/HDP/92 51	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	RIBOFAN	TIROFIBAN HYDROCHLORIDE	12.5 MG/50ML	MS PHARMA - JORDAN PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL- HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY VIALS	1X1X50 ML VIAL	28/09/2020

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4029	NDA/MAL/HDP/9252	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
4030	NDA/MAL/HDP/9264	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	APRITANT IV	FOSAPRIPITANT DIMEGLUMINE	150 MG/VIAL	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISION PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325-TELENGANA,	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 VIAL VIAL	08/09/2020
4031	NDA/MAL/HDP/9266	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, AURANGABAD - 431 136	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X30.0 TABLET CONTAINER, 1.0X6 0.0 TABLET CONTAINER	08/09/2020

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4032	NDA/MAL/HDP/9276	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ZYLODINE	LIDOCAINE HYDROCHLORIDE	20MG/ML	MS PHARMA - JORDANPLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL- HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY VIALS	1X25X50 ML VIAL	28/09/2020
4033	NDA/MAL/HDP/9278	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
4034	NDA/MAL/HDP/9279	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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4035	NDA/MAL/HDP/9280	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
4036	NDA/MAL/HDP/9286	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
4037	NDA/MAL/HDP/9287	GLENMARK PHARMACEUTICALS 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

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4038	NDA/MAL/HDP/9288	HETERO DRUGS LTD	AIVEEN (U) LIMITED	VIRDAC 60	DACLATASVIR DIHYDROCHLORIDE	60 MG	HETERO LABS LIMITED (UNIT V)SY NO. 436,440, 441 & 458, APIC 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
4039	NDA/MAL/HDP/9290	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
4040	NDA/MAL/HDP/9291	INTAS PHARMACEUTICALS LIMITED	STAR BIOTECH UGANDA LTD	SARTEL-80 LH	TELMISARTAN + HYDROCHLOROTHIAZIDE	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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4041	NDA/MAL/HDP/92 94	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (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
4042	NDA/MAL/HDP/92 95	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,PALGHAR, MAHARASHTRA 401404,INDIA	INDIA	VAGINAL SUPPOSITORIES	1.0X2.0X7.0 SUPPOSITORY STRIP	25/09/2020
4043	NDA/MAL/HDP/92 96	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	VAGID-CL	CLINDAMYCIN + CLOTRIMAZOLE	100 MG + 200 MG	BLISS GVS PHARMA LIMITED10,11 & 12,DEWAN UDYOG NAGAR,ALIYALI,PALGHAR, MAHARASHTRA 401404,INDIA	INDIA	VAGINAL SUPPOSITORIES	1.0X1.0X3.0 SUPPOSITORY STRIP	08/09/2020

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4044	NDA/MAL/HDP/9305	KOPRAN LIMITED	TATA UGANDA LIMITED	CELEKOP-200	CELECOXIB	200MG	KOPRAN LIMITEDVILLAGE - SAVROLI (KHOPOLI), TALUKA - KHALAPUR, DIST. RAIGAD 410202, MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	08/09/2020
4045	NDA/MAL/HDP/9306	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
4046	NDA/MAL/HDP/9313	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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4047	NDA/MAL/HDP/93 15	CENTAUR PHARMACEUTICAL S PVT. LTD	GITTOES PHARMACEUTICALS 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
4048	NDA/MAL/HDP/93 16	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
4049	NDA/MAL/HDP/93 22	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,1.0X9 0.0 TABLET CONTAINER,1.0X1 80.0 TABLET CONTAINER	08/09/2020

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4050	NDA/MAL/HDP/93 24	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,10.0X1.0 X10.0 TABLET BLISTER	08/09/2020
4051	NDA/MAL/HDP/93 25	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
4052	NDA/MAL/HDP/93 27	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	OXCIN-D	MOXIFLOXACIN + DEXAMETHASONE 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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4053	NDA/MAL/HDP/93 31	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
4054	NDA/MAL/HDP/93 45	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	FLUCONAZOL E 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
4055	NDA/MAL/HDP/93 50	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICALS LIMITED	NUROFEN	IBUPROFEN LYSINE	684MG	ASTRA ZENECA TURKEYNOTTINGHAM 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

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4056	NDA/MAL/HDP/9353	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	LUMITER DT	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	OXALIS LABS LIMITED VILLAGE 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, 30.0X1.0X12.0 TABLET BLISTER	09/12/2020
4057	NDA/MAL/HDP/9355	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	PLATINEX	CISPLATIN	1MG/ML	KHANDELWAL LABORATORIES PVT. LTD B-1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1X1X10 ML VIAL	22/12/2020
4058	NDA/MAL/HDP/9356	THE UNITED PHARMACEUTICALS 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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4059	NDA/MAL/HDP/93 65	HETERO BIOPHARMA LIMITED,	AIVEEN (U) LIMITED	BEVAAS 100	BEVACIZUMAB	100MG/4ML	HETERO BIOPHARMA LIMITEDSY. NO. 458 (PART), TSIC- FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL MAHABOBNAGAR DISTRICT – 509 301, TELANGANA STATE, INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X4.0 ML VIAL	09/12/2020
4060	NDA/MAL/HDP/93 66	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TOBRASON	TOBRAMYCIN + DEXAMETHASONE	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
4061	NDA/MAL/HDP/93 67	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	XENAMEX	TRANEXAMIC ACID	100MG/ML	MS PHARMA - JORDANPLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL- HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY VIALS	1.0X10.0X5.0 ML VIAL	09/12/2020

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4062	NDA/MAL/HDP/93 68	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
4063	NDA/MAL/HDP/93 70	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
4064	NDA/MAL/HDP/93 71	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

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4065	NDA/MAL/HDP/93 76	KOPRAN LIMITED	TATA UGANDA LIMITED	AZ-1 500	AZITHROMYCIN DIHYDRATE	500 MG	KOPRAN LIMITEDVILLAGE - 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
4066	NDA/MAL/HDP/93 77	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
4067	NDA/MAL/HDP/93 79	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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4068	NDA/MAL/HDP/93 81	POPULATION SERVICES INTERNATIONAL, UGANDA (PSIU)	POPULATION SERVICES INTERNATIONAL - UGANDA	PRONTA 1	LEVONORGESTREL	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
4069	NDA/MAL/HDP/93 83	SUN PHARMACEUTICAL INDUSTRIES LTD	STAR PHARMACEUTICALS 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 .0X90.0 TABLET CONTAINER	09/12/2020
4070	NDA/MAL/HDP/93 85	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BRUZOLIN	XYLOMETAZOLINE HYDROCHLORIDE	0.05% W/V	BRAWN LABORATORIES LIMITED 13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	NASAL SYSTEMIC DROPS	1.0X1.0X15.0 ML BOTTLE	09/12/2020

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4071	NDA/MAL/HDP/9387	SERUM INSTITUTE OF INDIA PVT LTD	NORVIK ENTERPRISES LIMITED	DIPHTHERIA AND TETENUS VACCINE ADSORBED FOR ADULTS AND ADOLESCENTS	DIPHTHERIA + TETANUS + ALUMINIUM PHOSPHATE	≤ 5 LF (≥ 2 IU) + ≤ 5 LF (≥ 40 IU) + ≤ 1.25 MG/DOSE	SERUM INSTITUTE OF INDIA PVT LTD .212/2, HADAPSAR, PUNE-411028, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0X10.0 DOSE VIAL,1.0X5.0X10.0 X1.0 DOSE AMPOULE	09/12/2020
4072	NDA/MAL/HDP/9388	CONCEPT PHARMACEUTICALS LTD	JEET PHARMACEUTICALS 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
4073	NDA/MAL/HDP/9389	SERUM INSTITUTE OF INDIA PVT LTD	NORVIK ENTERPRISES LIMITED	DIPHTHERIA, TETANUS, PERTUSSIS, HEPATITIS B AND HAEMOPHILUS INFLUENZAE TYPE B CONJUGATE VACCINE ADSORBED	DIPHTHERIA + TETANUS + PERTUSSIS + HEPATITIS B + HAEMOPHILUS INFLUENZAE TYPE B CONJUGATE + ALUMINIUM PHOSPHATE	≤ 25 LF (≥ 30 IU) + ≥ 2.5 LF (≥ 40 IU) + ≤ 16 OU (≥ 4.0 IU) + ≥ 10 MCG + ≥ 10 MCG + ≤ 1.25 MG/DOSE	SERUM INSTITUTE OF INDIA PVT LTD .212/2, HADAPSAR, PUNE-411028, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0X10.0 DOSE VIAL	09/12/2020

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4074	NDA/MAL/HDP/93 93	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	LESS-K	CALCIUM POLYSTYRENE SULFONATE	5 GM/SACKET	MEGA LIFESCIENCES PUBLIC COMPANY LTD PLANT 2; 515/1 MOO 4, SOI 8 BANGPOO INDUSTRIAL ESTATE PATTANA 3 ROAD, PHRAEKSA, MUEANG, SAMUTPRAKARN 10280, THAILAND	THAILAND	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0X5.0 G SACHET	09/12/2020
4075	NDA/MAL/HDP/93 94	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
4076	NDA/MAL/HDP/93 95	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

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4077	NDA/MAL/HDP/9401	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
4078	NDA/MAL/HDP/9403	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
4079	NDA/MAL/HDP/9404	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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4080	NDA/MAL/HDP/9408	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	ZIRIN	CETIRIZINE DIHYDROCHLORIDE	10 MG	MEGA LIFESCIENCES PUBLIC COMPANY LTD PLANT 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
4081	NDA/MAL/HDP/9409	HETERO LABS LTD	AIVEEN (U) LIMITED	STAVANCE 500	VANCOMYCIN HYDROCHLORIDE	500 MG/VIAL	ASPIRO PHARMA LIMITED SY. 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
4082	NDA/MAL/HDP/9410	HETERO LABS LTD	AIVEEN (U) LIMITED	STAVANCE 1	VANCOMYCIN HYDROCHLORIDE	1G/VIAL	ASPIRO PHARMA LIMITED SY. 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

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4083	NDA/MAL/HDP/94 11	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
4084	NDA/MAL/HDP/94 12	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
4085	NDA/MAL/HDP/94 13	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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4086	NDA/MAL/HDP/94 15	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
4087	NDA/MAL/HDP/94 16	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
4088	NDA/MAL/HDP/94 18	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, VISAKHAPTNAM, ANDRA PRADESH,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER,1.0X9 0.0 TABLET CONTAINER,1.0X1 80.0 TABLET CONTAINER	09/12/2020

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4089	NDA/MAL/HDP/94 21	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
4090	NDA/MAL/HDP/94 24	PHARCO B INTERNATIONAL,	GAMA PHARMACEUTICALS (U) LIMITED	CEFAXONE 1G I.V.	CEFTRIAZONE SODIUM HYDRATE	1G	PHARCO-B INTERNATIONAL PHARMACEUTICALS BORG 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
4091	NDA/MAL/HDP/94 26	PHARCO B INTERNATIONAL,	GAMA PHARMACEUTICALS (U) LIMITED	CEFAXONE 2G I.V.	CEFTRIAZONE SODIUM HYDRATE	2G	PHARCO-B INTERNATIONAL PHARMACEUTICALS BORG 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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4092	NDA/MAL/HDP/94 28	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
4093	NDA/MAL/HDP/94 30	SAGA LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	VALK PLUS SP	ACECLOFENAC + PARACETAMOL+ SERRATIOPEPTIDA SE	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,1.0X1.0X 10.0 TABLET BLISTER	09/12/2020
4094	NDA/MAL/HDP/94 31	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

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4095	NDA/MAL/HDP/94 32	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
4096	NDA/MAL/HDP/94 33	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
4097	NDA/MAL/HDP/94 36	SAKAR HEALTHCARE PVT LTD	TATA UGANDA LIMITED	SEFIXI-200	CEFIXIME TRIHYDRATE	200MG	SAKAR HEALTHCARE PVT LIMITEDPLOT 10/13 SARKHEJ-BAVLA ROAD, AHMEDABAD, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	09/12/2020

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4098	NDA/MAL/HDP/94 39	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
4099	NDA/MAL/HDP/94 40	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
4100	NDA/MAL/HDP/94 41	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	PARAVIN	PARACETAMOL	10MG/ML	MS PHARMA - JORDANPLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL- HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X12.0X100.0 ML VIAL,1.0X1.0X100. 0 ML VIAL	09/12/2020

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4101	NDA/MAL/HDP/94 42	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VOMIRAN	ONDANSETRON HYDROCHLORIDE	2MG/ML	MS PHARMA - JORDANPLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL- HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY VIALS	1X5X2 ML VIAL	22/12/2020
4102	NDA/MAL/HDP/94 44	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
4103	NDA/MAL/HDP/94 45	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

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4104	NDA/MAL/HDP/94 46	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
4105	NDA/MAL/HDP/94 47	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
4106	NDA/MAL/HDP/94 48	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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4107	NDA/MAL/HDP/94 49	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
4108	NDA/MAL/HDP/94 52	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
4109	NDA/MAL/HDP/94 53	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

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4110	NDA/MAL/HDP/94 55	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
4111	NDA/MAL/HDP/94 56	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
4112	NDA/MAL/HDP/94 81	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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4113	NDA/MAL/HDP/9490	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
4114	NDA/MAL/HDP/9494	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
4115	NDA/MAL/HDP/9500	POPULATION SERVICES INTERNATIONAL, UGANDA (PSIU)	POPULATION SERVICES INTERNATIONAL - UGANDA	MEURI	DESOGESTREL + ETHINYLESTRADIOL	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

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4116	NDA/MAL/HDP/9501	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
4117	NDA/MAL/HDP/9502	BESINS HEALTHCARE SA	SURGIPHARM (U) LIMITED	UTROGESTAN VAGINAL 200 MG	PROGESTERONE	200 MG	CYNDEA PHARMA, S.L.POLIGONO 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
4118	NDA/MAL/HDP/9503	BESINS HEALTHCARE SA	SURGIPHARM (U) LIMITED	UTROGESTAN 200 MG SOFT CAPSULES	PROGESTERONE	200 MG	CYNDEA PHARMA, S.L.POLIGONO 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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4119	NDA/MAL/HDP/9504	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
4120	NDA/MAL/HDP/9505	CADILA HEALTHCARE LIMITED "ZYDUS TOWER" -	ABACUS PHARMA (AFRICA) LIMITED	ODIMONT-LC	LEVOCETIRIZINE DIHYDROCHLORIDE + 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
4121	NDA/MAL/HDP/9506	TROIKAA PHARMACEUTICALS 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

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4122	NDA/MAL/HDP/9510	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS 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
4123	NDA/MAL/HDP/9511	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	SPASNIL FORTE TABLET	MEFENAMIC ACID + DICYCLOMINE HYDROCHLORIDE	250 MG + 10 MG	PINNACLE LIFE SCIENCE PVT LTD KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/02/2021
4124	NDA/MAL/HDP/9513	ALTHEA PHARMA PVT LTD.	JOINT MEDICAL STORE (UPMB - UCMB)	METRONIDAZOLE INFUSION BP	METRONIDAZOLE	0.5% W/V	ALTHEA PHARMA PRIVATE LIMITED WORKS: 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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4125	NDA/MAL/HDP/9514	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
4126	NDA/MAL/HDP/9515	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
4127	NDA/MAL/HDP/9525	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

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4128	NDA/MAL/HDP/95 26	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
4129	NDA/MAL/HDP/95 33	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
4130	NDA/MAL/HDP/95 34	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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4131	NDA/MAL/HDP/9535	ARISTO PHARMACEUTICALS 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
4132	NDA/MAL/HDP/9537	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
4133	NDA/MAL/HDP/9538	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	ECZEMUS 0.1% OINTMENT	TACROLIMUS MONOHYDRATE	0.1% W/W	BROOKES PHARMA (PRIVATE) LIMITED 58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	TOPICAL EXTERNAL OINTMENTS	1.0X10.0 G TUBE	24/02/2021

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4134	NDA/MAL/HDP/9541	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-GOIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	24/02/2021
4135	NDA/MAL/HDP/9542	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-GOIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	24/02/2021
4136	NDA/MAL/HDP/9543	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-GOIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	24/02/2021

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4137	NDA/MAL/HDP/9549	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	DUOSKIN	ISOCONAZOLE NITRATE + DIFLUCORTOLONE 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
4138	NDA/MAL/HDP/9550	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
4139	NDA/MAL/HDP/9551	DEVA HOLDING A.S	SHREEJI PHARMACEUTICALS 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

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4140	NDA/MAL/HDP/9552	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
4141	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, BWEYOGGERERE	UGANDA	ORAL LIQUID ORDINARY LIQUIDS	1X60 ML BOTTLE	04/03/2021
4142	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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4143	NDA/MAL/HDP/95 86	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
4144	NDA/MAL/HDP/95 88	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
4145	NDA/MAL/HDP/95 89	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

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4146	NDA/MAL/HDP/95 90	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
4147	NDA/MAL/HDP/95 91	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	AZITIZOZ-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
4148	NDA/MAL/HDP/95 94	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	ROSUVASTAT IN 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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4149	NDA/MAL/HDP/95 95	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	ROSUVASTAT IN 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
4150	NDA/MAL/HDP/95 96	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	ROSUVASTAT IN 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
4151	NDA/MAL/HDP/95 97	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,1.0X1 000.0 TABLET CONTAINER	03/06/2021

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4152	NDA/MAL/HDP/9600	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
4153	NDA/MAL/HDP/9601	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
4154	NDA/MAL/HDP/9602	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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4155	NDA/MAL/HDP/9603	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	KOCITAF	DOLUTEGRAVIR SODIUM + EMTRICITABINE + TENOFOVIR 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
4156	NDA/MAL/HDP/9609	ZIM LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	CETRIZIM L ODS	LEVOCETIRIZINE DIHYDROCHLORIDE	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
4157	NDA/MAL/HDP/9611	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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4158	NDA/MAL/HDP/96 12	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,1.0X3.0X 10.0 TABLET BLISTER	02/06/2021
4159	NDA/MAL/HDP/96 13	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
4160	NDA/MAL/HDP/96 14	CIPLA LTD	ABACUS PHARMA (AFRICA) LIMITED	IVABEAT 7.5	IVABRADINE HYDROCHLORIDE	7.5 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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4161	NDA/MAL/HDP/9615	ARTEPHARM CO., LTD.,	BHL HEALTHCARE LIMITED	ARTEQUICK	ARTEMISININ + PIPERAQUINE	62.5 MG + 375 MG	ARTEPHARM CO. LTD4 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
4162	NDA/MAL/HDP/9619	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
4163	NDA/MAL/HDP/9620	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICALS 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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4164	NDA/MAL/HDP/9621	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
4165	NDA/MAL/HDP/9624	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
4166	NDA/MAL/HDP/9625	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

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4167	NDA/MAL/HDP/9626	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	BIKTARVY	BICTEGRAVIR SODIUM + EMTRICITABINE + TENOFOVIR 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
4168	NDA/MAL/HDP/9627	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	RIMEXA	ROCURONIUM BROMIDE	50 MG/5ML	MS PHARMA - JORDANPLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH-WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1X10X5 ML VIAL	03/06/2021
4169	NDA/MAL/HDP/9628	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

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4170	NDA/MAL/HDP/9629	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
4171	NDA/MAL/HDP/9631	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
4172	NDA/MAL/HDP/9632	AGIO PHARMACEUTICALS 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

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4173	NDA/MAL/HDP/9633	AGIO PHARMACEUTICALS 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
4174	NDA/MAL/HDP/9634	SERUM INSTITUTE OF INDIA PVT LTD	NORVIK ENTERPRISES LIMITED	RABISHIELD - 100	RABIES HUMAN MONOCLONAL ANTIBODY (RDNA)	40 IU/ ML	SERUM INSTITUTE OF INDIA PVT LTD .212/2, HADAPSAR, PUNE- 411028, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X2.5 ML VIAL	02/06/2021
4175	NDA/MAL/HDP/9636	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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4176	NDA/MAL/HDP/9637	SERUM INSTITUTE OF INDIA PVT LTD	NORVIK ENTERPRISES LIMITED	PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE	PNEUMOCOCCAL SACCHARIDE FOR SEROTYPE 1, 5, 6A, 7F, 9V, 14, 19A, 19F AND 23F + SACCHARIDE FOR SEROTYPE 6B	{2 MCG OF PNEUMOCOCCAL SACCHARIDE FOR SEROTYPE 1, 5, 6A, 7F, 9V, 14, 19A, 19F AND 23F + 4 MCG OF SACCHARIDE FOR SEROTYPE 6B)/ DOSE	SERUM INSTITUTE OF INDIA PVT LTD .212/2, HADAPSAR, PUNE-411028, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0X1.0 DOSE VIAL,1.0X50.0X5.0 DOSE VIAL	02/06/2021
4177	NDA/MAL/HDP/9638	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
4178	NDA/MAL/HDP/9639	ZOTA HEALTHCARE LTD	HARLEYS UGANDA LIMITED	ZOMEPRAZOLE	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40 MG	ZOTA HEALTHCARE LIMITED PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY SATTION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1X3X10 TABLET BLISTER	03/06/2021

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4179	NDA/MAL/HDP/9640	BERLIN-CHEMIE AG -	PHILLIPS PHARMACEUTICALS (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
4180	NDA/MAL/HDP/9641	BERLIN-CHEMIE AG -	PHILLIPS PHARMACEUTICALS (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
4181	NDA/MAL/HDP/9642	GLENMARK PHARMACEUTICALS 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

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4182	NDA/MAL/HDP/9643	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS 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
4183	NDA/MAL/HDP/9645	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS 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,1.0X10.0X1.0 ML AMPOULE	02/06/2021
4184	NDA/MAL/HDP/9648	JAMJOOM PHARMACEUTICALS 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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4185	NDA/MAL/HDP/9651	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
4186	NDA/MAL/HDP/9652	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICALS 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
4187	NDA/MAL/HDP/9653	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

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4188	NDA/MAL/HDP/9655	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	METOCLOPRAMIDE INJECTION BP 5 MG/ML	METOCLOPRAMIDE 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
4189	NDA/MAL/HDP/9663	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
4190	NDA/MAL/HDP/9665	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYNAC-SP	ACECLOFENAC + PARACETAMOL + SERRATIOPEPTIDASE	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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4191	NDA/MAL/HDP/9666	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
4192	NDA/MAL/HDP/9667	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
4193	NDA/MAL/HDP/9668	LABORATE PHARMACEUTICALS INDIA LIMITED	HEALTHCARE LTD.	AZILAB-200	AZITHROMYCIN DIHYDRATE	200MG/5ML	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT I131, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X1.0X30.0 ML CONTAINER + 30 ML WFI IN LDPE CONTAINER	02/06/2021

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4194	NDA/MAL/HDP/9669	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	ZOCOLD	PARACETAMOL + CHLORPHENAMINE 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
4195	NDA/MAL/HDP/9670	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	CDGREL-75	CLOPIDOGREL BISULFATE	75MG	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	1X3X10 TABLET BLISTER	04/06/2021
4196	NDA/MAL/HDP/9671	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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4197	NDA/MAL/HDP/9672	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	NASO B12	METHYLCOBALAM IN	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
4198	NDA/MAL/HDP/9675	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (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), TSIIIC, 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
4199	NDA/MAL/HDP/9678	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

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4200	NDA/MAL/HDP/9679	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	AXABAN-DENK 5 MG	APIXABAN	5MG	COMBINO PHARM (MALTA) LIMITED HF60 HAL FAR INDUSTRIAL ESTATE BBG3000	MALTA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X60.0 TABLET CONTAINER	02/06/2021
4201	NDA/MAL/HDP/9681	SYNOKEM PHARMACEUTICALS 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
4202	NDA/MAL/HDP/9683	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

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4203	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
4204	NDA/MAL/HDP/9713	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
4205	NDA/MAL/HDP/9714	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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4206	NDA/MAL/HDP/9717	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
4207	NDA/MAL/HDP/9719	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
4208	NDA/MAL/HDP/9721	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

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4209	NDA/MAL/HDP/97 22	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
4210	NDA/MAL/HDP/97 23	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
4211	NDA/MAL/HDP/97 25	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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4212	NDA/MAL/HDP/97 26	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
4213	NDA/MAL/HDP/97 28	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
4214	NDA/MAL/HDP/97 29	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

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4215	NDA/MAL/HDP/97 31	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
4216	NDA/MAL/HDP/97 47	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
4217	NDA/MAL/HDP/97 48	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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4218	NDA/MAL/HDP/9749	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
4219	NDA/MAL/HDP/9754	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
4220	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

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4221	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
4222	NDA/MAL/HDP/9757	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
4223	NDA/MAL/HDP/9758	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SKUDEXA	TRAMADOL HYDROCHLORIDE + DEXKETOPROFEN	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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4224	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
4225	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
4226	NDA/MAL/HDP/9761	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	LOPICARD 10MG	AMLODIPINE BESILATE	10MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	29/09/2021

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4227	NDA/MAL/HDP/97 62	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	ADVANTEC	CANDESARTAN CILEXETIL + HYDROCHLOROTH IAZIDE	16MG + 12.5MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER	29/09/2021
4228	NDA/MAL/HDP/97 63	RAINE INDUSTRIES	HEALTH LINK PHARMACY LIMITED	ROLXIN 40/320	DIHYDROARTEMIS ININ + 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
4229	NDA/MAL/HDP/97 65	PANACEA BIOTEC LTD	VITACARE LIMITED	LIVOLUK	LACTULOSE	10.0 G/15 ML	PANACEA BIOTEC PHARMA LIMITEDMALPURI 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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4230	NDA/MAL/HDP/9766	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
4231	NDA/MAL/HDP/9767	IND SWIFT LIMITED	PLANET PHARMACEUTICALS 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
4232	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

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4233	NDA/MAL/HDP/9769	FERRING INTERNATIONAL CENTER SA	MACNAUGHTON LIMITED	CARBETOCIN FERRING, 100 µG/ML	CARBETOCIN	100 µG/ML	M/S STERIL-GENE LIFE SCIENCES (P) LTD45, MAIN ROAD, MANGALAM VILLAGE, VILLIANUR COMMUNE, PUDUCHERRY-605110	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0X1.0 ML AMPOULE	05/10/2021
4234	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
4235	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

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4236	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
4237	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
4238	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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4239	NDA/MAL/HDP/9778	FAES FARMA S.A	PHILLIPS PHARMACEUTICALS (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
4240	NDA/MAL/HDP/9779	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	EYLEA	AFLIBERCEPT	40 MG/ML	BAYER AG, BERLINMULLERSTRABE 178, 13353 BERLIN - GERMANY	GERMANY	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL	05/10/2021
4241	NDA/MAL/HDP/9780	IND SWIFT LIMITED	PLANET PHARMACEUTICALS 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/SYRUPS/DROPS	1.0X1.0X50.0 ML BOTTLE	12/10/2021

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4242	NDA/MAL/HDP/9781	IND SWIFT LIMITED	PLANET PHARMACEUTICALS 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/SYRUPS/DROPS	1.0X1.0X50.0 ML BOTTLE	12/10/2021
4243	NDA/MAL/HDP/9782	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 ECOOMIC ZONE, MIHAN, NAGPUR 441108, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE	05/10/2021
4244	NDA/MAL/HDP/9785	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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4245	NDA/MAL/HDP/97 86	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
4246	NDA/MAL/HDP/97 90	PANACEA BIOTEC PHARMA LTD	VITACARE LIMITED	WILLGO CR	ACECLOFENAC	200MG	PANACEA BIOTEC PHARMA LIMITEDMALPURI BADDI, DISTRICT SOLAN, HIMACHAL PRADESH- 173205 - INDIA	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X5.0X2.0X10.0 TABLET BLISTER	05/10/2021
4247	NDA/MAL/HDP/97 91	IMPACT RH360	UNITED HEALTHCARE DISTRIBUTORS LTD	AVIBELA	LEVONORGESTREL	52 MG/ SYSTEM	ODYSSSEA PHARMA SPRLRUE DU TRAVAIL 16, 4460 GRACE-HOLLOGNE	BELGIUM	VAGINAL INTRA UTERINE DEVICES	1.0X1.0X52.0 MG DEVICE	05/10/2021

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4248	NDA/MAL/HDP/97 92	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
4249	NDA/MAL/HDP/97 93	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
4250	NDA/MAL/HDP/97 94	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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4251	NDA/MAL/HDP/97 96	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
4252	NDA/MAL/HDP/97 97	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
4253	NDA/MAL/HDP/97 99	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VOMIRAN 8 MG/ 4ML	ONDANSETRON HYDROCHLORIDE DIHYDRATE	8MG/4ML	MS PHARMA - JORDANPLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL- HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY VIALS	1X5X4 ML VIAL	12/10/2021

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4254	NDA/MAL/HDP/9801	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-GOIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X7.0 CAPSULE BLISTER	05/10/2021
4255	NDA/MAL/HDP/9802	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-GOIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X7.0 CAPSULE BLISTER	05/10/2021
4256	NDA/MAL/HDP/9803	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-GOIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X7.0 CAPSULE BLISTER	05/10/2021

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4257	NDA/MAL/HDP/9804	LABORATOIRE AGUETTANT	PHILLIPS PHARMACEUTICALS (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
4258	NDA/MAL/HDP/9807	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
4259	NDA/MAL/HDP/9809	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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4260	NDA/MAL/HDP/9810	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
4261	NDA/MAL/HDP/9815	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
4262	NDA/MAL/HDP/9816	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	LOPICARD 5MG	AMLODIPINE	5MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	29/09/2021

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4263	NDA/MAL/HDP/9817	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	LARINEX	DES Loratidine	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
4264	NDA/MAL/HDP/9818	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
4265	NDA/MAL/HDP/9819	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

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4266	NDA/MAL/HDP/9820	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS 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
4267	NDA/MAL/HDP/9821	JERUSALEM PHARMACEUTICALS CO. LIMITED	GAMA PHARMACEUTICALS (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
4268	NDA/MAL/HDP/9823	ABACUS PHARMA (AFRICA) LIMITED	ABACUS PHARMA (AFRICA) LIMITED	HEDON PLUS	PARACETAMOL + ASPIRIN + ANHYDROUS CAFFEINE	500 MG + 500 MG + 50 MG	RATNAMANI HEALTHCARE PRIVATE LIMITEDSURVEY NO. 750/1, AHMEDABAD - MEHSANA HIGHWAY, VILLAGE-INDRAD, NR. CHHATRAL G.I.D.C., TALUKA-KADI, DIST-MEHSANA, PIN-382721 (NG), GUJARAT - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X1.0X2.0 TABLET STRIP	05/10/2021

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4269	NDA/MAL/HDP/9827	INTAS PHARMACEUTICALS 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
4270	NDA/MAL/HDP/9828	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS 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
4271	NDA/MAL/HDP/9829	RENATA LIMITED	MARIE STOPES UGANDA LIMITED	WELL-PLAN	LEVONORGESTREL + ETHINYLESTRADIOL	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

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4272	NDA/MAL/HDP/9831	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
4273	NDA/MAL/HDP/9834	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
4274	NDA/MAL/HDP/9835	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	METAPROMIDE	METOCLOPRAMIDE 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

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4275	NDA/MAL/HDP/9836	WALLACE PHARMACEUTICALS PVT. LTD	STAR PHARMACEUTICALS 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
4276	NDA/MAL/HDP/9839	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	DOLUTEGRAVIR AND LAMIVUDINE TABLETS 50 MG / 300 MG	DOLUTEGRAVIR SODIUM + LAMIVUDINE	50 MG + 300 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 INDUSTRIAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET CONTAINER, 1.0X90.0 TABLET CONTAINER	16/12/2021
4277	NDA/MAL/HDP/9842	LABORATOIRE AGUETTANT	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ADRENALINE AGUETTANT	ADRENALINE TARTRATE	1MG/10ML	LABORATOIRE AGUETTANT 1 RUE ALEXANDER FLEMING 69007, LYON - FRANCE	FRANCE	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X10.0X10.0 ML SYRINGE	16/12/2021

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4278	NDA/MAL/HDP/9843	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
4279	NDA/MAL/HDP/9845	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
4280	NDA/MAL/HDP/9846	GLOBELA PHARMA PVT. LTD.	TATA UGANDA LIMITED	SQUAM	DIHYDROARTEMISININ + 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

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4281	NDA/MAL/HDP/9848	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
4282	NDA/MAL/HDP/9849	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
4283	NDA/MAL/HDP/9850	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

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4284	NDA/MAL/HDP/9853	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
4285	NDA/MAL/HDP/9854	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
4286	NDA/MAL/HDP/9855	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TRADOX	TRAMADOL HYDROCHLORIDE	10 MG/2 ML	MS PHARMA - JORDAN PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH-WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY VIALS	1.0X5.0X2.0 ML VIAL	08/12/2021

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4287	NDA/MAL/HDP/9856	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	LARTEM DISPERSIBLE	ARTEMETHER + LUMEFANTRINE	20MG +120MG	S KANT HEALTHCARE LIMITED1802 – 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
4288	NDA/MAL/HDP/9858	VIIV HEALTHCARE UK LTD-	UNITED HEALTHCARE DISTRIBUTORS LTD	TIVICAY 25MG	DOLUTEGRAVIR SODIUM	25MG	GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS)PRIORITY STREET, WARE, SG12 ODJ	UNITED KINGDOM	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	08/12/2021
4289	NDA/MAL/HDP/9859	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)PRIORITY 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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4290	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
4291	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
4292	NDA/MAL/HDP/9865	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	PINFOL	FOLIC ACID	5MG	PINNACLE LIFE SCIENCE PVT LTD KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1X10X10 TABLET BLISTER	21/12/2021

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4293	NDA/MAL/HDP/9866	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)PRIORITY STREET, WARE, SG12 ODJ	UNITED KINGDOM	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	08/12/2021
4294	NDA/MAL/HDP/9867	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
4295	NDA/MAL/HDP/9871	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	RETALEX	ATRACURIUM BESYLATE	50MG/5ML	MS PHARMA - JORDAN PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH-WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY VIALS	1X5X5 ML VIAL	21/12/2021

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4296	NDA/MAL/HDP/9872	SAGA LIFESCIENCES LTD	ABACUS PHARMA (AFRICA) LIMITED	COL-COL	PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + CHLORPHENIRAMINE 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, 1.0X10.0X10.0 TABLET BLISTER	08/12/2021
4297	NDA/MAL/HDP/9873	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OMISEC	OMEPRAZOLE SODIUM	40MG/VIAL	MS PHARMA - JORDAN PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH-WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY DRY VIALS	1.0X40.0 MG VIAL, 1.0X5.0X40.0 MG VIAL	08/12/2021
4298	NDA/MAL/HDP/9874	OCTAPHARMA AG	PHILLIPS PHARMACEUTICALS (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

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4299	NDA/MAL/HDP/9875	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
4300	NDA/MAL/HDP/9876	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	LENIOL	PARACETAMOL	1000MG/100 ML	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITEDSURVEY 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
4301	NDA/MAL/HDP/9877	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

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4302	NDA/MAL/HDP/9878	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
4303	NDA/MAL/HDP/9879	LABORATE PHARMACEUTICALS 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
4304	NDA/MAL/HDP/9881	HETERO LABS LTD	AIVEEN (U) LIMITED	DOLUTEGRAVIR, EMTRICITABINE AND TENOFOVIR ALAFENAMIDE TABLETS 50MG/200MG/25MG	DOLUTEGRAVIR SODIUM + EMTRICITABINE + TENOFOVIR ALAFENAMIDE HEMIFUMARATE	50MG+200MG+25MG	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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4305	NDA/MAL/HDP/9882	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	KAMAGRA CT 50	SILDENAFIL CITRATE	50MG	AJANTA PHARMA LIMITED AJANTA 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
4306	NDA/MAL/HDP/9884	LABORATE PHARMACEUTICALS 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
4307	NDA/MAL/HDP/9885	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BECLOCORT	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

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4308	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
4309	NDA/MAL/HDP/9889	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
4310	NDA/MAL/HDP/9897	MEDOPHARM	PLANET PHARMACEUTICALS UGANDA LTD	CO-TRIMOXAZOLE TABLETS BP	TRIMETHOPRIM + SULPHAMETHOXAZOLE	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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4311	NDA/MAL/HDP/9899	MEDICAL UNION PHARMACEUTICALS.	KARURI PHARMACEUTICALS 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
4312	NDA/MAL/HDP/9902	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	SEVLAREN 800	SEVELAMER CARBONATE	800MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRIAL AREA,MEHATPUR-174 315, HIMACHAL PRADESH.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/12/2021
4313	NDA/MAL/HDP/9903	REGAL PHARMACEUTICALS 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

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4314	NDA/MAL/HDP/9904	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
4315	NDA/MAL/HDP/9906	INTAS PHARMACEUTICALS 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
4316	NDA/MAL/HDP/9907	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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4317	NDA/MAL/HDP/9911	THE UNITED PHARMACEUTICALS 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
4318	NDA/MAL/HDP/9912	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
4319	NDA/MAL/HDP/9913	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

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4320	NDA/MAL/HDP/9920	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	CIS-CURON	CIS-ATRACURIUMBESYLATE	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
4321	NDA/MAL/HDP/9921	REGAL PHARMACEUTICALS LTD	REGAL PHARMA U LIMITED	SONATEC MOUTHWASH MENTHOL BREEZE	CETYLPYRIDINIUM 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
4322	NDA/MAL/HDP/9922	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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4323	NDA/MAL/HDP/99 24	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
4324	NDA/MAL/HDP/99 25	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	TUSSIDEX LINCTUS	DEXTROMETHORP HAN	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
4325	NDA/MAL/HDP/99 31	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

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4326	NDA/MAL/HDP/9933	THE UNITED PHARMACEUTICALS MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BISOPROL® 10	BISOPROLOL FUMARATE	10MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY JORDAN - NUZHAT SAHAB	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/03/2022
4327	NDA/MAL/HDP/9936	GUFIC BIOSCIENCES LTD	EUROPA HEALTHCARE (U) LTD	VAMOCIN 1GM	VANCOMYCIN HYDROCHLORIDE	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
4328	NDA/MAL/HDP/9941	ALTHEA PHARMA PVT LTD.	JOINT MEDICAL STORE (UPMB - UCMB)	STERILIZED WATER FOR INJECTION	WATER FOR INJECTION	WATER FOR INJECTION	ALTHEA PHARMA PRIVATE LIMITED WORKS: 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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4329	NDA/MAL/HDP/99 42	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
4330	NDA/MAL/HDP/99 43	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
4331	NDA/MAL/HDP/99 44	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

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4332	NDA/MAL/HDP/9948	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
4333	NDA/MAL/HDP/9949	LABORATE PHARMACEUTICALS 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
4334	NDA/MAL/HDP/9950	XL LABORATORIES PRIVATE LIMITED	ROYAL PHARMA 2011 LIMITED	RETOVIT	VITAMIN A	200000 IU	XL LABORATORIES PRIVATE LIMITED A-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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4335	NDA/MAL/HDP/9951	ARCELIA LIFE SCIENCES LTD.	PLUTO PHARMACEUTICALS 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 LIMITED PLOT 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
4336	NDA/MAL/HDP/9952	ARCELIA LIFE SCIENCES LTD.	PLUTO PHARMACEUTICALS LIMITED	DEXAMETHASONE SODIUM PHOSPHATE INJECTION 4 MG/ML	DEXAMETHASONE 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
4337	NDA/MAL/HDP/9954	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

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4338	NDA/MAL/HDP/9955	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
4339	NDA/MAL/HDP/9956	ARCELIA LIFE SCIENCES LTD.	PLUTO PHARMACEUTICALS LIMITED	ARCELIA OMEPRAZOLE FOR INJECTION	OMEPRAZOLE SODIUM	40 MG/VIAL	SANJAR PHARMA LLP SURVEY 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
4340	NDA/MAL/HDP/9957	INDCHEMIE HEALTH SPECIALITIES PVT. LTD.	NUMED STORES SMC LIMITED	TERBICON CREAM	TERBINAFINE HYDROCHLORIDE	1.0%W/W	INDCHEMIE HEALTH SPECIALITIES PVT. LTD VILLAGE-THANA, BADDI, DIST. SOLAN, HIMACHAL PRADESH-173205.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X10.0 G TUBE	24/03/2022

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4341	NDA/MAL/HDP/9958	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
4342	NDA/MAL/HDP/9959	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
4343	NDA/MAL/HDP/9960	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

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4344	NDA/MAL/HDP/9961	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
4345	NDA/MAL/HDP/9962	ARCELIA LIFE SCIENCES LTD.	PLUTO PHARMACEUTICALS LIMITED	ARTEMETHER INJECTION 80 MG/ML	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
4346	NDA/MAL/HDP/9963	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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4347	NDA/MAL/HDP/99 64	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
4348	NDA/MAL/HDP/99 67	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
4349	NDA/MAL/HDP/99 68	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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4350	NDA/MAL/HDP/9972	MACLEODS PHARMACEUTICALS 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
4351	NDA/MAL/HDP/9973	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ARBITEL 80 H	TELMISARTAN + HYDROCHLOROTHIAZIDE	80MG + 12.5MG	MICRO LABS LIMITED .92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/03/2022
4352	NDA/MAL/HDP/9974	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	NEBTAS-H	NEBIVOLOL HYDROCHLORIDE + HYDROCHLOROTHIAZIDE	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

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4353	NDA/MAL/HDP/9975	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	RENERVE-P	PREGABALIN + MECOBALAMIN	75MG + 750MG	CORONA REMEDIES PVT. LTD VILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	ORAL SOLID ORDINARY CAPSULES	1X3X10 CAPSULE BLISTER	31/03/2022
4354	NDA/MAL/HDP/9976	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
4355	NDA/MAL/HDP/9977	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	EMTRICITABINE + TENOFOVIR DISOPROXIL FUMARATE TABLETS 200 MG/ 300 MG	EMTRICITABINE + TENOFOVIR 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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4356	NDA/MAL/HDP/9978	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
4357	NDA/MAL/HDP/9981	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VELOCE	LORNOXICAM	8MG PER VIAL	MS PHARMA - JORDANPLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH-WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY DRY VIALS	1X1 VIAL CARTON	31/03/2022
4358	NDA/MAL/HDP/9983	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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4359	NDA/MAL/HDP/9984	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
4360	NDA/MAL/HDP/9985	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
4361	NDA/MAL/HDP/9986	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

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4362	NDA/MAL/HDP/99 87	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
4363	NDA/MAL/HDP/99 91	CACHET PHARMACEUTICAL S PVT LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EASCOF-LS	LEVOSALBUTAMO L 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
4364	NDA/MAL/HDP/99 92	REGAL PHARMACEUTICAL S 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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4365	NDA/MAL/HDP/9995	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
4366	NDA/MAL/HDP/9996	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
4367	NDA/MAL/HDP/9997	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

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4368	NDA/MAL/HDP/99 98	LINCOLN PHARMACEUTICAL S 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
4369	NDA/MAL/HDP/99 99	SERUM INSTITUTE OF INDIA PVT LTD	NORVIK ENTERPRISES LIMITED	POLIOMYELITIS VACCINE (ORAL), BIVALENT TYPES 1 AND 3.	POLIO VIRUS (SABIN)	TYPE - I ≥106.0 CCID50 TYPE - III ≥105.8 CCID50	SERUM INSTITUTE OF INDIA PVT LTD .212/2, HADAPSAR, PUNE- 411028, INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X50.0X2.0 ML VIAL (20DOSES)	31/03/2022