

NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JUNE 2024

S/N	NDA REGISTRATION NUMBER	LICENSE HOLDER	LOCAL TECHNICAL REPRESENTATIVE	NAME OF DRUG	GENERIC NAME OF DRUG	STRENGTH OF DRUG	MANUFACTURING SITE	COUNTRY OF MANUFACTURE	DOSAGE FORM	PACK SIZE	REGISTRATION DATE
1	NDA/MAL/HDP/002	ABACUS PARENTERAL DRUGS LIMITED.	ABACUS PARENTERAL DRUGS LIMITED	X-SONE-N	DEXAMETHASON E+NEOMYCIN	0.1W/V+ 0.35W/V	ABACUS PARENTERAL DRUGS LTD.PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL,1.0X5.0 ML VIAL	01/07/2011
2	NDA/MAL/HDP/003	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	UMOXIL CLAV 625	AMOXICILLIN + CLAVULANATE POTASSIUM	500 MG + 125 MG	UNI MEDICOLABS21-22 PHARMACY SELAQUI DEHRADUN 248197	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2015

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3	NDA/MAL/HDP/006	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DIAMIDE	GLIBENCLAMIDE + METFORMIN HYDROCHLORIDE	5MG + 500MG	HOVID BERHAD, LOT 56442, 7 1/2 MILES JALAN IPOH/CHEMOR 31200, CHEMOR PERAK	MALAYSIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X12.0 TABLET BLISTER	01/07/2014
4	NDA/MAL/HDP/007	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	PROCIPIR SYRUP	CYPROHEPTADINE HYDROCHLORIDE	2MG/5ML	AGOG PHARMA LTD PLOT NO.33, SECTOR II, VASAI, TALUKA INDL CO-OP ESTATE LTD, GAURAI PADA, VASAI(E) DIST. THANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE, 1.0X200.0 ML BOTTLE	01/07/2013
5	NDA/MAL/HDP/012	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	PENGESIC SR	TRAMADOL HYDROCHLORIDE SR	100MG	HOVID BHD LOT 56442, 7.5 MILE JALAN IPOH/CHEMOR 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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6	NDA/MAL/HDP/0013	ORGANON SOUTH AFRICA (PTY) LTD	SURGIPHARM (U) LIMITED	IMPLANON NXT	ETONOGESTREL	68MG	N.V. ORGANONKLOOSTER STRAAT 6, 5349 AB OSS, THE NETHERLAND	NETHERLANDS	PARENTERAL RETARD IMPLANTS	1.0X68.0 MG IMPLANT	01/07/2015
7	NDA/MAL/HDP/0016	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	CODIMEX-CT TABLETS	CETIRIZINE DIHYDROCHLORIDE	10MG	REGAL PHARMACEUTICALS LIMITED PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
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, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X2.0 ML AMPOULE, 1.0X2.0X5.0X2.0 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/031	MANKIND PHARM LTD	TATA UGANDA LIMITED	CEFTATIME-SB 1.5	CEFTRIAZONE+SU LBACTAM	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/033	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, 1.0X10.0X10.0 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/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

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30	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
31	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
32	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.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	01/07/2014

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33	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.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X28.0 TABLET BLISTER	01/07/2014
34	NDA/MAL/HDP/0088	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	D-LYTE CO-PACK	ANHYDROUS GLUCOSE+SODIUM CHLORIDE+TRISODIUM CITRATE+POTASSIUM CHLORIDE/ZINC, ANHYDROUS GLUCOSE+SODIUM CHLORIDE+TRISODIUM CITRATE+POTASSIUM	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, 2.0X1000.0 ML SACHET + 1*10 BLISTERS	01/07/2015
35	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

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36	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
37	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,1.0X100.0 CAPSULE CONTAINER,1.0X100.0X10.0 CAPSULE BLISTER	01/07/1998
38	NDA/MAL/HDP/0102	MSN LABORATORIES PRIVATE LIMITED,	METRO PHARMACEUTICALS LIMITED	SILMELT 100	SILDENAFIL CITRATE	100MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X2.0 TABLET BLISTER	01/07/2014

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39	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
40	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
41	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

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42	NDA/MAL/HDP/0 110	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
43	NDA/MAL/HDP/0 111	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
44	NDA/MAL/HDP/0 112	NORVATIS PHARMA AG	SURGIPHARM (U) LIMITED	EXFORGE 5MG/160MG	AMLODIPINE + VALSARTAN	5 MG + 160 MG	NOVARTIS PHARMA STEIN AGH-4332 STEIN SCHAFFHAUSERTRASS E	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2007

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45	NDA/MAL/HDP/0114	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	BREATHEZY 4	MONTELUKAST SODIUM	4MG	MSN LABORATORIES LTD PLOT NO. 42 INDUSTRIAL ESTARE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
46	NDA/MAL/HDP/0116	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	BREATHEZY CW 5	MONTELUKAST SODIUM	5MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
47	NDA/MAL/HDP/0118	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZOCEF 750MG	CEFUROXIME SODIUM	750MG	SANCE LABORATORIES PVT LTD VI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA. ALKEM LABORATORIES LTD VILLAGE – 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

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48	NDA/MAL/HDP/0 119	DAWA LIMITED	SUPER MEDIC LTD	DACOLD	CAFFEINE ANHYDROUS+CHL ORPHENIRAMINE MALEATE+PARAC ETAMOL+PSEUDO EPHEDRINE	30MG+4MG+400M G+30MG	DAWA LIMITED BABA DOGO RWARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013
49	NDA/MAL/HDP/0 121	SHELYS PHARMACEUTICAL S LTD	BETA HEALTHCARE UGANDA LIMITED	PEDZINC	ZINC SULPHATE	20MG	BETA HEALTH CARE INTERNATIONAL LIMITED/-PLOT NO. LR 209/ 6534 MOGADISHU ROAD, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2015
50	NDA/MAL/HDP/0 124	DAWA LIMITED	SUPER MEDIC LTD	AMPECIN	AMPICILLIN TRIHYDRATE	125MG/5ML	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2015

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51	NDA/MAL/HDP/0 125	DAWA LIMITED	SUPER MEDIC LTD	SULPHUR OINTMENT	SULPHUR	10%W/W	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE	01/07/2013
52	NDA/MAL/HDP/0 135	SHELYS PHARMACEUTICAL S LTD	BETA HEALTHCARE UGANDA LIMITED	HEMOVIT SYRUP	IRON + FOLIC ACID + PYRIDOXINE + CYANOCOBALAMI N + ZINC	200MG + 1.5MG + 0.5MG + 50 MCG + 2.33MG	BETA HEALTHCARE INTERNATIONAL LTD -PLOT NO LR 209/6534 MOGADISHU ROAD	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2013
53	NDA/MAL/HDP/0 139	DAWA LIMITED-	SUPER MEDIC LTD	MOXAFORTE	FLUCLOXACILLIN SODIUM + AMOXICILLIN TRIHYDRATE	250MG + 250MG	DAWA PHARMACEUTICALS LIMITEDPLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2014

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54	NDA/MAL/HDP/0 141	COSMOS LTD	ASTRA PHARMA (U) LIMITED	NYCOSTAT SUSPENSION	NYSTATIN	100,000 I.U/ML	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/1998
55	NDA/MAL/HDP/0 157	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RECODIN	CODEINE PHOSPHATE + CHLORPHENIRAM INE MALEATE	10MG + 4MG /5ML	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2015
56	NDA/MAL/HDP/0 158	MEGA LIFSCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	KIPEL 10	MONTELUKAST SODIUM	10MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2015

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57	NDA/MAL/HDP/0 160	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	TIZIGESIC	TIZANIDINE HYDROCHLORIDE	2MG	UNICHEM LABORATORIES LIMITEDC-31,32 & D- 10, INDUSTRIAL AREA, MEERUT ROAD, GHAZIABAD, U.P.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
58	NDA/MAL/HDP/0 161	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	TRAMAREN	TRAMADOL HYDROCHLORIDE	50MG	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2014
59	NDA/MAL/HDP/0 162	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	COSYP-D LINCTUS	DEXTROMETHOR PHAN HYDROBROMIDE + CHLORPHENAMIN E MALEATE	10MG +4MG /5ML	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2015

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60	NDA/MAL/HDP/0 163	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	PHENAREN	PROMETHAZINE HYDROCHLORIDE	5MG/5ML	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2015
61	NDA/MAL/HDP/0 164	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
62	NDA/MAL/HDP/0 165	TORRENT PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S LTD.	TOLANZ 5	OLANZAPINE ORODISPERSIBLE TABLETS	5MG	TORRENT PHARMACEUTICALS LTD .,AHMEDABAD- MEHSANA HIGHWAY, TALUKA- KADI, DIST. MEHSANA, INDRAD- 382721, GUJARAT	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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63	NDA/MAL/HDP/0 166	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
64	NDA/MAL/HDP/0 167	TORRENT PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S 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
65	NDA/MAL/HDP/0 168	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S LIMITED	FEBUDAY	FEBUXOSTAT	80MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014

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66	NDA/MAL/HDP/0 175	BAYER SCHERING PHARMA	SURGIPHARM (U) LIMITED	XARELTO 10MG	RIVAROXABAN	10MG	BAYER HEALTHCARE AG,D-51368, LEVERKUSEN	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2009
67	NDA/MAL/HDP/0 178	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	COLD CAP DAYTIME AND NIGHT TIME CAPSULE	DAY TIME(PARACETA MOL +CAFFEINE ANHYDROUS+PSE UDOEPHEDRINE HCL) AND NIGHT TIME(PARACETA MOL +CHLORPHENIRA MINE MALEATE)	DAY TIME (500MG + 30MG + 30MG) AND NIGHT TIME (500MG +2MG)	REGAL PHARMACEUTICALS LIMITED PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X8.0 CAPSULE BLISTER	01/07/2013
68	NDA/MAL/HDP/0 182	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S LIMITED	FEBUDAY 40	FEBUXOSTAT	40MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014

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69	NDA/MAL/HDP/0 186	WIDE SPECTRUM ENTERPRISES (U) LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BBC SPRAY	BENZOCAINE+BE NZYDAMINE+CAT ALKONIUM CHLORIDE	1.5%W/V+0.15%W /V+0.0413%W/V	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	EGYPT	ORAL TOPICAL SPRAYS WITHOUT GAS	1.0X25.0 ML BOTTLE	01/07/2014
70	NDA/MAL/HDP/0 187	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	KAPRON TABLET	TRANEXAMIC ACID	500 MG	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2014
71	NDA/MAL/HDP/0 188	AMOUN PHARMACEUTICAL S LTD	BOOTS PHARMACEUTICAL S LIMITED	LEVOXIN	LEVOFLOXACIN	500MG	AMOUN PHARMACEUTICALS CO. S.A.E1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	EGYPT	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0 TABLET BLISTER	01/07/2014

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72	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
73	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/SYR UPS/DROPS	1.0X70.0 ML BOTTLE	01/07/2013
74	NDA/MAL/HDP/0193	MEDOPHARM, INDIA	VITACARE LIMITED	CLEDOMOX 625	AMOXICILLIN + CLAVULANIC ACID	500 MG + 125 MG	MEDOPHARM PVT LTD.NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER, 1.0X2.0X10.0 TABLET STRIP	01/07/2013

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75	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
76	NDA/MAL/HDP/0203	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	SERETIDE EVOHALER 250	SALMETEROL XINAFOATE + FLUTICASONE PROPIONATE	25MCG + 250MCG	GLAXO WELLCOME PRODUCTION ZONE INDUSTRIELLE NO. 2 23, RUE LAVOISIER 27000 EVREUX	FRANCE	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER	01/07/2015
77	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

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78	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
79	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
80	NDA/MAL/HDP/0210	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	HEPATICUM	SILYMARIN	140MG	MEDICAL UNION PHARMACEUTICAL CO.PLANT: ABUSULTAN, ISMAILIA, EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2011

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81	NDA/MAL/HDP/0 212	MEDICAL UNION PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	HEPATICUM	SILYMARIN	1G/100ML	MEDICAL UNION PHARMACEUTICAL CO.PLANT: ABU- SULTAN, ISMAILIA, EGYPT	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X120.0 ML BOTTLE	01/07/2012
82	NDA/MAL/HDP/0 221	DAWA LIMITED	SUPER MEDIC LTD	AMPICLO-DAWA	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	DAWA PHARMACEUTICALS LIMITEDPLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013
83	NDA/MAL/HDP/0 222	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	AVIR-200	ACYCLOVIR	200MG	S KANT HEALTHCARE LIMITED1802 – 1805, G.I.D.C., PHASE III, VAPI - 396195 GUJARAT, INDIA. LINCOLN PHARMACEUTICALS LTD .10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT KESAR	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013

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84	NDA/MAL/HDP/0 226	AMOUM PHARMACEUTICALS LTD	BOOTS PHARMACEUTICALS LIMITED	ULTRASOLV SYRUP	OXOMEMAZINE HCL & CARBOCYSTEINE & GUAIFENESIN	2MG+125MG+100 MG/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
85	NDA/MAL/HDP/0 230	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	COMBIART	ARTHEMETHER + LUMEFANTRINE	20MG +120MG	UNIVERSAL CORPORATION LIMITED PLOT NO 13777, PO BOX 1748- 00902 KIKUYU CLUB RD STRIDES PHARMA SCIENCE LIMITED (STRIDES SHASUN)KRS GARDENS, PLOT 36/7 SURAGAJKKANAHAL LI, INDLAWADI CROSS, ANKAL TALUK, BANGALORE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X6.0 TABLET BLISTER,1.0X1.0X6. 0 TABLET BLISTER,1.0X1.0X12 .0 TABLET BLISTER,1.0X1.0X18 .0 TABLET BLISTER,1.0X1.0X24 .0 TABLET BLISTER,1.0X24.0 TABLET BLISTER,1.0X30.0X1 8.0 TABLET BLISTER,1.0X30.0X2 4.0 TABLET BLISTER	01/07/2013
86	NDA/MAL/HDP/0 232	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	BRANTA	LOSARTAN POTASSIUM + AMLODIPINE BESILATE	50MG + 5MG	TORRENT PHARMACEUTICALS LTD .,AHMEDABAD- MEHSANA HIGHWAY, TALUKA- KADI, DIST. MEHSANA, INDRAD- 382721, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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87	NDA/MAL/HDP/0 233	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 ATHANASSIOUS LIMASSOL CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0 TABLET BLISTER	01/07/2014
88	NDA/MAL/HDP/0 234	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,1.0X2.0X5. 0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2014
89	NDA/MAL/HDP/0 235	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	AXETINE 500	CEFUROXIME AXETIL	500MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET STRIP	01/07/2014

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90	NDA/MAL/HDP/0 239	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	KOMEFAN 140	ARTEMETHER + LUMEFANTRINE	20 MG+ 120 MG	MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0X3.0 TABLET BLISTER,1.0X18.0 TABLET BLISTER,1.0X24.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X2.0X6. 0 TABLET BLISTER	01/07/2014
91	NDA/MAL/HDP/0 244	SAKAR HEALTHCARE PVT LTD	ROYAL PHARMA 2011 LIMITED	HYOCIN	HYOSCINE BUTYLBROMIDE	20MG/ML	SAKAR HEALTHCARE PVT LTDBLOCK NO. 10-13, NR. M.N DESAI PETRO PUMP, SARKHEJ-BAVLA ROAD, CHANGODAR, DIST: AHMEDABAD- 382213, GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE	01/07/2014
92	NDA/MAL/HDP/0 248	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	PANTONEX DR-40	PANTOPRAZOLE	40 MG	.IPCA LABORATORIES LTD PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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93	NDA/MAL/HDP/0250	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 BILESHWARPURA CHHATRAL- -382729	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G CONTAINER	01/07/2013
94	NDA/MAL/HDP/0252	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
95	NDA/MAL/HDP/0254	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CONCOR 5	BISOPROLOL HEMIFUMARATE	5MG	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	01/07/2013

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96	NDA/MAL/HDP/0 255	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
97	NDA/MAL/HDP/0 256	HETERO LABS LTD	AIVEEN (U) LIMITED	CAPETERO 500	CAPECITABINE	500MG	HETERO LABS (UNIT VI), INDIAAPIIC, FORMULATION SEZ, POLEPALLY (V),JEDCHERLA(M) MAHABOBNAGER DISTRICT ANDHRA PRADESH-509301, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X120.0 TABLET CONTAINER	01/07/2015
98	NDA/MAL/HDP/0 266	ASTRA PHARMA (UK) LTD	ASTRA PHARMA (U) LIMITED	BENZATHINE PENICILLIN INJECTION	BENZATHINE PENICILLIN	2.400.000 IU	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTDNO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSH OP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0 VIAL CARTON	01/07/2001

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99	NDA/MAL/HDP/0 269	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	VOMISTAT-8	ONDANSETRON	8MG	LINCOLN PHARMACEUTICALS LIMITED 10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X1.0X10.0 TABLET BLISTER	01/07/2014
100	NDA/MAL/HDP/0 270	HETERO LABS LTD	AIVEEN (U) LIMITED	LEVIN 500MG	LEVOFLOXACIN HEMIHYDRATE	500MG	HETERO LABS LTD (UNIT- V)SY.NO.438,439,44 0 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOONNAGAR 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
101	NDA/MAL/HDP/0 271	BIOLOGICAL E. LTD	GITTOES PHARMACEUTICAL S LIMITED	BETT	TETANUS VACCINE ADSORBED	40 I.U	BIOLOGICAL E LTD PLOT NO.1, S.P BIOTECHNOLOGY PARK, PHASE II KOLTHER (V), SHAMEERPET(M), RANGA REDDY(DIST), ANDHRA PRADESH, INDIA 500078	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X20.0X10.0 ML AMPOULE,1.0X24.0 X10.0 ML AMPOULE,1.0X5.0 ML VIAL (10 DOSES)	01/07/2015

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102	NDA/MAL/HDP/0 272	HETERO LABS LTD	AIVEEN (U) LIMITED	LEVIN 250	LEVOFLOXACIN	250MG	HETERO LABS LTD. UNIT (V)439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2019
103	NDA/MAL/HDP/0 275	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	ZENTEL	ALBENDAZOLE	400MG	GLAXOSMITHKLINE CONSUMER HEALTHCARE S.A (PTY) LIMITED39 HAWKINS AVENUE, EPPING INDUSTRIA 1, 7460, CAPE TOWN, SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0 TABLET BLISTER	01/07/2011
104	NDA/MAL/HDP/0 276	MICRO LABS LTD	LABOREX UGANDA LIMITED	MELANOV 80	GLICLAZIDE	80MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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105	NDA/MAL/HDP/0 278	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CHLORPROMAZIN E TABLETS B.P 100MG	CHLORPROMAZIN E HYDROCHLORIDE	100MG	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10 0.0 TABLET CONTAINER,10.0X1 0.0 TABLET BLISTER	01/07/1998
106	NDA/MAL/HDP/0 283	DAWA LIMITED	SUPER MEDIC LTD	AMPICLO-DAWA	AMPICILLIN + CLOXACILLIN	125 MG + 125 MG	DAWA PHARMACEUTICALS LIMITEDPLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2013
107	NDA/MAL/HDP/0 290	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	NATOA	MEBENDAZOLE	100MG	LABORATORY & ALLIED LTD-PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X6.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1997

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108	NDA/MAL/HDP/0 296	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PRAZITEL TABLETS	PRAZIQUANTEL	600MG	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	2.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/1998
109	NDA/MAL/HDP/0 298	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	SEFIXI-50 DRY SYRUP	CEFIXIME	50MG	SAKAR HEALTH CARE PVT, LTDBLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ- BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X60.0 ML BOTTLE	01/07/2013
110	NDA/MAL/HDP/0 301	HETERO LABS LTD	AIVEEN (U) LIMITED	MONAST 10	MONTELUKAST SODIUM	10MG	HETERO LABS LTD. UNIT (V)S.NO.439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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111	NDA/MAL/HDP/0 303	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
112	NDA/MAL/HDP/0 305	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	CEFAX-250 DRY SYRUP	CEFALEXIN	250MG/5ML	SAKAR HEALTH CARE PVT, LTDBLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ- BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X1.0X50.0 ML BOTTLE,1.0X1.0X10 0.0 ML BOTTLE	01/07/2013
113	NDA/MAL/HDP/0 307	HETERO DRUGS LTD	AIVEEN (U) LIMITED	LAMIVUDINE ORAL SOLUTION	LAMIVUDINE	10MG/ML	HETERO DRUGS LTD, UNIT III 22-110, IDA, JEEDIMETLA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X240.0 ML CONTAINER	01/07/2013

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114	NDA/MAL/HDP/0 308	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	CEFAX-250	CEFALEXIN	250MG	SAKAR HEALTH CARE PVT, LTDBLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ- BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013
115	NDA/MAL/HDP/0 311	MARTINDALE PHARMACEUTICAL S 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
116	NDA/MAL/HDP/0 312	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/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2013

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117	NDA/MAL/HDP/0314	MARTINDALE PHARMACEUTICALS LTD	LABOREX UGANDA LIMITED	SUXAMETHONIUM CHLORIDE SOLUTION FOR INJECTION	SUXAMETHONIUM CHLORIDE	50MG/ML	MARTINDALE PHARMA BAMPPTON ROAD, HAROLD HILL,ROMFORD,RM3 844	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2013
118	NDA/MAL/HDP/0317	YURIA PHARM LTD-UKRAINE	PHARMA VILLE LIMITED	CIPROFLOXACIN-UF	CIPROFLOXACIN	2MG/ML	YURIA-PHARM LLC MANUFACTURING SITE NO. 1108, KOBZARSKA STREET, CHERKASY, 18030	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X200.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2013
119	NDA/MAL/HDP/0318	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

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120	NDA/MAL/HDP/0 320	DAWA LIMITED	SUPER MEDIC LTD	DAZOLE	CLOTRIMAZOLE	1%W/W	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2013
121	NDA/MAL/HDP/0 322	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	NEBILONG-5	NEBIVOLOL HCL	5MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2009
122	NDA/MAL/HDP/0 326	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	OSTEBON	CALCIUM + COLECALCIFEROL	250MG + 125 IU	ARISTO PHARMACEUTICALS PVT LIMITEDPLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP- 462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	01/07/2014

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123	NDA/MAL/HDP/0333	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
124	NDA/MAL/HDP/0335	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
125	NDA/MAL/HDP/0337	IND-SWIFT	PLANET PHARMACEUTICALS UGANDA LTD	SWAZI *500	AZITHROMYCIN	500MG	IND SWIFT LTD GLOBAL BUSINESS UNIT JAWAHARPUR OFF NH-21 DERABASSI DIST MOHALI PUNJAB 140507	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0 TABLET BLISTER, 1.0X10.0X1.0X3.0X10.0 TABLET BLISTER	01/07/2014

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126	NDA/MAL/HDP/0 339	IND-SWIFT	PLANET PHARMACEUTICAL S UGANDA LTD	SWAZI *250	AZITHROMYCIN	250MG	IND SWIFT LTDGLOBAL BUSINESS UNIT JAWAHARPUR OFF NH-21 DERABASSI DIST MOHALI PUNJAB 140507	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X6.0 TABLET BLISTER, 1.010.0X1.0X6.0 TABLET BLISTER	01/07/2014
127	NDA/MAL/HDP/0 341	IND SWIFT LTD	PLANET PHARMACEUTICAL S UGANDA LTD	TELSWIFT- H 40	TELMISARTAN + HYDROCHLOROT HIAZIDE	40MG + 12.5MG	IND SWIFT LTDGLOBAL BUSINESS UNIT JAWAHARPUR OFF NH-21 DERABASSI DIST MOHALI PUNJAB 140507	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2014
128	NDA/MAL/HDP/0 342	IND SWIFT LTD	PLANET PHARMACEUTICAL S UGANDA LTD	TELSWIFT- H 80	TELMISARTAN + HYDROCHLOROT HIAZIDE	80MG + 12.5MG	IND SWIFT LTDGLOBAL BUSINESS UNIT JAWAHARPUR OFF NH-21 DERABASSI DIST MOHALI PUNJAB 140507	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER,3.0X10.0 TABLET BLISTER	01/07/2014

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129	NDA/MAL/HDP/0 348	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	XBETA	BETAMETHASONE SODIUM PHOSPHATE	0.1%W/V	ABACUS PARENTERAL DRUGS LIMITEDBLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL,1.0X5.0 ML VIAL	01/07/2015
130	NDA/MAL/HDP/0 349	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICAL S LIMITED	CLAXY 1.2 G	COAMOXICLAV	1.2G	SWISS PARENTERALS (UNIT-2), PLOT 402, 412-414, KERALA INDUSTRIAL ESTATE, G.I.D.C., NR. BAVLA, DIST. AHMEDABAD- 382 220, GUJARAT, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.2 G VIAL	01/07/2013
131	NDA/MAL/HDP/0 350	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	CETRIREN	CETIRIZINE HYDROCHLORIDE	10MG	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2015

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132	NDA/MAL/HDP/0 351	MANKIND PHARM LTD	TATA UGANDA LIMITED	DEPREGDINA	LEVONORGESTRE L	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
133	NDA/MAL/HDP/0 354	KOPRAN LIMITED	TATA UGANDA LIMITED	LEVOKOP	LEVOFLOXACIN	500MG	KOPRAN LIMITEDVILLAGE- SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2013
134	NDA/MAL/HDP/0 355	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	BICO VITA	THIAMINE HCL + RIBOFLAVIN + PYRIDOXINE HCL + NICOTINAMIDE	10MG + 0.1MG + 1MG + 10MG	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2015

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135	NDA/MAL/HDP/0 358	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	STREPTOCIN	STREPTOMYCIN SULPHATE	1GM	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY I M VIALS	1.0X1.0 G VIAL	01/07/2014
136	NDA/MAL/HDP/0 360	ASTRA ZENECA AB	MACNAUGHTON LIMITED	NEXIUM 20MG	ESOMEPRAZOLE	20MG	ASTRA ZENECA AB, SODERTALJEGARTUN AYEGEN, SODERTALJE	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER,1.0X7.0 TABLET BLISTER,1.0X14.0 TABLET CARTON	01/07/2001
137	NDA/MAL/HDP/0 362	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	BUPI	BUPIVACAINE	5 MG/ML	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL	01/07/2015

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138	NDA/MAL/HDP/0 363	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	AGYCIN	AZITHROMYCIN	250MG	BLISS GVS PHARMA LIMITEDNO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X6.0 TABLET BLISTER	01/07/2014
139	NDA/MAL/HDP/0 366	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	AGYCIN 500	AZITHROMYCIN	500MG	BLISS GVS PHARMA LIMITEDNO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0 TABLET BLISTER	01/07/2014
140	NDA/MAL/HDP/0 370	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	NEBILONG-H	NEBIVOLOL + HYDROCHLOROT HIAZIDE	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

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141	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
142	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
143	NDA/MAL/HDP/0386	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	LOMOH-80	ENOXAPARIN SODIUM	80MG/ 0.8ML	EMCURE PHARMACEUTICALS LTD PLOT NO. P-1 ITBT PARK PHASE II MIDC HINJWADI PUNE 411057	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X1.0 ML PRE-FILLED SYRINGE	01/07/2014

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144	NDA/MAL/HDP/0 388	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	AZUCLOX	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE STRIP,1.0X250.0 CAPSULE CONTAINER,1.0X10 00.0 CAPSULE CONTAINER,1.0X50 0.0 CAPSULE CONTAINER,1.0X10 0.0X10.0 CAPSULE BLISTER	01/07/1997
145	NDA/MAL/HDP/0 389	PT SANBE FARMA	MEDVIN PHARMA LIMITED	SANMOL INFUSION IV	PARACETAMOL	1000MG/100ML	PT SANBE FARMA JI INDUSTRINO.8 KOMPLEKS INDUSTRI CIMAREME PADALARANG BANDUNG	INDONESIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2014
146	NDA/MAL/HDP/0 394	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

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147	NDA/MAL/HDP/0397	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ASOMEX-LT	AMLODIPINE + LOSARTAN POTASSIUM	2.5 MG + 50 MG	EMCURE PHARMACEUTICALS LTD LANE 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
148	NDA/MAL/HDP/0401	FOURRTS (INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	L MONTUS	LEVOCETIRIZINE HYDROCHLORIDE + MONTELUKAST SODIUM	5MG + 10MG	FOURRTS (INDIA) LABORATORIES (PVT) LTD FOURRTS AVENUE, VANDALUR ROAD	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET STRIP	01/07/2015
149	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

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150	NDA/MAL/HDP/0 405	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	CHEMLET	LETROZOLE	2.5MG	NEON LABORATORIES LTD PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
151	NDA/MAL/HDP/0 406	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	EVATOCIN	OXYTOCIN	10 I.U./ ML	NEON LABORATORIES LTD PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY I V AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE	01/07/2015
152	NDA/MAL/HDP/0 407	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

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153	NDA/MAL/HDP/0 408	MSN LABORATORIES LTD	METRO PHARMACEUTICAL S LIMITED	ALGIC - P	ACECLOFENAC + PARACETAMOL	100 MG + 500 MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
154	NDA/MAL/HDP/0 409	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
155	NDA/MAL/HDP/0 410	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LDNIL 20	ROSUVASTATIN CALCIUM	20MG	MSN LABORATORIES LTD PLOT NO.42, ANRICH INDUSTRIAL ESTATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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156	NDA/MAL/HDP/0411	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	JADELLE SINE	LEVONORGESTREL	150MG	BAYER OYPANSIONATE 47 20210 TURKU FINLAND	FINLAND	PARENTERAL RETARD IMPLANTS	1.0X10.0X1.0X2.0X75.0 MG IMPLANT	01/07/2003
157	NDA/MAL/HDP/0413	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
158	NDA/MAL/HDP/0415	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	RELEX	DIPHENHYDRAMINE HYDROCHLORIDE +AMMONIUM CHLORIDE+SODIUM CITRATE+MENTHOL	14.03MG+138MG+57.03MG+0.90MG	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997

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159	NDA/MAL/HDP/0418	ASTRA ZENECA	MACNAUGHTON LIMITED	KOMBIGLYZE XR 5MG/1000	SAXAGLIPTIN + METFORMIN	5MG + 1000MG	ASTRAZENECA PHARMACEUTICALS LP.4601 HIGHWAY 62 EAST MOUNT VERNON INDIANA 47620 USA	UNITED STATES	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE,1.0X4.0X7. 0 TABLET BLISTER	01/07/2013
160	NDA/MAL/HDP/0419	ASTRAZENECA	MACNAUGHTON LIMITED	KOMBIGLYZE XR 2.5MG/1000MG	SAXAGLIPTIN + METFORMIN	2.5MG + 1000MG	ASTRAZENECA PHARMACEUTICALS LP.4601 HIGHWAY 62 EAST MOUNT VERNON INDIANA 47620 USA	UNITED STATES	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2013
161	NDA/MAL/HDP/0421	MSN LABORATORIES PRIVATE LIMITED,	METRO PHARMACEUTICAL S LIMITED	PREGASAFE 150	PREGABALIN	150MG	MSN LABORATORIES LTD PLOT NO.42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2014

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162	NDA/MAL/HDP/0422	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	PARAFLAM	IBUPROFEN + PARACETAMOL	100MG + 162.5MG /5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2013
163	NDA/MAL/HDP/0423	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOTRAM	TRAMADOL	50MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0X10.0 CAPSULE BLISTER	01/07/2013
164	NDA/MAL/HDP/0424	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CHLORPROMAZINE TABLETS B.P 25MG	CHLORPROMAZINE	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,1.0X1000.0 TABLET CONTAINER,10.0X100.0 TABLET BLISTER	01/07/1998

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165	NDA/MAL/HDP/0427	MICRO LABS LTD	LABOREX UGANDA LIMITED	AMLOZAAR -H	LOSARTAN POTASSIUM + AMLODIPINE BESILATE + HYDROCHLOROT HIAZIDE	50MG + 5MG + 12.5MG	MICRO LABS LTD .57, SIPCOT INDUSTRIAL COMPLEX, HOSUR-635126, TAMIIL NADU	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2015
166	NDA/MAL/HDP/0428	MICRO LABS LTD	LABOREX UGANDA LIMITED	MICROMOX-400	MOXIFLOXACIN	400MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X5.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	01/07/2013
167	NDA/MAL/HDP/0429	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	FLEXON MR	IBUPROFEN + PARACETAMOL + CHLORZOXAZONE	400MG + 325MG + 250MG	ARISTO PHARMACEUTICALS PVT. LIMITED PLOT NO. 208, NEW INDUSTRIAL AREA NO. II, MANDIDEEP-462046, DIST. - RAISEN, MADHYA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X1.0X10.0 TABLET BLISTER,1.0X10.0X1.0X10.0 TABLET BLISTER	01/07/2014

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168	NDA/MAL/HDP/0430	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO ACECLOPLUS	ACECLOFENAC+PARACETAMOL	100MG+500MG	ARISTO PHARMACEUTICALS PVT LIMITED PLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP-462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X15.0X10.0 TABLET BLISTER	01/07/2013
169	NDA/MAL/HDP/0432	FOURRTS (INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	K MAC ORAL SOLUTION	POTASSIUM CITRATE + MAGNESIUM CITRATE	22MG + 7.5MG	FOURRTS INDIA LABORATORIES PVT. LIMITED VANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X200.0 ML BOTTLE	01/07/2013
170	NDA/MAL/HDP/0433	PT SAMBE FARMA	MEDVIN PHARMA LIMITED	PROANES MCT/LCT	PROPOFOL	1%W/V	PT SANBE FARMA JI INDRAMATI 8 KOMPLEKS INDUSTRIAL CIMA REDE PADALARANG BANDUNG	INDONESIA	PARENTERAL ORDINARY I V AMPOULES	1.0X5.0X20.0 ML AMPOULE	01/07/2014

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171	NDA/MAL/HDP/0434	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,1.0X10.0X10.0 CAPSULE STRIP	01/07/2010
172	NDA/MAL/HDP/0441	AGIO PHARMACEUTICALS LTD	ROYAL PHARMA 2011 LIMITED	AGISEC	SECNIDAZOLE	1GM	AGIO PHARMACEUTICALS LTD PLOT NO. T-81, 82 MIDC, BHOSARI, PUNE-26	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0 TABLET BLISTER	01/07/2015
173	NDA/MAL/HDP/0447	PT SANBE FARMA	MEDVIN PHARMA LIMITED	SANEXON®125	METHYLPREDNISOLONE SODIUM SUCCINATE	125MG/VIAL	PT SANBE FARMA UNIT 3.JL INDUSTRI CIMAREME NO.8 PADALARANG 40533 BANDUNG	INDONESIA	PARENTERAL ORDINARY DRY VIALS	1.0X125.0 MG VIAL + 1*2ML AMPOULE OF WFI	01/07/2014

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174	NDA/MAL/HDP/0449	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AMINO GUARD GRANULES	CYANOCOBALAMIN	5MCG	STEDMAN PHARMACEUTICALS PVT LIMITED NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPURUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL SOLID ORDINARY GRANULES	1.0X10.0X5.0 G SACHET	01/07/2013
175	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
176	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, THIRUPURUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X200.0 ML BOTTLE	01/07/2013

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177	NDA/MAL/HDP/0 454	PT SANBE FARMA	MEDVIN PHARMA LIMITED	LEVOCIN INFUSION	LEVOFLOXACIN HEMIHYDRATE	500 MG	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
178	NDA/MAL/HDP/0 456	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
179	NDA/MAL/HDP/0 460	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

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180	NDA/MAL/HDP/0463	GITTOES PHARMACEUTICALS 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, 1.0X100.0X10.0 CAPSULE BLISTER	01/07/2011
181	NDA/MAL/HDP/0467	DAWA PHARMACEUTICALS LIMITED	SUPER MEDIC LTD	CURAMOL PLUS	PARACETAMOL/CAPPAINE	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
182	NDA/MAL/HDP/0470	NOVO NORDISK PHARMA GULF FZ-LLC	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 LTDA AV. "C", 1413, DISTRITO INDUSTRIAL - 390404 004 MONTES CLAROS, MINAS GERAIS - BRAZIL	DENMARK BRAZIL FRANCE	PARENTERAL ORDINARY DRY PRE-FILLED PENS	1.0X5.0X3.0 ML PREFILLED PEN	01/07/2014

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183	NDA/MAL/HDP/0471	NOVO NORDISK PHARMA GULF FZ-LC	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NOVORAPID FLEXPEN	INSULIN ASPART	100 I.U./ML	NOVO NORDISK PRODUCTION SAS45 AVENUE D'ORLEANS, 28000 CHARTRES, FRANCE NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDAAV. "C", 1413, DISTRITO INDUSTRIAL - 390404 004 MONTES CLAROS, MINAS GERAIS - BRAZIL	DENMARK BRAZIL FRANCE	PARENTERAL ORDINARY PREFILLED PENS	1.0X5.0X3.0 ML PREFILLED PEN	01/07/2014
184	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
185	NDA/MAL/HDP/0475	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	TINI-500	TINIDAZOLE	500MG	LINCOLN PHARMACEUTICALS LIMITED 10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X25.0X4.0 TABLET BLISTER	01/07/2015

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186	NDA/MAL/HDP/0 477	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S 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
187	NDA/MAL/HDP/0 482	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
188	NDA/MAL/HDP/0 489	LEBEN LABORATORIES PVT.LTD	MALIX PHARMA (U) LIMITED	CEBAY-200 DT	CEFIXIME	200MG	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0 TABLET BLISTER	01/07/2014

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189	NDA/MAL/HDP/0 491	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABCHLOR EYE DROPS	CHLORAMPHENIC OL	0.5% W/V	ABACUS PARENTERAL DRUGS LTD PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X5.0 ML VIAL, 1.0X10.0 ML VIAL	01/07/2013
190	NDA/MAL/HDP/0 493	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PRASUSAFE 10	PRASUGREL	10MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1X3X10 TABLET BLISTER	01/07/2013
191	NDA/MAL/HDP/0 496	ADCOCK INGRAM LIMITED	SURGIPHARM (U) LIMITED	MYPRODOL	PARACETAMOL + IBUPROFEN + CODEINE PHOSPHATE	250MG + 200MG + 10MG	ADCOCK INGRAM LIMITED 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE 560099, KARNATAKA STATE, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X20.0 CAPSULE BLISTER, 1.0X3.0X10 .0 CAPSULE BLISTER	01/07/2014

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192	NDA/MAL/HDP/0497	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	KEMOXYL DRY SUSPENSION	AMOXYCILLIN TRIHYDRATE	125MG/5ML	LABORATORY & ALLIED LTD PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997
193	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
194	NDA/MAL/HDP/0507	FOURRTS (INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	FILDILOL 12.5	CARVEDILOL	12.5 MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITED VANDALUR ROAD, KELAMBAKKA M-603 103, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014

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195	NDA/MAL/HDP/0 509	FOURRTS (INDIA) LABORATORIES (PVT) LTD	DELMAW ENTERPRISES LIMITED	FILDILOL 25	CARVEDILOL	25MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDA LUR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2015
196	NDA/MAL/HDP/0 510	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S 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
197	NDA/MAL/HDP/0 512	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	FILSTAT 10	ATORVASTATIN CALCIUM	10MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDA LUR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014

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198	NDA/MAL/HDP/0 515	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	FILSTAT 20	ATORVASTATIN	20MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDA LUR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014
199	NDA/MAL/HDP/0 518	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
200	NDA/MAL/HDP/0 520	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	FILSTAT 40	ATORVASTATIN CALCIUM	40MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDA LUR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2014

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201	NDA/MAL/HDP/0 521	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PAN 40	PANTOPRAZOLE SODIUM	40MG	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY 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,1.0X3.0X10 .0 TABLET BLISTER	01/07/2014
202	NDA/MAL/HDP/0 526	LEBEN LABORATORIES LTD	MALIX PHARMA (U) LIMITED	AMILEB- 25	AMITRIPTYLINE	25MG	LEBEN LABORATORIES PVT. LTD PLOT NO. L-4, PHASE-III, MIDC, AKOLA- 444 104 (MS).	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X20.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2014
203	NDA/MAL/HDP/0 531	LEBEN LABORATORIES LTD	MALIX PHARMA (U) LIMITED	ENDERM-GM	CLOBETASOL PROPIONATE + GENTAMYCIN + MICONAZOLE NITRATE	0.05%W/W + 0.10%W/W + 2.0%W/W	LEBEN LABORATORIES PVT. LTD.PLOT NO. L-4, PHASE –III, M.I.D.C, AKOLA, 444104, MAHARASHTRA, INDIA.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE,1.0X15.0 G TUBE	01/07/2014

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204	NDA/MAL/HDP/0 538	MICRO LABS LTD	LABOREX UGANDA LIMITED	XONADINE 180	FEXOFENADINE HYDROCHLORIDE	180 MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X1.0X10 .0 TABLET BLISTER	01/07/2013
205	NDA/MAL/HDP/0 541	MICRO LABS LTD	LABOREX UGANDA LIMITED	XONADINE 120	FEXOFENADINE HYDROCHLORIDE	120MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
206	NDA/MAL/HDP/0 542	DAWA LIMITED	SUPER MEDIC LTD	PHENBITAL	PHENOBARBITAL	30MG	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014

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207	NDA/MAL/HDP/0 543	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	GLIMERYL 2	GLIMEPIRIDE	2MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTDP.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL- RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
208	NDA/MAL/HDP/0 544	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
209	NDA/MAL/HDP/0 547	NAARI LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	MISO-KARE	MISOPROSTOL	200MCG	NAARI PHARMA PRIVATE LIMITEDPLOT NO. 14- 16 &55-57, SECTOR- 5, IIE, PANTNAGAR, RUDRAPUR-263153, DIST. U.S. NAGAR, UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0 TABLET BLISTER (COMBIPACK),1.0X3 .0X4.0 TABLET BLISTER	01/07/2013

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210	NDA/MAL/HDP/0 548	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNICAST	MONTELUKAST	5MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD .-P.O BOX 69 AMMAM 11591 JORDAN NUZHAT SAHID AL- RAQEEM NEAR PUBLIC HOUSING SECURITY	JORDAN	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2012
211	NDA/MAL/HDP/0 550	DAWA LIMITED	SUPER MEDIC LTD	DA-ZEPAM	DIAZEPAM	5MG	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2014
212	NDA/MAL/HDP/0 553	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	EQUIRAB	RABIES ANTISERUM	1000IU/ 5ML	BHARAT SERUMS AND VACCINES LIMITED,PLOT NO. K- 27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X5.0 ML VIAL (5 DOSE VIAL)	01/07/2013

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213	NDA/MAL/HDP/0 555	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	CARZEPIN	CARBAMAZEPINE	200MG	HOVID BHDLOT 56442,71/2 MILES JALAN IPOH,PERAK,MALAY SIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
214	NDA/MAL/HDP/0 558	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABGENTA EYE DROPS	GENTAMICIN SULPHATE	0.3% W/V	ABACUS PARENTERAL DRUGS LIMITEDBLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE,1.0X5.0 ML VIAL	01/07/2014
215	NDA/MAL/HDP/0 559	HOVID BHD	MEDICAL ACCESS (UGANDA) LIMITED	DIABETMIN RETARD	METFORMIN HYDROCHLORIDE	850MG	HOVID BHDLOT 56442,71/2 MILES JALAN IPOH,PERAK,MALAY SIA	MALAYSIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014

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216	NDA/MAL/HDP/0 563	IND SWIFT LTD	PLANET PHARMACEUTICAL S UGANDA LTD	EZO 40	ESOMEPRAZOLE MAGNESIUM	40MG	IND-SWIFT- LTD,GLOBAL BUSINESS UNIT, JAWAHARPUR, OFF NH-21 DERABASSI	INDIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
217	NDA/MAL/HDP/0 566	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	CEFROTIL SUSPENSION	CEFUROXIME AXETIL	125MG/5ML	SAKAR HEALTHCARE PVT. LTD PLOT 10/13 SAKHEJ-BAVLA ROAD, AHMEDABAD,GUJJUR AT,INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X1.0X50.0 ML BOTTLE	01/07/2013
218	NDA/MAL/HDP/0 568	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	FLUOXIREN	FLUOXETINE	20MG	RENE INDUSTRIES LIMITED PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013

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219	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
220	NDA/MAL/HDP/0572	NORVATIS PHARMA AG-SWITZERLAND	LABOREX UGANDA LIMITED	AZARGA	BRINZOLAMIDE + TIMOLOL	10MG/ML + 5MG/ML	ALCON COUVREUR NVRIKSWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML VIAL	01/07/2010
221	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

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222	NDA/MAL/HDP/0 574	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
223	NDA/MAL/HDP/0 576	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	DUODART	DUTASTERIDE + TAMSULOSIN	0.5MG + 0.4MG	CATALENT GERMANY SCHONDORF GMBH STEINBEISSTRASSE 1- 2, 73614 SCHORNDORF, GERMANY	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X30.0 CAPSULE CONTAINER	01/07/2015
224	NDA/MAL/HDP/0 580	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLUCAP	MULTINGREDIENT	MULTINGREDIENT	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1997

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225	NDA/MAL/HDP/0582	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ACECLO SERA	ACECLOFENAC+PARACETAMOL+SERTRATIOPEPTIDASE	100MG + 500MG + 15MG	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, 1.0X10.0X10.0 TABLET BLISTER	01/07/2015
226	NDA/MAL/HDP/0584	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	TRIGLIMIPREX 1	GLIMEPIRIDE+PIOGlitazone+METFORMIN HYDROCHLORIDE	1MG+15MG+500MG	ARISTO PHARMACEUTICALS PVT LTD--VILLAGE MAKHNUMAJRA P.O BHUD BADDI DISTRICT SOLAN (H.P) 173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER, 1.0X10.0X10.0 TABLET BLISTER	01/07/2014
227	NDA/MAL/HDP/0587	CADILA PHARMACEUTICALS LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	CADIGREL	CLOPIDOGREL	75MG	CADILA PHARMACEUTICALS LIMITED 1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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228	NDA/MAL/HDP/0588	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROFORT	PREDNISOLONE ACETATE	1%W/V	AUROLABNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA	INDIA	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML BOTTLE	01/07/2013
229	NDA/MAL/HDP/0589	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	TRIGLIMIPREX 2	GLIMEPIRIDE+PIOGlitazone+METFORMIN HYDROCHLORIDE	2MG+15MG+500MG	ARISTO PHARMACEUTICALS PVT LTD--VILLAGE MAKHNUMAJRA P.O BHUD BADDI DISTRICT SOLAN (H.P) 173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/2014
230	NDA/MAL/HDP/0592	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROCHROME	CROMOLYN SODIUM	2%W/V	AUROLABNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA	INDIA	OPHTHALMIC LIQUIDS	1.0X10.0 ML CONTAINER	01/07/2013

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231	NDA/MAL/HDP/0 593	ARISTO PHARMACEUTICAL S 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
232	NDA/MAL/HDP/0 595	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,1.0X3.0X10 .0 TABLET BLISTER	01/07/2015
233	NDA/MAL/HDP/0 596	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (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

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234	NDA/MAL/HDP/0598	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LIPICURE-20	ATORVASTATIN	20MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2003
235	NDA/MAL/HDP/0599	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	GRAMOCEF-O-400	CEFIXIME	400MG	MICROLABS LIMITEDPLOT 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
236	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

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237	NDA/MAL/HDP/0 603	MEDLEY PHARMACEUTICAL S 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
238	NDA/MAL/HDP/0 605	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
239	NDA/MAL/HDP/0 609	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

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240	NDA/MAL/HDP/0 610	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
241	NDA/MAL/HDP/0 611	GALPHAR LABORATORIES LTD	DAWASANA PHARMACEUTICAL S LTD	GALCIPRO 500	CIPROFLOXACIN HYDROCHLORIDE	500MG	GALPHA LABORATORIES LIMITEDVILLAGE "A" THANA BADDI, TEHSIL BADDI SOLAN HIMACHAL PRADESH-173 205 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2015
242	NDA/MAL/HDP/0 614	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	CLAVULIN	AMOXICILLIN + CLAVULANIC ACID	125MG/5ML + 31.25MG/5ML	SMITHKLINE BEECHAM PHARMACEUTICALS, CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X70.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/1998

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243	NDA/MAL/HDP/0 617	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	SILVEX	SILVER SULFADIAZINE + CHLORHEXIDINE	1%W/W + 0.2%W/W	LINCOLN PHARMACEUTICALS LTD .10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2014
244	NDA/MAL/HDP/0 619	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	D10	GLUCOSE	10%W/V	ABACUS PARENTERAL DRUGS LTD PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE,1.0X250.0 ML BOTTLE	01/07/2013
245	NDA/MAL/HDP/0 623	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	GELCID	MAGNESIUM SULPHATE	50%W/V	LINCOLN PHARMACEUTICALS LTD-11 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ- 382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X5.0X10.0 ML AMPOULE,1.0X10.0 X5.0X5.0 ML AMPOULE IN BLISTER PACK,1.0X5.0 ML AMPOULE IN BLISTER PACK	01/07/2015

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246	NDA/MAL/HDP/0 626	KPI INDUSTRIES(1996) LTED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	CARDIPAC-10	AMLODIPINE BESILATE	10MG	KPI INDUSTRIES (1996) LTD PLOT NO.M444B STRETCHER RD, NTINDA, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0X10.0 TABLET BLISTER	01/07/2015
247	NDA/MAL/HDP/0 627	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	AMOXIKID	AMOXICILLIN TRIHYDRATE	125MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD PLOT M 444B STRETCHER ROAD NTINDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP,1.0X2.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2015
248	NDA/MAL/HDP/0 633	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

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249	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
250	NDA/MAL/HDP/0635	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGO-AMIN	AMINOPHYLLINE	100MG	AGOG PHARMA LTD PLOT NO.33, SECTOR II, VASAI, TALUKA INDL CO-OP ESTATE LTD, GAURAI PADA, VASAI(E) DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X1000.0 TABLET CONTAINER, 1.0X100.0X10.0 TABLET BLISTER	01/07/2009
251	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.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0 TABLET BLISTER	01/07/2014

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252	NDA/MAL/HDP/0 637	NABIQASIM INDUSTRIES (PVT) LIMITED	JEET PHARMACEUTICAL S LIMITED	ZUDICORT	FUSIDIC ACID + BETAMETHASONE VALERATE	20MG + 1MG/G	NABIQASIM INDUSTRIES (PVT) LIMITED17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2014
253	NDA/MAL/HDP/0 638	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABLOL-5 EYE DROPS	TIMOLOL MALEATE	0.5% W/V	ABACUS PARENTERAL DRUGS LTD PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL	01/07/2013
254	NDA/MAL/HDP/0 639	NEM LABORATORIES (PVT) LTD	RENE PHARMACY LTD	RHEUMATIC CREAM	MULTI- INGREDIENT	MULTI- INGREDIENT	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997

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255	NDA/MAL/HDP/0 654	NVS KENYA LTD	SURGIPHARM (U) LIMITED	GALVUS MET	VILDAGLIPTIN / METFORMIN	50MG/500MG	NORVATIS PHARMA PRODUCTIONS GMBH, WEHRGERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2013
256	NDA/MAL/HDP/0 657	NVS KENYA LTD	SURGIPHARM (U) LIMITED	GALVUS MET	VILDAGLIPTIN / METFORMIN	50MG / 850MG	NORVATIS PHARMA PRODUCTIONS GMBH, WEHRGERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X6.0X10 .0 TABLET BLISTER	01/07/2013
257	NDA/MAL/HDP/0 658	NVS KENYA LTD	SURGIPHARM (U) LIMITED	GALVUS MET	VILDAGLIPTIN/ METFORMIN	50MG/1000MG	NORVATIS PHARMA PRODUCTIONS GMBH, WEHRGERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X6.0X10 .0 TABLET BLISTER	01/07/2013

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258	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) MAHABOONNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2013
259	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) MAHABOONNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER	01/07/2013
260	NDA/MAL/HDP/0667	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXEL MICONAZOLE	MICONAZOLE NITRATE	2%W/W	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE,1.0X15.0 G TUBE	01/07/2013

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261	NDA/MAL/HDP/0 668	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
262	NDA/MAL/HDP/0 669	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXEL FUNGICORT CREAM	MICONAZOLE NITRATE + HYDROCORTISON E	2% W/W + 1% W/W	KOTRA PHARMA SDN BDN-1, 2, &3, JALANTTC12 CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE,1.0X15.0 G TUBE	01/07/2013
263	NDA/MAL/HDP/0 670	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	FLUNAZ-200	FLUCONAZOLE	200MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0 CAPSULE BLISTER,1.0X5.0X4. 0 CAPSULE BLISTER	01/07/2014

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264	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
265	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
266	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, MALAYSIA KESAR 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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267	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
268	NDA/MAL/HDP/0678	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL HYDROCORTISON E CREAM	HYDROCORTISON E	1%W/W	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE, 1.0X5.0 G TUBE	01/07/2014
269	NDA/MAL/HDP/0679	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	MEFENA-250 CAPSULES	MEFENAMIC ACID	250MG	AGOG PHARMA LTD PLOT NO.33, SECTOR II, VASAI, TALUKA INDL CO-OP ESTATE LTD, GAURAI PADA, VASAI(E) DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER, 1.0X100.0X10.0 CAPSULE BLISTER	01/07/2013

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270	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
271	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
272	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

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273	NDA/MAL/HDP/0 688	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	HBB	HYOSCINE BUTYLBROMIDE	10MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
274	NDA/MAL/HDP/0 689	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGONAL	NALIDIXIC ACID	500MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
275	NDA/MAL/HDP/0 690	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	HEALTHSEASE CREAM	BECLOMETHASON E DIPROPIONATE + PHENYLEPHRINE HCL + LIGNOCAINE HCL + CHLOROCRESOL	0.025%W/W + 0.1%W/W + 2.5%W/W + 0.1%W/W	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	01/07/2014

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276	NDA/MAL/HDP/0 691	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (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
277	NDA/MAL/HDP/0 692	DAWA LIMITED	SUPER MEDIC LTD	DAWACLOX -250	CLOXACILLIN SODIUM	250MG	DAWA LIMITED BABA DOGO RWARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/2015
278	NDA/MAL/HDP/0 693	DAWA LIMITED	SUPER MEDIC LTD	MOXACIL -250	AMOXYCILLIN TRIHYDRATE	250MG	DAWA PHARMACEUTICALS LIMITEDPLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/2014

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279	NDA/MAL/HDP/0 694	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S 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, 1.0X10.0X1 0.0 TABLET CARTON	01/07/2013
280	NDA/MAL/HDP/0 696	BYANSI SERVICES LIMITED	AIVEEN (U) LIMITED	RITONAVIR	RITONAVIR	100MG	HETERO LABS LTD 22- 110 IDA JEEDIMETLA HYDERABAD 500- 055 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2014
281	NDA/MAL/HDP/0 702	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	SEPTOCIN	STREPTOMYCIN SULPHATE	1GM	REYOUNG PHARMACEUTICAL CO. LIMITED NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X1.0 G VIAL, 1.0X100.0X1.0 G VIAL, 1.0X10.0X1.0 G VIAL	01/07/2014

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282	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
283	NDA/MAL/HDP/0704	HETERO LABS LTD UNIT IX	AIVEEN (U) LIMITED	M-FLOX	MOXIFLOXACIN HYDROCHLORIDE	400MG	HETERO LABS LTDUNIT II & III BADDI THE NALAGARH DIST SOLAN H.P HETERO LABS LTD (UNIT-V)SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,10.0X1.0X5.0 TABLET BLISTER	01/07/2013
284	NDA/MAL/HDP/0705	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	ACICLOVIR	ACICLOVIR	5%W/W	LINCOLN PHARMACEUTICAL LIMITEDTRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE	01/07/2011

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285	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
286	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
287	NDA/MAL/HDP/0710	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	ROVAS 20	ROSUVASTATIN	20MG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI-248197, DEHRADUN UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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288	NDA/MAL/HDP/0 712	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	ZENTEL	ALBENDAZOLE	100MG/5ML	ASPEN BAD OLDESLOE GMBH, INDUSTRIESTRASSE I INDUSTRIESTRASSE 32-36, 23843 BAD OLDESLOE	FRANCE	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X20.0 ML BOTTLE	01/07/1997
289	NDA/MAL/HDP/0 713	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
290	NDA/MAL/HDP/0 715	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

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291	NDA/MAL/HDP/0718	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	GLYMET-2	GLIMEPIRIDE+METFORMIN HYDROCHLORIDE	2MG + 500MG	LINCOLN PHARMACEUTICALS L.T.D.TRIMUL ESTATE KHATRAJ 382721 GHANDINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X5.0X10.0 TABLET BLISTER	01/07/2014
292	NDA/MAL/HDP/0719	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	WEPOX 4000	RECOMBINANT HUMAN ERYTHROPOIETIN	4000 I.U	WOCKHARDT LIMITED - WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X0.4 ML PRE-FILLED SYRINGE	01/07/2011
293	NDA/MAL/HDP/0720	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	JUSDEE 400 DROPS	COLECALCIFEROL	400 I.U/ML	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X15.0 ML BOTTLE	01/07/2013

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294	NDA/MAL/HDP/0722	FDC LTD	AIVEEN (U) LIMITED	IOTIM 0.5%	TIMOLOL MALEATE	0.5% W/V	FDC LIMITED B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.☒	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2014
295	NDA/MAL/HDP/0726	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	T DOL RAPID	TRAMADOL HYDROCHLORIDE	50MG	TROIKAA PHARMACEUTICALS LTD SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2014
296	NDA/MAL/HDP/0727	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	STOMACH FIT SYRUP	BISMUTH AMMONIUM CITRATE+BELLADONA DRY EXTRACT+THYMO L+MENTHOL	140MG+9MG+0.15 MG+0.2/5ML	TORQUE PHARMACEUTICALS LTD DISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X225.0 ML BOTTLE	01/07/2013

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297	NDA/MAL/HDP/0728	IPCA LABORATOIES LTD	MEDVIN PHARMA LIMITED	ARTESUNATE AND AMODIAQUINE 25/67.5	ARTESUNATE+AMODIAQUINE	25MG+67.5MG	IPCA LABORATORIES LIMITED -SEJAVTA VILLAGE, DIST. RATLAM (M.P) 457002 INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER	01/07/2013
298	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
299	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

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300	NDA/MAL/HDP/0 734	AIVEEN (U) LIMITED	AIVEEN (U) LIMITED	OMMED -20	OMEPRAZOLE	20MG	MEDICO REMEDIES PVT LIMITED8 & 9 DEWAN & SONS, UDYOG NAGAR PALGAR, DISTRICT THANE MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	01/07/2015
301	NDA/MAL/HDP/0 736	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
302	NDA/MAL/HDP/0 740	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	COTRIM	CO-TRIMOXAZOLE	960MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X17.0X6.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2013

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303	NDA/MAL/HDP/0 741	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MEDOCIPRIN	CIPROFLOXACIN	500MG	MEDOCHEMIE LTD (FACTORY AZ)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS, INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL, CYPRUS	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2013
304	NDA/MAL/HDP/0 742	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	BROT	METFORMIN HYDROCHLORIDE	500MG	MEDOCHEMIE (FACTORY AZ).-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
305	NDA/MAL/HDP/0 746	COSMOS LTD	ASTRA PHARMA (U) LIMITED	DTS-Z KIT	TABLET-ZINC, SACHET-NACL + KCL + TRISODIUM CITRATE + ANHYDROUS GLUCOSE	TABLET-54.89MG , SACHET 1.3G + 0.75G + 1.45G + 6.75G	COSMOS LIMITED, KENYARANGWE ROAD, OFF LUNGA ROAD, INDUSTRIAL AREA NAIROBI - KENYA	KENYA	ORAL LIQUID ORDINARY UNIT DOSE POWDERS	1.0X4.0X10.3 G SACHET + 1.0X10.0 TABLET BLISTER	01/07/2013

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306	NDA/MAL/HDP/0 748	BAYER PHARMA	SURGIPHARM (U) LIMITED	XARELTO 15MG	RIVAROXABAN	15MG	BAYER PHARMA AG 51368 LEVERKUSENBAYER PHARMA AG 51368 LEVERKUSEN	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X14.0 TABLET BLISTER	01/07/2013
307	NDA/MAL/HDP/0 749	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	MEROGRAM 1000	MEROPENEM	1000MG	AURONEXT PHARMA PVT LTD.A- 1128 RIICO INDUSTRIAL AREA, PHASE III, DISTALWAR, BHIWADI	INDIA	PARENTERAL ORDINARY DRY VIALS	1X1 G VIAL	01/07/2014
308	NDA/MAL/HDP/0 750	BAYER PHARMA	SURGIPHARM (U) LIMITED	XARELTO 20MG	RIVAROXABAN	20MG	BAYER PHARMA AG 51368 LEVERKUSENBAYER PHARMA AG 51368 LEVERKUSEN	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X14.0 TABLET BLISTER	01/07/2013

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309	NDA/MAL/HDP/0 751	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	DOLOWIN	ACECLOFENAC	100MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
310	NDA/MAL/HDP/0 754	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
311	NDA/MAL/HDP/0 759	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

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312	NDA/MAL/HDP/0 764	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	CORVADIL 5	AMLODIPINE	5MG	UNICHEM LABORATORIES LIMITED UNIT IIVILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2011
313	NDA/MAL/HDP/0 765	SHANGHAI DAHUA PHARMACEUTICAL CO., LTD.	UNITED HEALTHCARE DISTRIBUTORS LTD	LEVOPLANT	LEVONORGESTRE L	75MG	SHANGHAI DAHUA PHARMACEUTICAL CO. LTDCHANG ZENG FARM, CHONGMING COUNTY, SHANGHAI	CHINA	PARENTERAL RETARD IMPLANTS	1.0X10.0X2.0 ROD IMPLANT	01/07/2010
314	NDA/MAL/HDP/0 768	FDC LTD	AIVEEN (U) LIMITED	PYRIMON EYE DROP	DEXAMETHASON E/CHLORAMPHEN ICOL	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

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315	NDA/MAL/HDP/0770	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
316	NDA/MAL/HDP/0772	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	LIGABA - 150	PREGABALIN	150MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2014
317	NDA/MAL/HDP/0775	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	LIGABA - 75	PREGABALIN	75MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2014

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318	NDA/MAL/HDP/0781	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	TRICOLD	PARACETAMOL/P HENYLEPHRINE HYDROCHLORIDE/CAFFEINE ANHYDROUS/CHL ORPHENIRAMINE	500MG/10MG/30 MG/2MG	TRIVENI FORMULATIONS LIMITED -PLOT NO 52-54,62-64 ALEAP INDUSTRIAL ESTATE SURAMPALLI (V) VIJAYAWADA A.P	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X50.0X4 .0 TABLET BLISTER	01/07/2013
319	NDA/MAL/HDP/0784	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
320	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

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321	NDA/MAL/HDP/0794	REMINGTON PHARMACEUTICAL INDUSTRIES PVT LTD	HEALTHCARE LTD.	AMYGYDEX	TOBRAMYCIN/DEXAMETHASONE	3MG+1MG/ML	REMINGTON PHARMACEUTICALS (PVT) LTD18KM, MULTAN ROAD, LAHORE 53800, PAKISTAN	PAKISTAN	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2014
322	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
323	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 AGSCHAFFHARVSETRASSE CH-4332 STEIN SWITZERLAND.	SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER	01/07/2015

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324	NDA/MAL/HDP/0 811	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	DOLOWIN -SR	ACECLOFENAC	200MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
325	NDA/MAL/HDP/0 816	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	GLIMEPIRIDE DENK 2	GLIMEPIRIDE	2MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2012
326	NDA/MAL/HDP/0 821	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	GLIMEPIRIDE DENK 3	GLIMEPIRIDE	3MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2012

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327	NDA/MAL/HDP/0 822	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	CLOXCIN-500	CLOXACILLIN SODIUM	500MG	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X0.5 G VIAL,1.0X100.0X0.5 G VIAL,1.0X10.0X0.5 G VIAL	01/07/2014
328	NDA/MAL/HDP/0 824	VITACARE 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
329	NDA/MAL/HDP/0 826	VITACARE 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

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330	NDA/MAL/HDP/0827	GALPHA LABORATORIES LTD	DAWASANA PHARMACEUTICALS LTD	CLANOXY 1.2	AMOXICILLIN + CLAVUNATE POTASSIUM	1000MG/200MG	GALPHA LABORATORIES LTDAT: ALKEM LABORATORIES LTD PLOT 167/2 MAHATMA UDYOG NAGAR AMALIYA DAMAN 396210	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.2 G VIAL + 1*20ML VIAL OF WFI	01/07/2015
331	NDA/MAL/HDP/0830	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	EUTHYROX 25 MCG	LEVOTHYROXINE SODIUM	25 MCG	MERCK KGAA - FRANKFRUTER STRASSE 250, D-64293,DARMSTADT-GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X30.0 TABLET BLISTER,1.0X4.0X25.0 TABLET BLISTER	01/07/2015
332	NDA/MAL/HDP/0831	CARE PHARMA LIMITED	VITACARE LTD	AMPICILLIN CAPSULES	AMPICILLIN	250MG	MEDICO REMEDIES PVT LTD,-8 & 9 DEWAN AND SONS, UDYOG NAGAR, PALGHAR, DIST. THANE-401404, MAHARSHITRA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/2013

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333	NDA/MAL/HDP/0 832	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
334	NDA/MAL/HDP/0 834	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S 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
335	NDA/MAL/HDP/0 835	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S 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

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336	NDA/MAL/HDP/0 836	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S 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,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2012
337	NDA/MAL/HDP/0 842	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	SAC	SECNIDAZOLE	1000MG	LINCOLN PHARMACEUTICALS LIMITED 10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X2.0 TABLET BLISTER	01/07/2013
338	NDA/MAL/HDP/0 843	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	COXERIN	CYCLOSERINE	250MG	MACLEODS PHARMACEUTICALS LTD .PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	01/07/2013

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339	NDA/MAL/HDP/0 845	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICAL S LIMITED	OLEVO-500	LEVOFLOXACIN	500 MG	LINCOLN PHARMACEUTICALS LIMITED 10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER,1.0X5.0X1. 0X10.0 TABLET BLISTER	01/07/2013
340	NDA/MAL/HDP/0 846	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	MOXIMAC	MOXIFLOXACIN	400MG	MACLEODS PHARMACEUTICALS LTD-PLOT 25-27 SURVEY NO. 366 PREMIER INDUSTRIAL ESTATE KACHIGAM DAMAN	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0 TABLET BLISTER	01/07/2014
341	NDA/MAL/HDP/0 848	MACLEODS PHARMACEUTICAL S 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

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342	NDA/MAL/HDP/0 850	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S 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
343	NDA/MAL/HDP/0 853	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICAL S LTD	BRUSTAN GEL	IBUPROFEN + LEVOMENTHOL	5% W/W+ 3%W/W	SUN PHARMACEUTICAL IND. LTD PLOT NO. B- 2, MADKAI INDUSTRIAL ESTATE, PONDA- GOA, INDIA- 403404	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X50.0 G CONTAINER	01/07/2012
344	NDA/MAL/HDP/0 855	HETERO LABS LTD	AIVEEN (U) LIMITED	LAZINE	LEVOCETIRIZINE DIHYDROCHLORID E	5MG	HETERO LABS LTD22- 110 IDA JEEDIMETLA HYDERABAD 500- 055 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	01/07/2013

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345	NDA/MAL/HDP/0 857	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	CANDID-V6 VAGINAL TABLETS	CLOTRIMAZOLE	100MG	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	VAGINAL TABLETS	1.0X6.0 PESSARY STRIP	01/07/2000
346	NDA/MAL/HDP/0 858	ASTRA ZENECA	MACNAUGHTON LIMITED	PLENDIL	FELODIPINE	5MG	ASTRAZENECA SWEDEN OPERATIONSASTRAZ ENECA SWEDEN OPERATIONS SE-151 85 SODERTALJE ASTRAZENECA PHARMACEUTICAL CO LTD.NO. 2 HUANGSHAN ROAD, WUXI, 214028, JIANGSU	CHINA SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2001
347	NDA/MAL/HDP/0 861	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	PROZINE	PROMETHAZINE	25MG/ML	SAKAR HEALTHCARE PVT. LTD PLOT 10/13 SAKHEJ-BAVLA ROAD, AHMEDABAD,GUJJUR AT,INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	2.0X5.0X2.0 ML AMPOULE	01/07/2013

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348	NDA/MAL/HDP/0 864	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, MAHABOONNAGAR (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
349	NDA/MAL/HDP/0 866	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	LIZOLID	LINEZOLID	2MG/ML	AMANTA HEALTHCARE LIMITEDPLOT NO. 876 N.H. NO. 8 VILLAGE-HIRIYALA TALUKA, MATAR, DIST KHEDA-387 411, GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X300.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2013
350	NDA/MAL/HDP/0 868	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	VARMIKA-500	AMIKACIN	500MG	SAKAR HEALTH CARE PVT, LTDBLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ- BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X2.0X6.0X2.0 ML VIAL	01/07/2013

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351	NDA/MAL/HDP/0 870	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TROY-K	PHYTOMENADIO NE	10MG/ML	TROIKAA PHARMACEUTICALS LIMITEDHOL, DIST. MEHSANA-382728, GUJARAT,INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2010
352	NDA/MAL/HDP/0 871	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	DEXA	DEXAMETHASON E 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
353	NDA/MAL/HDP/0 873	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S 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

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354	NDA/MAL/HDP/0874	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	LEBASMA-4	SALBUTAMOL	4MG	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X20.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/2014
355	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
356	NDA/MAL/HDP/0879	COSMOS LTD.	ASTRA PHARMA (U) LIMITED	TRIBEES 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

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357	NDA/MAL/HDP/0 882	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
358	NDA/MAL/HDP/0 883	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
359	NDA/MAL/HDP/0 889	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	DNS	SODIUM CHLORIDE + GLUCOSE	0.9%W/V + 5% W/V	ABACUS PARENTERAL DRUGS LIMITEDBLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X250.0 ML BOTTLE,1.0X500.0 ML BOTTLE	01/07/2012

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360	NDA/MAL/HDP/0 895	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	HYORTH	SODIUM HYALURONATE	10MG/1ML	VIRCHOW BIOTECH PVT, LTDSURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DIST	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X2.0 ML PRE- FILLED SYRINGE	01/07/2015
361	NDA/MAL/HDP/0 897	VIRCHOW HEALTHCARE PVT LTD	LEGIT MEDEQ 2007 LIMITED	DEBRIDACE	PAPAIN + UREA	521700UNITS+100 MG/G	VIRCHOW BIOTECH PVT, SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DISTRICT TELANGANA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/2015
362	NDA/MAL/HDP/0 899	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

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363	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
364	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
365	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

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366	NDA/MAL/HDP/0 914	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	OSTEOTIDE	TERIPARATIDE [RECOMBINANT HUMAN PARATHYROID HORMONE (1-34)] INJECTION	250MCG/ML	VIRCHOW BIOTECH PVT LTD SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DISTRICT ANDHRA PRADESH	INDIA	PARENTERAL ORDINARY VIALS	1.0X3.0 ML VIAL,1.0X3.0 ML PREFILLED PEN	01/07/2015
367	NDA/MAL/HDP/0 920	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BUPITROY HEAVY	BUPIVACAINE HYDROCHLORIDE	5MG/ML	TROIKAA PHARMACEUTICALS LTD .SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0X4.0 ML VIAL	01/07/2012
368	NDA/MAL/HDP/0 926	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	BACTOCLAV-375	AMOXICILLIN +CLAVULANATE POTASSIUM	250MG + 125MG	MICRO LABS LIMITED.PLOT 16, VEERASANDRA IND. AREA,ANEKAL TALUK, BANGALORE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET STRIP,1.0X2.0X10.0 TABLET STRIP	01/07/2004

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369	NDA/MAL/HDP/0 928	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	INSTACLOP 75	CLOPIDOGREL	75MG	AJANTA PHARMA LIMITEDPLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT- 392130 AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013
370	NDA/MAL/HDP/0 929	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	DUOQUIN	DIHYDROARTEMI SININ + PIPERAQUINE PHOSPHATE	40MG +320MG	IPCA LABORATORIES LTD PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X1.0X9.0 TABLET BLISTER,10.0X1.0X8 .0 TABLET BLISTER	01/07/2012
371	NDA/MAL/HDP/0 938	FEROZSONS LABORATORIES LTD	HEALTHCARE LTD.	ESOMEGA 20MG	ESOMEPRAZOLE AS MAGNESSIUM TRIHYDRATE PELLETS	20MG	FEROZSONS LABORATORIES LTDAMANGARH- NOWSHERA, (KHYBER PAKHTOONKHWA), PAKISTAN	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER	01/07/2013

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372	NDA/MAL/HDP/0 940	FEROZSONS LABORATORIES LTD	HEALTHCARE LTD.	ESOMEGA 40MG	ESOMEPRAZOLE AS MAGNESSIUM TRIHYDRATE PELLETS	40MG	FEROZSONS LABORATORIES LTDAMANGARH- NOWSHERA, (KHYBER ☐ PAKHTOONKHWA), PAKISTAN	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER	01/07/2013
373	NDA/MAL/HDP/0 941	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ZAHA	AZITHROMYCIN	200MG/5ML	AJANTA PHARMA LIMITED31-0 MIDC INDUSTRIAL AREA CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA STATE	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X15.0 ML BOTTLE	01/07/2013
374	NDA/MAL/HDP/0 948	COSMOS LTD	ASTRA PHARMA (U) LIMITED	LORHISTINA SYRUP 5MG/5ML	LORATADINE	5MG/5ML	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL LIQUID ORDINARY LIQUIDS	1.0X60.0 ML BOTTLE	01/07/2013

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375	NDA/MAL/HDP/0 951	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	NORAD	STERILE NORADRENALINE CONCENTRATE	2MG/2ML	NEON LABORATORIES LTD PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY S C AMPOULES	1.0X5.0X2.0 ML AMPOULE	01/07/2013
376	NDA/MAL/HDP/0 952	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	EFFECTAL	CEFTRIAXONE	1G	NEON LABORATORIES LTD PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2013
377	NDA/MAL/HDP/0 953	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	CIZCAN	CISPLATIN	10MG/10ML	NEON LABORATORIES LTD PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	01/07/2013

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378	NDA/MAL/HDP/0 954	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	ANAWIN	BUPIVACAINE	50MG/20ML	NEON LABORATORIES LTD PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL RETARD OTHER VIALS	1.0X20.0 ML VIAL	01/07/2013
379	NDA/MAL/HDP/0 957	MACK BROWN PHARMACEUTICAL S PVT LIMITED	SHURIK LTD	LYRED SYRUP	VITAMINE A + VITAMINE E ACETATE + ASCORBIC ACID + SELENIUM + ZINC	2500 IU + 10 IU + 50MG + 35MCG + 3MG	TORQUE PHARMACEUTICALS PVT LTDISAAPUR P.O DAPPAR 140056 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2012
380	NDA/MAL/HDP/0 959	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 MANUFACT URING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X12.0 TABLET BLISTER, 1.0X6.0 TABLET BLISTER, 1.0X30.0X6 .0 TABLET BLISTER, 1.0X30.0X1 2.0 TABLET BLISTER	01/07/2013

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381	NDA/MAL/HDP/0 969	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	ASOMEX-2.5	AMLODIPINE BESILATE	2.5MG	EMCURE PHARMACEUTICALS LTD LANE NO.3 PHASE II,SIDCO INDUSTRIAL COMPLEX,BARI- BRAHMANA JAMMU 181 133, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2005
382	NDA/MAL/HDP/0 974	SQUARE CEPHALOSPORINS LTD	GAMA PHARMACEUTICAL S (U) LIMITED	CEF-3	CEFIXIME	100MG/5ML	SQUARE CEPHALOSPORINS LTDKALIAKOIR, GAZIPUR – 1750, BANGLADESH	BANGLADESH	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X50.0 ML BOTTLE	01/07/2015
383	NDA/MAL/HDP/0 978	SQUARE PHARMACEUTICAL S LTD	GAMA PHARMACEUTICAL S (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

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384	NDA/MAL/HDP/0 981	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
385	NDA/MAL/HDP/0 986	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CONVENTIN	GABAPENTIN	100MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2013
386	NDA/MAL/HDP/0 988	CADILA PHARMACEUTICAL S LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	CADITOR 20	ATORVASTATIN	20MG	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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387	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
388	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
389	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

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390	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
391	NDA/MAL/HDP/1000	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TROYCURIUM	ATRACURIUM	10MG/ML	TROIKAA PHARMACEUTICALS LIMITEDTHOL, DIST. MEHSANA-382728, GUJARAT,INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.5 ML AMPOULE	01/07/2012
392	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

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393	NDA/MAL/HDP/1 0018	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
394	NDA/MAL/HDP/1 002	SQUARE PHARMACEUTICAL S LTD	GAMA PHARMACEUTICAL S (U) LIMITED	CIPROKIN 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
395	NDA/MAL/HDP/1 0030	SAKAR HEALTHCARE LIMITED -	TATA UGANDA LIMITED	NISTAN	NYSTATIN	100,000IU	SAKAR HEALTHCARE PVT LTDBLOCK NO. 10-13, NR. M.N DESAI PETRO PUMP, SARKHEJ-BAVLA ROAD, CHANGODAR, DIST: AHMEDABAD- 382213, GUJARAT	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1X30 ML BOTTLE	17/05/2022

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396	NDA/MAL/HDP/1 0033	MEDOPHARM	PLANET PHARMACEUTICAL S UGANDA LTD	EMCAR	CARBAMAZEPINE	200 MG	MEDOPHARMNO. 34B, INDUSTRIAL AREA, MALUR- 563160, KARNATAKA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER,1.0X50.0X1 0.0 TABLET BLISTER,1.0X100.0X 1.0X10.0 TABLET BLISTER	14/07/2022
397	NDA/MAL/HDP/1 0034	AUROLAB	SWASTIK PHARMACEUTICAL LTD	M-FLOX	MOXIFLOXACIN HYDROCHLORIDE	0.5 %W/V	AUROLAB LIMITEDNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI " 625 020 TAMIL NADU INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	14/07/2022
398	NDA/MAL/HDP/1 0036	MEDOPHARM	PLANET PHARMACEUTICAL S UGANDA LTD	MEDOMOL	PARACETAMOL	500 MG	MEDOPHARMNO. 34B, INDUSTRIAL AREA, MALUR- 563160, KARNATAKA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER,1.0X50.0X1 0.0 TABLET BLISTER,1.0X100.0X 1.0X10.0 TABLET BLISTER	14/07/2022

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399	NDA/MAL/HDP/1 0037	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BORINI-K	LANSOPRAZOLE + TINIDAZOLE + CLARITHROMYCIN	30 MG + 500 MG + 250 MG	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X7.0X1.0X6.0 TABLET STRIP	14/07/2022
400	NDA/MAL/HDP/1 0038	MEDOPHARM PRIVATE LIMITED	VITACARE LIMITED	CLEDOMOX 312.5 MG/5 ML	AMOXILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	312.5 MG/5 ML	MEDOPHARM PVT LIMITEDNO. 50 KAYARAMBEDU VILLAGE, GUDUVANCHERY- 603202	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X100.0 ML CONTAINER	14/07/2022
401	NDA/MAL/HDP/1 0039	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

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402	NDA/MAL/HDP/1 0041	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	PUMPINOX	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	20MG	PHARMA INTERNATIONAL CO. LTD AL QASTAL AIRPORT ROAD, P.O. BOX 334 AL JUBAIHA 11941, AMAAN	JORDAN	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X1.0X14.0 TABLET CONTAINER	06/07/2022
403	NDA/MAL/HDP/1 0042	GLOBELA PHARMA PVT. LTD.	SHREEJI CARE LIMITED	BACIPRO	CIPROFLOXACIN HYDROCHLORIDE	500 MG	GLOBELA PHARMA PVT.LTD.357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	19/07/2022
404	NDA/MAL/HDP/1 0043	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROYO- ADRENALINE	ADRENALINE ACID TARTRATE	1 MG/ML	SANJAR PHARMACEUTICALS LIMITEDSURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1X1X10X1 ML AMPOULE,	19/07/2022

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405	NDA/MAL/HDP/1 0044	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	TERBI RO 250	TERBINAFINEHYD ROCHLORIDE	250 MG	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	19/07/2022
406	NDA/MAL/HDP/1 0045	PHARMACTIV FZCO	HEALTHCARE LTD.	SURGITEC	CEFOTAXIME SODIUM	1 G/VIAL	SURGE LABORATORIES (PVT) LTD.,10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN.	PAKISTAN	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 1*5ML, WFI IN A CLEAR GLASS AMPOULE	19/07/2022
407	NDA/MAL/HDP/1 0046	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ARTEMETHER INJECTION 80 MG/ML	ARTEMETHER	80 MG/ ML	SCOTT-EDIL PHARMACIA LTD (UNIT I)56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X6.0X1.0 ML AMPOULE	19/07/2022

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408	NDA/MAL/HDP/1 0048	JOSHPA AFRICA LTD	AAFIYA (A) LIMITED	AAFISUNATE 60 MG	ARTESUNATE	60 MG/VIAL	SANJAR PHARMACEUTICALS LIMITED SURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1X60 MG VIAL	19/07/2022
409	NDA/MAL/HDP/1 0049	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ERYTHROMYCIN ESTOLATE ORAL SUSPENSION USP 125 MG/5ML	ERYTHROMYCIN ESTOLATE	125 MG/5ML	SCOTT-EDIL PHARMACIA LTD (UNIT I)56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	19/07/2022
410	NDA/MAL/HDP/1 0050	SERUM INSTITUTE OF INDIA PVT LTD	NORVIK ENTERPRISES LIMITED	ROTAVIRUS VACCINE, LIVE ATTENUATED (ORAL) ROTASIIL 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

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411	NDA/MAL/HDP/1 0052	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HI DEE 5000 IU	CHOLECALCIFERO L	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
412	NDA/MAL/HDP/1 0054	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
413	NDA/MAL/HDP/1 0055	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	FIMABUTE-400	CEFIXIME TRIHYDRATE	400MG	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	19/07/2022

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414	NDA/MAL/HDP/1 0056	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	AVARIN	SIMETHICONE+ ALVERINE CITRATE	300 MG + 60 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	1X5X1X10 CAPSULE BLISTER	19/07/2022
415	NDA/MAL/HDP/1 0059	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
416	NDA/MAL/HDP/1 006	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TRIPRIDE-2	GLIMEPIRIDE + PIOGLITAZONE+ METFORMIN	2MG+15MG+500M G	MICRO LABS LTD 92 SIPCOT 92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2012

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417	NDA/MAL/HDP/1 0061	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	INSTACLOP PLUS	CLOPIDOGREL + ASPIRIN	75 MG + 75 MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	19/07/2022
418	NDA/MAL/HDP/1 0062	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BRUCLOX-500	CLOXACILLIN SODIUM	500MG	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	19/07/2022
419	NDA/MAL/HDP/1 0063	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	CARDIONE 25	SPIRONOLACTON E	25MG	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	19/07/2022

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420	NDA/MAL/HDP/1 0065	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	EFAVIRENZ, LAMIVUDINE AND TENOFVIR DISOPROXIL FUMARATE TABLETS 600 MG/ 300 MG/ 300 MG	EFAVIRENZ + LAMIVUDINE + TENOFVIR 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
421	NDA/MAL/HDP/1 0066	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	FEMPRO	LETROZOLE	2.5MG	CIPLA LTDUNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X3X10 TABLET BLISTER	19/07/2022
422	NDA/MAL/HDP/1 0067	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	TRITINI	TINIDAZOLE	500MG	TRIVENI FORMULATIONS LTD PLOT NO. 52,53,54,63,62,64 ALEAP INDUSTRIUAL ESTATE SARAMPALLI VIJAYWADA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X25.0X4.0 TABLET BLISTER	19/07/2022

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423	NDA/MAL/HDP/1 0068	LEGIT MEDEQ 2007 LIMITED	LEGIT MEDEQ 2007 LIMITED	Z- ENOX	ENOXAPARIN SODIUM	10 MG/0.1 ML	ZEN PHARMA PVT LTD75/1, GIDC. VAPI- 396 195 GUJARAT,	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X0.6.0 ML PRE- FILLED SYRINGE, 1.0X0.4.0 ML PRE- FILLED SYRINGE	14/07/2022
424	NDA/MAL/HDP/1 0069	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	OPELAN ODT 5	OLANZAPINE	5 MG	MICRO LABS LIMITED .,92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X3.0X10.0 TABLET BLISTER	14/07/2022
425	NDA/MAL/HDP/1 007	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

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426	NDA/MAL/HDP/1 0074	TAURUS CHEMICALS (P) LTD.	HEALTHCARE LTD.	MAGACID SUSPENSION	ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE	(215 MG + 80 MG + 25 MG)/5ML	AL FAZAL PHARMA INDUSTRIES (PVT) LTD-PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X120.0 ML BOTTLE,1.0X1.0X20 0.0 ML BOTTLE	14/07/2022
427	NDA/MAL/HDP/1 0075	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	TEPPER 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
428	NDA/MAL/HDP/1 0076	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	RO-CID INJ	OMEPRAZOLE SODIUM	40MG	SANJAR PHARMA LLPSURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 MG VIAL + 10 ML WATER FOR INJECTION AMPOULE	14/07/2022

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429	NDA/MAL/HDP/1 0080	COMED CHEMICALS LTD.	LEGIT MEDEQ 2007 LIMITED	LYSER-D	DICLOFENAC SODIUM + SERRATIOPEPTID ASE	50 MG + 10 MG	COMED CHEMICALS LTD (UNIT-III)VILL: DASSOMATRA BADDI, NALAGARGH ROAD DISTRICT: SOLAN, PIN.173205 HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	14/07/2022
430	NDA/MAL/HDP/1 0083	THE SEARLE COMPANY LIMITED	SURGIPHARM (U) LIMITED	MORCET	ESCITALOPRAM OXALATE	20 MG	SEARLE PAKISTAN LTD..F-319, S.I.T.E., OPP. KESC POWER STATION, KARACHI	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X14.0 TABLET BLISTER	14/07/2022
431	NDA/MAL/HDP/1 0084	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	SEDAFOL	PROPOFOL	10 MG/ ML	ASPIRO PHARMA LIMITEDSY. NO. 321, BIOTECH PARK, PHASE-III, KARKAPATLA, MARKOOK MANDAL, SIDDIPET DISTRICT- 502 281, TELANGANA, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X20.0 ML VIAL	14/07/2022

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432	NDA/MAL/HDP/1 0087	MACLEODS PHARMACEUTICAL S 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
433	NDA/MAL/HDP/1 0089	NABIQASIM INDUSTRIES (PVT) LIMITED	HEALTHCARE LTD.	CEFEXOL DS SUSPENSION	CEFIXIME TRIHYDRATE	200 MG/5 ML	NABIQASIM INDUSTRIES (PVT) LTD .17/24 KORANGI INDUSTRIAL AREA KORANGI KARACHI	PAKISTAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1X1X30 ML BOTTLE	14/07/2022
434	NDA/MAL/HDP/1 009	TROIKAA PHARMACEUTICAL S 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

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435	NDA/MAL/HDP/1 0090	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/SYR UPS/DROPS	1X1X30 ML BOTTLE	14/07/2022
436	NDA/MAL/HDP/1 0091	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	PG-150	PREGABALIN	150 MG	ZOTA HEALTHCARE LIMITEDPLOT 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
437	NDA/MAL/HDP/1 0092	SYNOKEM PHARMACEUTICAL S LIMITED	ROYAL PHARMA 2011 LIMITED	ROTHISTRONE 5	NORETHISTERON E	5 MG	SYNOKEM PHARMACEUTICALS LTD-PLOT NO.- 35- 36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	14/07/2022

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438	NDA/MAL/HDP/1 0093	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MUCOSIL BR	SALBUTAMOL + BROMHEXINE HYDROCHLORIDE + GUAIFENESIN + MENTHOL	2.0 MG + 4.0 MG + 100 MG + 1.0 MG	RAVIAN LIFE SCIENCE PVT LTD PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1X1X100 ML BOTTLE	18/07/2022
439	NDA/MAL/HDP/1 0095	COMED CHEMICALS LTD.	LEGIT MEDEQ 2007 LIMITED	RAPCO -20	RABEPRAZOLE SODIUM	20 MG	COMED CHEMICALS LTD (UNIT-III)VILL: DASSOMATRA BADDI, NALAGARGH ROAD DISTRICT: SOLAN, PIN.173205 HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	18/07/2022
440	NDA/MAL/HDP/1 0096	COMED CHEMICALS LTD.	LEGIT MEDEQ 2007 LIMITED	ZACY- SR	ACECLOFENAC	200 MG	COMED CHEMICALS LTD (UNIT-III)VILL: DASSOMATRA BADDI, NALAGARGH ROAD DISTRICT: SOLAN, PIN.173205 HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	18/07/2022

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441	NDA/MAL/HDP/1 0097	ALKEM LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	NULOC 20	ESOMEPRAZOLE MAGNESIUM	20 MG	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1X3X10 TABLET BLISTER	18/07/2022
442	NDA/MAL/HDP/1 0098	ALKEM LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	NULOC 40	ESOMEPRAZOLE MANESIUM	40 MG	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1X3X10 TABLET BLISTER	18/07/2022
443	NDA/MAL/HDP/1 0099	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	GLYFERON 1000	METFORMIN HYDROCHLORIDE	1000 MG	BILIM ILAC SAN.VE TIC.A.SGEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X3X10 TABLET BLISTER	18/07/2022

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444	NDA/MAL/HDP/1 0100	HETERO LABS LTD	AIVEEN (U) LIMITED	PANTIN	PANTOPRAZOLE SODIUM SESQUIHYDRATE	40 MG/VIAL	ASPIRO PHARMA LIMITEDSY. NO. 321, BIOTECH PARK, PHASE-III, KARKAPATLA, MARKOOK MANDAL, SIDDIPET DISTRICT- 502 281, TELANGANA, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X40.0 MG VIAL	18/07/2022
445	NDA/MAL/HDP/1 0101	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	VILDARIL 50	VILDAGLIPTIN	50 MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	18/07/2022
446	NDA/MAL/HDP/1 0102	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	VILDARIL 100	VILDAGLIPTIN	100 MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	18/07/2022

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447	NDA/MAL/HDP/1 0103	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	COLDPIL	PARACETAMOL +PHENYLEPHRINE HYDROCHLORIDE + CHLORPEHNAMIN E MALEATE	650 MG + 5 MG + 2 MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1X10X10 TABLET BLISTER	18/07/2022
448	NDA/MAL/HDP/1 0104	IND-SWIFT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	TELSWIFT 40	TELMISARTAN	40 MG	IND-SWIFT LIMITED /VILL-JAWAHARPUR, OFF NH21, DERABASSI DIST: MOHALI, PUNJAB	INDIA	TABLETS (COATED	1.0X3.0X10.0 TABLET BLISTER	06/07/2022
449	NDA/MAL/HDP/1 0105	IND-SWIFT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	TELSWIFT 80	TELMISARTAN	80 MG	IND-SWIFT LIMITED /VILL-JAWAHARPUR, OFF NH21, DERABASSI DIST: MOHALI, PUNJAB	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER	06/07/2022

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450	NDA/MAL/HDP/1 0106	VEERAM HEALTHCARE (U) LIMITED	VEERAM HEALTHCARE (U) LIMITED	SERAFEN	DICLOFENAC POTASSIUM + SERRATIOPEPTID ASE	50 MG + 10 MG	KESAR PHARMA PVT LTD PLOT SURVEY NO. 50/2. VILLAGE BILSHWARPURA 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
451	NDA/MAL/HDP/1 0107	VEERAM HEALTHCARE (U) LIMITED	VEERAM HEALTHCARE (U) LIMITED	EXPECT	AMBROXOL HYDROCHLORIDE + TERBUTALINE SULPHATE + GUAIFENESIN	(15 MG + 1.25 MG + 50 MG)/ 5 ML	KESAR PHARMA PVT LTD PLOT SURVEY NO. 50/2. VILLAGE BILSHWARPURA 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
452	NDA/MAL/HDP/1 0108	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	PIRO 20	PIROXICAM	20 MG	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL SOLID ORDINARY CAPSULES	1X10X10 CAPSULE BLISTER	14/07/2022

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453	NDA/MAL/HDP/1 0109	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	RO MIFEN 500	MEFENAMIC ACID	500 MG	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	14/07/2022
454	NDA/MAL/HDP/1 0110	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	RO TAMIC 500	TRANEXAMIC ACID	500 MG	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X10X10 TABLET BLISTER	14/07/2022
455	NDA/MAL/HDP/1 0112	KESAR PHARMA	ABACUS PHARMA (AFRICA) LIMITED	KESKETO	KETOCONAZOLE	2 % W/W	KESAR PHARMA PVT LTD PLOT SURVEY NO. 50/2. VILLAGE BILSHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	14/07/2022

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456	NDA/MAL/HDP/1 0113	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
457	NDA/MAL/HDP/1 0114	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LAMIVUDINE AND TENOFIVIR DISOPROXIL FUMARATE TABLETS 300/300 MG	LAMIVUDINE + TENOFIVIR 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
458	NDA/MAL/HDP/1 0115	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ASPIRIN DELAYED RELEASE TABLETS USP 75MG	ASPIRIN	75 MG	SCOTT-EDIL PHARMACIA LTD (UNIT I)-56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	14/07/2022

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459	NDA/MAL/HDP/1 0117	FAES FARMA S.A	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	VENOSMIL	HIDROSMIN	200 MG	FAES FARMA SAMAXIMO AGUIRRE 14. 48940 LEIOA – SPAIN	SPAIN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	06/07/2022
460	NDA/MAL/HDP/1 012	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	LOX 2%	LIDOCAINE	2% W/V	NEON LABORATORIES LTD PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY OTHER VIALS	1.0X50.0 ML VIAL,1.0X20.0 ML VIAL	01/07/2013
461	NDA/MAL/HDP/1 0129	HETERO LABS LTD	AIVEEN (U) LIMITED	DARUNAVIR AND RITONAVIR TABLETS 400 MG/50 MG	DARUNAVIR ETHANOLATE + RITONAVIR	400 MG + 50 MG	HETERO LABS PRIVATE LIMITED UNIT 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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462	NDA/MAL/HDP/1 013	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	THIOSOL	THIOPENTAL SODIUM	500MG	NEON LABORATORIES LTD PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X20.0 ML VIAL	01/07/2013
463	NDA/MAL/HDP/1 0134	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	ISONIAZID/ RIFAPENTINE COATED TABLETS 300 MG + 300 MG	ISONIAZID + RIFAPENTINE	300MG +300MG	OXALIS LABS LIMITED VILLAGE THEDA, P.O LODHIMAJRA, TEHSIL, BADDI, DIST. SOLAN, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X12.0 TABLET STRIP	18/07/2022
464	NDA/MAL/HDP/1 0135	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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465	NDA/MAL/HDP/1 0138	NABIQASIM INDUSTRIES (PVT) LIMITED	HEALTHCARE LTD.	CLARITHRO TABLETS	CLARITHROMYCIN	500MG	NABIQASIM INDUSTRIES (PVT) LTD .17/24 KORANGI INDUSTRIAL AREA KORANGI KARACHI	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1X1X10 TABLET BLISTER	18/07/2022
466	NDA/MAL/HDP/1 014	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	TIDAZOL TABLETS	TINIDAZOLE	500MG	ELYS CHEMICAL INDUSTRIES LIMITED- ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X20.0X4.0 TABLET BLISTER	01/07/2015
467	NDA/MAL/HDP/1 0140	UNICHEM LABORATORIES LIMITEDV	EUROPA HEALTHCARE (U) LTD	ALDROL 5	DONEPEZIL HYDROCHLORIDE	5MG	UNICHEM LABORATORIES BADI- UNIT IIVILLAGE BHATAULI, BADDI HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	06/07/2022

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468	NDA/MAL/HDP/1 0141	UNICHEM LABORATORIES LIMITEDV	EUROPA HEALTHCARE (U) LTD	ALDROL 10	DONEPEZIL HYDROCHLORIDE	10MG	UNICHEM LABORATORIES BADI- UNIT IIVILLAGE BHATAULI, BADDI HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	06/07/2022
469	NDA/MAL/HDP/1 0144	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
470	NDA/MAL/HDP/1 0145	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	I-PILL	LEVONORGESTRE L	1.5MG	CIPLA LTD-UNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X1.0 TABLET BLISTER	12/13/2023

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471	NDA/MAL/HDP/1 0146	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	UMBILICA GEL	CHLORHEXIDINE GLUCONATE	4%W/W	ATCO LABS LTD,B- 18, S.I.T.E, KARACHI	PAKISTAN	TOPICAL EXTERNAL GELS AND SOLS	1X10 G TUBE	18/07/2022
472	NDA/MAL/HDP/1 0148	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	RALEF 60	ETORICOXIB	60MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X7.0 TABLET BLISTER	18/07/2022
473	NDA/MAL/HDP/1 0149	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	RALEF 90	ETORICOXIB	90MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X7.0 TABLET BLISTER	18/07/2022

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474	NDA/MAL/HDP/1 015	DAWA LIMITED	SUPER MEDIC LTD	ORACEF	CEFALEXIN	250MG	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1X10X10 CAPSULE STRIP	01/07/2013
475	NDA/MAL/HDP/1 0150	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	RALEF 120	ETORICOXIB	120MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X7.0 TABLET BLISTER	18/07/2022
476	NDA/MAL/HDP/1 0151	S KANT HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	FUNGARIN	MICONAZOLE	2%W/W	S KANT HEALTHCARE LIMITED1802 – 1805, G.I.D.C., PHASE III, VAPI - 396195 GUJARAT, INDIA.	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X1.0X30.0 G TUBE	06/07/2022

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477	NDA/MAL/HDP/1 0152	BIOFARMA PLASMA LIMITED LIABILITY COMPANY	ONCOPHARM (U) LTD	ALBUMIN- BIOPHARMA	HUMAN ALBUMIN	20G/100ML	BIOPHARMA PLASMA LIMITED LIABILITY COMPANY37-V KYIVSKA ST., BILA TSERKVA, KYIV REGION, 09100 - UKRAINE	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1X1X100 ML VIAL	18/07/2022
478	NDA/MAL/HDP/1 0155	MEDIPAK LIMITED	HEALTHCARE LTD.	MEDISOL NS	SODIUM CHLORIDE	0.9%W/V	MEDIPAK LTD132/2/ INDUSTRIAL ESTATE KOT LAKHPAT, LAHORE	PAKISTAN	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	02/09/2022
479	NDA/MAL/HDP/1 0156	MEDIPAK LIMITED	HEALTHCARE LTD.	MEDISOL 5%	DEXTROSE	5%W/V	MEDIPAK LTD132/2/ INDUSTRIAL ESTATE KOT LAKHPAT, LAHORE	PAKISTAN	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	02/09/2022

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480	NDA/MAL/HDP/1 0164	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ASPIRIN TABLETS	ACETYLSALICYCLI C ACID	300MG	ELYS CHEMICAL INDUSTRIES LIMITED,-OFF ENTERPRISE ROAD, OPP HILLOCK-INN ROAD B, INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET STRIP,1.0X200.0 TABLET TIN,1.0X1000.0 TABLET TIN	02/09/2022
481	NDA/MAL/HDP/1 0168	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	LYFE	ORAL REHYDRATION SALT	N/A	ELYS CHEMICAL INDUSTRIES LIMITED,-OFF ENTERPRISE ROAD, OPP HILLOCK-INN ROAD B, INDUSTRIAL AREA	KENYA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X14.0 G SACHET,1.0X28.0 G SACHET	02/09/2022
482	NDA/MAL/HDP/1 0169	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ORODAR	SULFADOXINE+PY RIMETHAMINE	500MG+25MG	ELYS CHEMICAL INDUSTRIES LIMITED,-OFF ENTERPRISE ROAD, OPP HILLOCK-INN ROAD B, INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X30.0X3.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	02/09/2022

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483	NDA/MAL/HDP/1 017	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYCLOX	AMPICILLIN/CLOX ACILLIN	125MG/125MG	ELYS CHEMICAL INDUSTRIES LIMITEDROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2015
484	NDA/MAL/HDP/1 0170	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	PREDNISOLONE TABLETS	PREDNISOLONE	5MG	ELYS CHEMICAL INDUSTRIES LIMITED,-OFF ENTERPRISE ROAD, OPP HILLOCK-INN ROAD B, INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	02/09/2022
485	NDA/MAL/HDP/1 0172	SURGE LABORATORIES (PVT.) LTD.	HEALTHCARE LTD.	SURGICOMB INJECTION 2G	CEFOPRAZONE SODIUM + SULBACTUM SODIUM	(1G + 1G)/VIAL	SURGE LABORATORIES (PVT) LTD.,,10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN.	PAKISTAN	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X2.0 G VIAL + 10ML WFI CLEAR GLASS AMPOULE	09/09/2022

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486	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
487	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
488	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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489	NDA/MAL/HDP/1 0185	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (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
490	NDA/MAL/HDP/1 0186	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICAL S LIMITED	AARLOFLOX OZ	OFLOXACIN + ORNIDAZOLE	200 MG + 500 MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X20.0X10.0 TABLET BLISTER	09/09/2022
491	NDA/MAL/HDP/1 0187	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICAL S LIMITED	AARCET 5	CETIRIZINE HYDROCHLORIDE	5 MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	09/09/2022

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492	NDA/MAL/HDP/1 0188	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICAL S LIMITED	AARLEFLOX 750	LEVOFLOXACIN HEMIHYDRATE	750 MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	09/09/2022
493	NDA/MAL/HDP/1 0189	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICAL S LIMITED	ETRICOX 120	ETORICOXIB	120 MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022
494	NDA/MAL/HDP/1 0192	INFUGEN PHARMA PVT. LTD.	TATA UGANDA LIMITED	INFUTAXIM 1 GM	CEFOTAXIME SODIUM	1 G/ VIAL	ZEISS PHARMACEUTICALS PRIVATE LIMITEDPLOT NO. 72 EPIP-PHASE-1 JHARMAJRI BADDI DISTRICT SOLAN (H.P.)INNOVA CAPTAB LIMITED 1281/1, HILLTOP INDUSTRIAL ESTATE, NEAR EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN [H.P] - INDIA	INDIA	PARENTERAL RETARD DRY VIALS	1.0X1.0X1.0 G VIAL	09/09/2022

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495	NDA/MAL/HDP/10193	UNITED PHARMACEUTICALS MANUFACTURING LIMITED COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VIVAZAC PLUS	IRBESARTAN + HYDROCHLOROT HIAZIDE	300 MG + 12.5 MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022
496	NDA/MAL/HDP/10196	CONCEPT PHARMACEUTICALS 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
497	NDA/MAL/HDP/10197	CENTURION LABORATORIES PVT. LTD.	SHREEJI PHARMACEUTICALS LIMITED	LEVOZINE	LEVOCETIRIZINE DIHYDROCHLORIDE	5 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIOTECH PARK, MANJUSAR, 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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498	NDA/MAL/HDP/10199	MEGA LIFSCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	GOFEN 200	IBUPROFEN	200 MG	MEGA LIFSCIENCES PUBLIC CO. LTD PLANT 1; 384 MOO 4, SOI 6, BANGPOO INDUSTRIAL ESTATE, PATTANA 3 ROAD, PHRAEKSA, MUEANG, SAMUTPRAKARN 10280 THAILAND	THAILAND	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X6.0X1.0X1.0X1.0X1.0 CAPSULE BLISTER	09/09/2022
499	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
500	NDA/MAL/HDP/10200	UNITED PHARMACEUTICALS MANUFACTURING LIMITED COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SENERGY PLUS 5/160/12.5 MG	AMLODIPINE BESYLATE + VALSARTAN + HYDROCHLOROT HIAZIDE	5 MG + 160 MG + 12.5 MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/09/2022

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501	NDA/MAL/HDP/10201	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICALS LIMITED	ETRICOX 60	ETORICOXIB	60 MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022
502	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
503	NDA/MAL/HDP/10209	FERRER INTERNATIONAL, S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TRAMAPA FORT 75MG/650MG	TRAMADOL HYDROCHLORIDE + PARACETAMOL	75 MG + 650 MG	FERRER INTERNATIONAL, S.AC/ JOAN BUSCALLA, 1-9 08173 SANT CUGAT DEL VALLES,	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	09/09/2022

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504	NDA/MAL/HDP/1 0210	FDC LTD	AIVEEN (U) LIMITED	IOPROST EYE DROPS	LATANOPROST	0.005%W/V	FDC LIMITED, WALUJ .PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD	INDIA	OPHTHALMIC LIQUIDS	1.0X1.0X5.0 ML BOTTLE	29/09/2022
505	NDA/MAL/HDP/1 0211	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICAL S LIMITED	SPAZNOL	DICLOFENAC SODIUM + PARACETAMOL + CHLORZOXAZON	50 MG + 325 MG + 250 MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	09/09/2022
506	NDA/MAL/HDP/1 0212	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICAL S LIMITED	SPASNIL P	MEFENAMIC ACID + PARACETAMOL	500 MG + 325 MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022

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507	NDA/MAL/HDP/1 0213	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	PANTAKIND-40	PANTOPRAZOLE SODIUM	40 MG	MANKIND PHARMA LIMITED UNIT - II, VILLAGE KISHANPURA, P.O. JAMNIWALA, TEHSIL PAONTA SAHIB, DISTRICT SIRMOUR - 173025, HIMACHAL PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X6.0X10.0 TABLET BLISTER	09/09/2022
508	NDA/MAL/HDP/1 0214	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ILAXTEN 20 MG TABLETS	BILASTINE	20MG	A. MENARINI MANUFACTURING LOGISTICS AND SERVICES SRL-VIA CAMPO DI PILE 67100 L'AQUILA (AQ)	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER, 1.0X1.0X4. 0 TABLET BLISTER	09/09/2022
509	NDA/MAL/HDP/1 0215	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	PARACETAMOL INTRAVENOUS INFUSION	PARACETAMOL	10 MG/ML	ABARIS HEALTHCARE PVT. LTDSURVEY NO. 1407/11, VILLAGE RAJPUR, TAL KADI DIST. MEHSANA, GUJARAT-382740	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML CONTAINER	09/09/2022

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510	NDA/MAL/HDP/1 0216	KLM LABORATORIES PVT. LTD.	REDDYS PHARMA LIMITED	LULIZOL CREAM	LULICONAZOLE	1%W/W	CURETECH SKINCAREPLOT NO. 33 & 34, PHASE IV, BHATOLI KALAN, BADDI DISTT. SOLAN (HP) 173205	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	29/09/2022
511	NDA/MAL/HDP/1 0218	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	COMIT-100	SILDENAFIL CITRATE	100 MG	BLISS GVS PHARMA LIMITED10,11 & 12,DEWAN UDYOG NAGAR,ALIYALI,PAL GHAR,MAHARASHTR A 401404,INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	09/09/2022
512	NDA/MAL/HDP/1 0219	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	COMIT-50	SILDENAFIL CITRATE	50 MG	BLISS GVS PHARMA LIMITED10,11 & 12,DEWAN UDYOG NAGAR,ALIYALI,PAL GHAR,MAHARASHTR A 401404,INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	09/09/2022

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513	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
514	NDA/MAL/HDP/10225	LUKAS LAB LTD	PLUTO PHARMACEUTICALS LIMITED	LUSNAT 60	ARTESUNATE	60 MG	BLISS INDAS LIFESCIENCE P. LTD..PLOT 73-76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X60.0 MG VIAL + 1ML OF 5.0%W/V SODIUM BICARBONATE VIAL + 5ML OF 0.9%W/V SODIUM CHLORIDE VIAL	09/09/2022
515	NDA/MAL/HDP/10226	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

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516	NDA/MAL/HDP/10228	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	SEPTOPRIM 960	TRIMETHOPRIM + SULFAMETHOXAZOLE	160 MG + 800 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIOTECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. -	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	09/09/2022
517	NDA/MAL/HDP/10229	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	SEPTOPRIM - S	TRIMETHOPRIM + SULFAMETHOXAZOLE	(40 MG + 200 MG)/5 ML	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIOTECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. -	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	09/09/2022
518	NDA/MAL/HDP/1023	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ZINNIA P	LEVONORGESTREL + ETHINYLESTRADIOL	150MCG + 30MCG	MYLAN LABORATORIES LIMITED..PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, AHMEDABAD, GUJARAT, INDIA 382213 MYLAN LABORATORIES LIMITED.-PLOT NO.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X28.0 TABLET BLISTER,3.0X28.0 TABLET BLISTER	01/07/2013

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519	NDA/MAL/HDP/1 0230	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	MBEN	MEBENDAZOLE	100 MG/5 ML	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. -	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X30.0 ML BOTTLE	09/09/2022
520	NDA/MAL/HDP/1 0231	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	MBEN 100	MEBENDAZOLE	100 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. -	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X20.0X6.0 TABLET BLISTER	09/09/2022
521	NDA/MAL/HDP/1 0232	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	TOPGYL	METRONIDAZOLE BENZOATE	125 MG/5 ML	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	09/09/2022

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522	NDA/MAL/HDP/1 0233	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	PAINFORCE 400	IBUPROFEN	400 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	09/09/2022
523	NDA/MAL/HDP/1 0234	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	TERBINAFORCE 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
524	NDA/MAL/HDP/1 0235	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	LOFNAC GEL	LINSEED OIL + DICLOFENAC DIETHYLAMINE + METHYL SALICYLATE + MENTHOL	3.00%W/W + 1.16% W/W + 10.00%W/W + 5.00%W/W	KREMOINT PHARMA PVT LTD PLANT IIB-8, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST) DIST. THANE 421506	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X1.0X30.0 G TUBE	09/09/2022

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525	NDA/MAL/HDP/1 0239	B&O PHARM	TRIDEM PHARMA UGANDA LIMITED	ZITMYC	AZITHROMYCIN	500MG	CSPC OUYI PHARMACEUTICAL CO. LTD.WORKSHOPS 112,113 AND 117 PLOT NO. 88 YANGZI ROAD,ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHIJIAZHANG CITY, HEBEI PROVINCE, CHINA	CHINA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	09/09/2022
526	NDA/MAL/HDP/1 0240	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	OLMESAR 40	OLMESARTAN MEDOXOMIL	40MG	MACLEODS PHARMACEUTICALS LIMITED, UNIT VIVILLAGE THEDA, KHARUNI LODHI MAJRA RD, TEHSIL BADDI N2, DISTRICT SOLAN, HIMACHAL PRADESH-174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	09/09/2022
527	NDA/MAL/HDP/1 0241	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

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528	NDA/MAL/HDP/1 0242	EMCURE PHARMACEUTICAL S LTD -	HARLEYS UGANDA LIMITED	INSTGRA	DOLUTEGRAVIR SODIUM	50MG	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	1.0X1.0X30.0 TABLET BOTTLE	09/09/2022
529	NDA/MAL/HDP/1 0246	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICAL S LTD	GLENDES	DESLORATADINE	5MG	GLENMARK PHARMACEUTICALS LIMITED PLOT NO. S - 7, COLVALE, INDUSTRIAL ESTATE COLVALE, BARDEZ 403513, GOA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	19/09/2022
530	NDA/MAL/HDP/1 0247	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	MOXIKIND-CV 228.5	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	200MG/5ML + 28.5MG/5ML	COPMED PHARMACEUTICALS PVT LTD-UNIT II. ,PLOT 50, GONDPUR INDUSTRIAL AREA, PAONTA, SAHIB, SIRMOUR, HIMACHAL PRADESH- 173025, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X100.0 ML BOTTLE	09/09/2022

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531	NDA/MAL/HDP/1 0249	FDC LTD	AIVEEN (U) LIMITED	IOPROST – T	LATANOPROST + TIMOLOL MALEATE	(50 MCG + 5 MG)/ML	FDC LIMITED, WALUJ .PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD	INDIA	OPHTHALMIC DROPS	1.0X1.0X2.5 ML BOTTLE	09/09/2022
532	NDA/MAL/HDP/1 0250	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	SINUTAB SINUS PAIN EXTRA STRENGTH	CODEINE PHOSPHATE +CHLORPHENIRA MINE MALEATE +PSEUDOEPHEDRI NE HYDROCHLORIDE + PARACETAMOL	10 MG + 2 MG + 30 MG + 500 MG	JOHNSON & JOHNSON (PTY) LTD241 MAIN ROAD, RETREAT, 7945, CAPE TOWN	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X12.0 TABLET BLISTER	09/09/2022
533	NDA/MAL/HDP/1 0251	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CITADONE	BETAMETHASONE	0.6 MG/5 ML	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE	09/09/2022

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534	NDA/MAL/HDP/1 0254	CENTURION LABORATORIES PVT. LTD.	SHREEJI PHARMACEUTICAL S LIMITED	AZICEN 500	AZITHROMYCIN	500MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	09/09/2022
535	NDA/MAL/HDP/1 0258	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SENERGY PLUS 5/160 25 MG	AMLODIPINE BESYLATE + VALSARTAN + HYDROCHLOROT HIAZIDE	5 MG + 160 MG + 25 MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022
536	NDA/MAL/HDP/1 0259	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SENERGY PLUS 10/160 12.5 MG	AMLODIPINE BESYLATE + VALSARTAN + HYDROCHLOROT HIAZIDE	10 MG + 160 MG + 12.5 MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022

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537	NDA/MAL/HDP/1 0261	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	NTCLOT-C75	CLOPIDOGREL BILSULFATE	75 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. -	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	09/09/2022
538	NDA/MAL/HDP/1 0262	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROFLOX	OFLOXACIN	0.3%W/V	AUROLAB LIMITED NO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI - 625 020 TAMIL NADU INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	19/09/2022
539	NDA/MAL/HDP/1 0263	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	WORMAID ORAL SUSPENSION	ALBENDAZOLE	200 MG/5ML	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. -	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X10.0 ML BOTTLE	09/09/2022

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540	NDA/MAL/HDP/1 0267	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
541	NDA/MAL/HDP/1 0268	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	WORMAID TABLET	ALBENDAZOLE	400 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. -	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X1.0 TABLET BLISTER	09/09/2022
542	NDA/MAL/HDP/1 0269	NATIONAL PHARMACEUTICAL INDUSTRIES CO.	MEDVIN PHARMA LIMITED	DIOCLAV 625 MG	AMOXICILLIN + CLAVULANATE POTASSIUM	500 MG + 125 MG	NATIONAL PHARMACEUTICAL INDUSTRIES COMPANY OMANP.O.BOX 120, RUSAYL, POSTAL CODE-124, SULTANATE OF OMAN	OMAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET STRIP	09/09/2022

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543	NDA/MAL/HDP/1 0280	INDCHEMIE HEALTH SPECIALITIES PVT. LTD.	NUMED STORES SMC LIMITED	ZENOXIM 500	CEFUROXIME AXETIL	500 MG	INDCHEMIE HEALTH SPECIALITIES PVT. LTDVILLAGE-THANA, BADDI, DIST. SOLAN, HIMACHAL PRADESH- 173 205.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	09/09/2022
544	NDA/MAL/HDP/1 0282	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	MUPIWAYS	MUPIROCIN	2.0 W/W	NEXT WAVERAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X10.0 G TUBE	09/09/2022
545	NDA/MAL/HDP/1 0283	DAWA LIMITED-	SUPER MEDIC LTD	DAZOLE	CLOTRIMAZOLE	100MG	DAWA LIMITEDPLOT NO. 7879/8 BABADOGO ROAD, RUARAKA P. O. BOX 16633-00620 NAIROBI, KENYA	KENYA	VAGINAL TABLETS	1.0X1.0X6.0 PESSARY BLISTER	09/09/2022

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546	NDA/MAL/HDP/1 0284	NATIONAL PHARMACEUTICAL INDUSTRIES CO.	MEDVIN PHARMA LIMITED	MACROMAX 500	AZITHROMYCIN	500MG	NATIONAL PHARMACEUTICAL INDUSTRIES COMPANY OMANP.O.BOX 120, RUSAYL, POSTAL CODE-124, SULTANATE OF OMAN	OMAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	09/09/2022
547	NDA/MAL/HDP/1 0285	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	DOLUTEGRAVIR SODIUM TABLET FOR ORAL SUSPENSION (DISPERSIBLE TABLETS) 10MG	DOLUTEGRAVIR SODIUM	10 MG	MACLEODS PHARMACEUTICALS LTD „PHASE I & II, PLOT NO. 25-27 SURVEY NO. 366, PREMIERE INDUSTRIAL ESTATE, KACHIGAN, DAMAN- 396210	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X90.0 TABLET CONTAINER	09/09/2022
548	NDA/MAL/HDP/1 0286	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	PERLEX 250	CEFALEXIN MONOHYDRATE	250 MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	09/09/2022

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549	NDA/MAL/HDP/1 0287	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	VILDA DENK 50 MG	VILDAGLIPTIN	50 MG	DENK PHARMA GMBH & CO. KGGOLLSTR. 1, 84529, TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER	09/09/2022
550	NDA/MAL/HDP/1 0292	SAGA LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	SPASMOTRIT	DICYCLOMINE HYDROCHLORIDE + PARACETAMOL	20MG + 500MG	SAGA LIFESCIENCES LIMITEDSURVEY NO. 198/2 & 198/3, CHACHRAWADI VASNA, TA-SANAND, DIST. AHMEDABAD - 382210, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	09/09/2022
551	NDA/MAL/HDP/1 0294	ALTHEA PHARMA PVT LTD.	JOINT MEDICAL STORE (UPMB - UCMB)	ALTCIP	CIPROFLOXACIN	200MG	ALTHEA PHARMA PRIVATE LIMITEDWORKS: PLOT NO. 374, SHED NO. 'E', ALPHA INDL. PARK, ATHIAWAD, DABHEL, NANI DAMAN - 396210 (U.T.), INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	09/09/2022

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552	NDA/MAL/HDP/1 0296	LUPIN LIMITED-	AIVEEN (U) LIMITED	RIFAMPIN, ISONIAZID, PYRAZINAMIDE, ETHAMBUTOL HYDROCHLORIDE TABLETS USP150/75/400/2 75MG	RIFAMPIN + ISONIAZID + PYRAZINAMIDE + ETHAMBUTOL HYDROCHLORIDE	150MG + 75MG + 400MG + 275MG	LUPIN LTDA-28/1, M.I.D.C., CHIKALTHANA, AURANGABAD- 431210, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X24.0X14.0 TABLET BLISTER	09/09/2022
553	NDA/MAL/HDP/1 0297	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	ACECLAV 1000	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	875 MG + 125 MG	MEDICEF PHARMA- NO. 28, PHASE 1, EPIP, JHARRMAJRI, BADDI, DIST SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	09/09/2022
554	NDA/MAL/HDP/1 0298	ZOTA HEALTHCARE LTD	HARLEYS UGANDA LIMITED	COXZOTA 90	ETORICOXIB	90 MG	ZOTA HEALTHCARE LIMITEDPLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY SATTION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022

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555	NDA/MAL/HDP/10299	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
556	NDA/MAL/HDP/1030	LABORATORIOS SALVAT SA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MALACUR	DIHYDROARTEMISININ + PIPERAQUINE PHOSPHATE	40MG + 320MG	CIRON DRUGS PHARMACEUTICALS PRIVATE LTD,35-37, 43-45, CFC-B DEWAN UDYOG NAGAR, ALIYALI, DIST - PALGHAR 401 404, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X12.0 TABLET BLISTER,1.0X1.0X9.0 TABLET BLISTER	01/07/2014
557	NDA/MAL/HDP/10300	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	ACECLAV 375	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	250 MG + 125 MG	MEDICEF PHARMA-NO. 28, PHASE 1, EPIP, JHARRMAJRI, BADDI, DIST SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	09/09/2022

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558	NDA/MAL/HDP/1 0303	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DAPZIN-5	DAPAGLIFLOZIN	5 MG	MICRO LABS LIMITED, HOSURNO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022
559	NDA/MAL/HDP/1 0304	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DAPZIN-10	DAPAGLIFLOZIN	10 MG	MICRO LABS LIMITED, HOSURNO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022
560	NDA/MAL/HDP/1 0305	SAGA LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	SPASCOLIC	DICYCLOMINE HYDROCHLORIDE + MEFENAMIC ACID	10 MG + 250 MG	SAGA LIFESCENCES LIMITEDSURVEY NO. 198/2 & 198/3, CHACHRAWADI VASNA, TA-SANAND, DIST. AHMEDABAD - 382210, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	09/09/2022

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561	NDA/MAL/HDP/1 0307	ZOTA HEALTHCARE LTD	HARLEYS UGANDA LIMITED	DESLOZED-5	DESLORATADINE	5 MG	ZOTA HEALTHCARE LIMITEDPLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY SATTION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	09/09/2022
562	NDA/MAL/HDP/1 031	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MOXIFLOX	MOXIFLOXACIN	400MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X1.0X5.0 TABLET BLISTER	01/07/2013
563	NDA/MAL/HDP/1 0310	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ZINRO INFUSION	ORNIDAZOLE	500MG/100ML	ABACUS PARENTERAL DRUGS LIMITEDPLOT 114, BLOCK 191, KINGA	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	09/09/2022

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564	NDA/MAL/HDP/1 0311	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	LOPINAVIR AND RITONAVIR TABLETS USP	LOPINAVIR + RITONAVIR	200MG + 50MG	LAURUS LABS LTD (UNIT 2)PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X120.0 TABLET BOTTLE	09/09/2022
565	NDA/MAL/HDP/1 0313	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	LOPINAVIR AND RITONAVIR TABLETS USP	LOPINAVIR + RITONAVIR	100MG + 25MG	LAURUS LABS LTD (UNIT 2)PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET BOTTLE	09/09/2022
566	NDA/MAL/HDP/1 0315	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	INDOMETHACIN	INDOMETHACIN	25MG	M/S SCOTT-EDIL PHARMACIA LIMITED-56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE TIN,1.0X500.0 CAPSULE TIN,1.0X10.0X10.0 CAPSULE BLISTER	01/07/2008

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567	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
568	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
569	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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570	NDA/MAL/HDP/1 0323	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	XELTIN	TOFACITINIB CITRATE	5MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022
571	NDA/MAL/HDP/1 0324	APEX LABORATORIES PRIVATE LIMITED	NORVIK ENTERPRISES LIMITED	ZINCOVIT TABLETS	VITAMIN A (AS ACETATE) + VITAMIN D3 (CHOLECALCIFER OL) + VITAMIN E (AS DL- TOCOPHERYL ACETATE) + THIAMINE NITRATE + RIBOFLAVIN + PYRIDOXINE HYDROCHLORIDE + CYANOCOBALAMI	5000IU + 400IU + 15MG +10MG + 10MG + 2MG + 7.5MCG + 50MG + 10MG + 75 MG + 30MG + 2.8MG + 2MG + 63MG +70MCG	APEX LABORATORIES PRIVATE LIMITED- PLANT 1-B-23, SIDCO PHARMACEUTICAL COMPLEX ALATHUR, KANCHEEPURAM DISTRICT 603 110	INDIA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER	09/09/2022
572	NDA/MAL/HDP/1 0325	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	ONCET	CETIRIZINE DIHYDROCHLORID E	5MG/5ML	MEDLEY PHARMACEUTICALS LTD PLOT 18 & 19 SURVEY NO. 378/7&8, 379/2&3 ZARI CAUSEWAY ROAD, KACHIGAM DAMAN-396210, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE	09/09/2022

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573	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
574	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
575	NDA/MAL/HDP/10332	MIDDLE EAST PHARMACEUTICAL INDUSTRIES CO. LTD. (AVALON PHARMA)	GAMA PHARMACEUTICALS (U) LIMITED	AVOCOM	MOMETASONE FUROATE	0.05%W/W	MIDDLE EAST PHARMACEUTICAL INDUSTRIES COMPANY LIMITED (AVALON PHARMA) P.O. BOX 4180, RIYADH 11491, 2ND INDUSTRIAL CITY, RIYADH, SAUDI ARABIA	SAUDI ARABIA	NASAL TOPICAL PRESSURISED AEROSOLS	1.0X1.0X120.0 METERED DOSE BOTTLE	19/09/2022

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576	NDA/MAL/HDP/1 0335	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	PRIDOCAINE	LIDOCAINE + PRILOCAINE	2.5% W/W + 2.5%W/W	GLOBAL NAPI PHARMACEUTICALS- 2ND INDUSTRIAL ZONE, ST 18, 6TH OCTOBER CITY	EGYPT	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	09/09/2022
577	NDA/MAL/HDP/1 0338	NEOMI PHARMACEUTICAL S PVT LTD -	ROYAL PHARMA 2011 LIMITED	ROART 20/120	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X24.0 TABLET BLISTER	09/09/2022
578	NDA/MAL/HDP/1 034	VOGEN LABORATORIES LTD	BUFFALO HEALTH CARE LTD	DURAMOX	AMOXICILLIN	250MG/5ML	VOGEN LABORATORIES LTD70, M.HERACLEOUS STR. AYIOS ATHANASIOS INDUSTRIAL AREA, LIMASSOL, CYPRUS	CYPRUS	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2007

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579	NDA/MAL/HDP/1 0340	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	KERELLA	BETAMETHASONE DIPROPIONATE + SALICYLIC ACID	(0.5 MG+ 220 MG)/G	GLOBAL NAPI PHARMACEUTICALS- 2ND INDUSTRIAL ZONE, ST 18, 6TH OCTOBER CITY	EGYPT	TOPICAL EXTERNAL LOTIONS	1.0X1.0X30.0 ML BOTTLE	09/09/2022
580	NDA/MAL/HDP/1 0343	DAWA LIMITED-	SUPER MEDIC LTD	KENAZOLE	KETOCONAZOLE	2%W/W	DAWA LIMITEDPLOT NO. 7879/8 BABADOGO ROAD, RUARAKA P. O. BOX 16633-00620 NAIROBI, KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	09/09/2022
581	NDA/MAL/HDP/1 0346	EAST AFRICAN (INDIA) OVERSEAS	ROYAL PHARMA 2011 LIMITED	LACTORIV	LACTULOSE	10 G/15 ML	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X120.0 ML BOTTLE	09/09/2022

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582	NDA/MAL/HDP/1 0349	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	GLUMAC	ARTEMETHER + LUMEFANTRINE	80MG + 480MG	GUILIN PHARMACEUTICAL CO LTD .NO. 43, QULIDIAN ROAD, GUILIN 541004	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X6.0 TABLET BLISTER,30.0X6.0 TABLET BLISTER	09/09/2022
583	NDA/MAL/HDP/1 0353	BIOMATRIX HEALTHCARE PVT LTD.-	MEDIWORLD PHARMA AFRICA LTD	PAINAID	PARACETAMOL + IBUPROFEN + CAFFEINE	400 MG + 325 MG + 40 MG	BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD – 382 220, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	09/09/2022
584	NDA/MAL/HDP/1 0355	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	RIVATAS 15	RIVAROXABAN	15 MG	INTAS PHARMACEUTICALS LTD.PLOT NO. 457, 458, & 191/218P,VILLAGE: MATODA, TAL. SANAND, AHMEDABAD, GUJARAT, 382210 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022

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585	NDA/MAL/HDP/1 0356	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	RIVATAS 20	RIVAROXABAN	20MG	INTAS PHARMACEUTICALS LTD.PLOT NO. 457, 458, & 191/218P,VILLAGE: MATODA, TAL. SANAND, AHMEDABAD, GUJARAT, 382210 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X0.01 TABLET BLISTER	09/09/2022
586	NDA/MAL/HDP/1 0358	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	VOLDIC - K	DICLOFENAC POTASSIUM	50MG	PHARMA INTERNATIONAL CO. LTD AL QASTAL AIRPORT ROAD, P.O. BOX 334 AL JUBAIHA 11941, AMAAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	09/09/2022
587	NDA/MAL/HDP/1 0361	AFRICURE PHARMACEUTICAL S (INDIA) PVT. LTD	AFRICURE PHARMACEUTICAL S U LIMITED	AFRICAL	CALCIUM LACTATE	300 MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9- 12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1X10X10 TABLET BLISTER	19/09/2022

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588	NDA/MAL/HDP/1 0363	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	RO - AMIKACIN	AMIKACIN SULFATE	500 MG/2 ML	SANJAR PHARMA LLPSURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X2.0 ML VIAL	19/09/2022
589	NDA/MAL/HDP/1 0365	MYLAN LABORATORIES LIMITED-	KIMSY MEDS LTD	MYLTEGA DT	DOLUTEGRAVIR SODIUM	10MG	MYLAN LABORATORIES LTD PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR - 454775; DIST; DHAR; MADHYA PRADESH;	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X90.0 TABLET BOTTLE	09/09/2022
590	NDA/MAL/HDP/1 0369	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

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591	NDA/MAL/HDP/1 0370	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SITAPRIL 100	SITAGLIPTIN PHOSPHATE MONOHYDRATE	100MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022
592	NDA/MAL/HDP/1 0371	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROLEXIN 250	CEFALEXIN MONOHYDRATE	250MG	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	19/09/2022
593	NDA/MAL/HDP/1 0376	SURGE LABORATORIES (PVT.) LTD.	HEALTHCARE LTD.	SURGICOMB 1G INJECTION	CEFOPRAZONE SODIUM + SULBACTAM 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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594	NDA/MAL/HDP/1 0378	CENTURION LABORATORIES PVT. LTD.	SHREEJI PHARMACEUTICAL S LIMITED	ESOMIZAP	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	09/09/2022
595	NDA/MAL/HDP/1 0379	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
596	NDA/MAL/HDP/1 038	SQUARE CEPHALOSPORINS LTD	GAMA PHARMACEUTICAL S (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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597	NDA/MAL/HDP/1 0380	ACINO PHARMA (PTY) LTD	LABOREX UGANDA LIMITED	ORATANEÂ® 20 MG	ISOTRETINOIN	20MG	DOUGLAS MANUFACTURING LIMITEDCORNER TE PAI PLACE AND CENTRAL PARK DRIVE, LINCOLN, AUCKLAND 0610 - NEW ZEALAND SWISS CAPS AG HUSENSTRASSE 35, CH-9533 KIRCHBERG (SG) - SWITZERLAND	NEW ZEALAND SWITZERLAND	ORAL SOLID ORDINARY OTHER CAPSULES	1X4X15 CAPSULE BLISTER	19/09/2022
598	NDA/MAL/HDP/1 0381	ACINO PHARMA (PTY) LTD	LABOREX UGANDA LIMITED	ORATANEÂ® 40 MG	ISOTRETINOIN	40MG	DOUGLAS MANUFACTURING LIMITEDCORNER TE PAI PLACE AND CENTRAL PARK DRIVE, LINCOLN, AUCKLAND 0610 - NEW ZEALAND SWISS CAPS AG HUSENSTRASSE 35, CH-9533 KIRCHBERG (SG) - SWITZERLAND	NEW ZEALAND	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X15.0 CAPSULE BLISTER	19/09/2022
599	NDA/MAL/HDP/1 0382	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICAL S LIMITED	PINN-TRYPTILLIN	AMITRIPTYLINE HYDROCHLORIDE	25MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	09/09/2022

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600	NDA/MAL/HDP/1 0385	XL LABORATORIES PRIVATE LIMITED-	ROYAL PHARMA 2011 LIMITED	SOFKOF	DEXTROMETHOR PHAN HYDROBROMIDE + PHENYLEPHRINE HYDROCHLORIDE + CHORPHENIRAMI NE MALEATE	10MG + 5MG + 2MG	XL LABORATORIES PRIVATE LIMITEDA- 141, EPIP INDUSTRIAL AREA, NEEMRANA, DIST. ALWAR, RAJASTHAN - 301705 (INDIA)	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	19/09/2022
601	NDA/MAL/HDP/1 0386	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	OLMAC 5	OLANZAPINE	5MG	MACLEODS PHARMACEUTICALS LIMITED, UNIT VIVILLAGE THEDA, KHARUNI LODHI MAJRA RD, TEHSIL BADDI N2, DISTRICT SOLAN, HIMACHAL PRADESH-174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022
602	NDA/MAL/HDP/1 0387	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	OLMAC 10	OLANZAPINE	10MG	MACLEODS PHARMACEUTICALS LIMITED, UNIT VIVILLAGE THEDA, KHARUNI LODHI MAJRA RD, TEHSIL BADDI N2, DISTRICT SOLAN, HIMACHAL PRADESH-174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022

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603	NDA/MAL/HDP/1 0389	EAST AFRICAN (INDIA) OVERSEAS	ROYAL PHARMA 2011 LIMITED	VIREXIM INJECTION	CEFTRIAXONE SODIUM	1G	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, 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
604	NDA/MAL/HDP/1 0390	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
605	NDA/MAL/HDP/1 0391	SANDOZ GMBH .	SURGIPHARM (U) LIMITED	HYDROXYUREA 100MG	HYDROXYCARBA MIDE	100MG	HAUPT PHARMA AMAREG GMBH- DONAUSTAUFER STRASSE 378, 93055 REGENSBURG	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X60.0 TABLET BOTTLE, 1.0X1.0X90 .0 TABLET BOTTLE, 1.0X1.0X12 0.0 TABLET BOTTLE, 1.0X200.0 TABLET BOTTLE	09/09/2022

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606	NDA/MAL/HDP/1 0392	SANDOZ GMBH .	SURGIPHARM (U) LIMITED	HYDROXYUREA 1000MG	HYDROXYCARBA MIDE	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
607	NDA/MAL/HDP/1 040	SQUARE CEPHALOSPORINS LTD	GAMA PHARMACEUTICAL S (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
608	NDA/MAL/HDP/1 0418	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	KAMAGRA CT 100	SILDENAFIL CITRATE	100 MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X4.0 TABLET BLISTER	08/02/2023

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609	NDA/MAL/HDP/1 0419	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	SITAPRIL M 50/1000	SITAGLIPTIN PHOSPHATE MONOHYDRATE + METFORMIN HYDROCHLORIDE	50 MG + 1000 MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023
610	NDA/MAL/HDP/1 042	ARISTO PHARMACEUTICAL S 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
611	NDA/MAL/HDP/1 0420	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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612	NDA/MAL/HDP/1 0421	MEGA LIFSCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	MIOPOLOL ER 50	METOPROLOL SUCCINATE	50MG	INVENTIA HEALTHCARE PVT LTD F1-F1/1 ADDITIONAL MIDC AMBERNATH (E) DIST. THANE	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023
613	NDA/MAL/HDP/1 0422	MEGA LIFSCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	MIOPOLOL ER 25	METOPROLOL SUCCINATE	25MG	INVENTIA HEALTHCARE PVT LTD F1-F1/1 ADDITIONAL MIDC AMBERNATH (E) DIST. THANE	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023
614	NDA/MAL/HDP/1 0427	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	CELMAC 400	CELECOXIB	40 MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	08/02/2023

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615	NDA/MAL/HDP/1 0428	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	AMOXI-DENK 1000	AMOXICILLIN TRIHYDRATE	1000 MG	PENCEF PHARMA GMBHBREITENBACH STRABE 13-14, 13509 BERLIN - GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	08/02/2023
616	NDA/MAL/HDP/1 0429	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	AMOXI-DENK 500	AMOXICILLIN TRIHYDRATE	500 MG	PENCEF PHARMA GMBHBREITENBACH STRABE 13-14, 13509 BERLIN - GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	08/02/2023
617	NDA/MAL/HDP/1 0430	CIPLA LIMITED.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	QUADRIMUNE	ABACAVIR + LAMIVUDINE + LOPINAVIR + RITONAVIR	30 MG + 15 MG + 40 MG +10 MG	CIPLA LIMITED, GOA (UNIT X)PLOT NO. S- 103 TO S-105, S-107 TO S-112, L-147, L- 147/1 TO L-147/3, L- 138 AND L-147/A, VERNA INDUSTRIAL ESTATE, VERNA, SALCETTE, GOA. PIN: 403722	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X120.0 CAPSULE CONTAINER	08/02/2023

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618	NDA/MAL/HDP/1 044	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ANGINET 80MG	VALSARTAN	80MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTDP.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL- RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
619	NDA/MAL/HDP/1 0441	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	PREDNOVA 5	PREDNISOLONE	5MG	BIOMATRIX HEALTHCARE PRIVATE LIMITEDSURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/02/2023
620	NDA/MAL/HDP/1 0447	PT SANBE FARMA	MEDVIN PHARMA LIMITED	TRADOSIK	TRAMADOL HYDROCHLORIDE	50 MG/ML	PT. SANBE FARMA STERILE PREPARATION PLANT - (UNIT 3)JALAN INDUSTRI CIMAREME NO. 8 DESA CIMAREME, KECAMATAN PADALARANG, KABUPATEN BANDUNG BARAT 40553 - INDONESIA	INDONESIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X1.0X5.0X2. 0 ML AMPOULE	08/02/2023

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621	NDA/MAL/HDP/1 0448	PT SANBE FARMA	MEDVIN PHARMA LIMITED	DOLONES	LIDOCAINE + PRILOCAINE	(25 MG + 25 MG)/G	PT CAPRIFARMINDO LABORATORIES ,JALAN INDUSTRI CIMAREME NO. 8 DESA CIMAREME, KECAMATAN PADALARANG, KABUPATEN BANDUNG BARAT 40553 - INDONESIA	INDONESIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X5.0 G TUBE	08/02/2023
622	NDA/MAL/HDP/1 045	SQUARE PHARMACEUTICAL S LTD	GAMA PHARMACEUTICAL S (U) LIMITED	ZIMAX 500	AZITHROMYCIN	500MG	SQUARE CEPHALOSPORINS LTDKALIAKOIR, GAZIPUR – 1750, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	01/07/2013
623	NDA/MAL/HDP/1 0450	PT SANBE FARMA	MEDVIN PHARMA LIMITED	MEFINAL 500	MEFENAMIC ACID	500 MG	PT CAPRIFARMINDO LABORATORIES ,JALAN INDUSTRI CIMAREME NO. 8 DESA CIMAREME, KECAMATAN PADALARANG, KABUPATEN BANDUNG BARAT 40553 - INDONESIA	INDONESIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	08/02/2023

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624	NDA/MAL/HDP/1 0451	GUANGZHOU WONDFO BIOTECH CO. LTD	METRO PHARMACEUTICAL S LIMITED	WAXFREE	SODIUM BICARBONATE	5%W/V	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	NASAL TOPICAL LIQUIDS	1.0X1.0X10.0 ML BOTTLE	08/02/2023
625	NDA/MAL/HDP/1 0452	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	OPTIPRED	PREDNISOLONE ACETATE	1.0% W/V	JAMJOOM PHARMACEUTICALS COMPANY - PLOT NO: ME1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 - KINGDOM OF SAUDI ARABIA	SAUDI ARABIA	OPHTHALMIC SUSPENSIONS	1.0X1.0X5.0 ML BOTTLE	08/02/2023
626	NDA/MAL/HDP/1 0455	UNIMED LABORATORIES	OMAB UGANDA LIMITED	ENOXAMED 2000 IU ANTI-XA /0.2 ML	ENOXAPARIN SODIUM	2000 IU ANTI-XA /0.2 ML (EQUIVALENT TO 20 MG PER 0.2 ML)	UNIMED LABORATORIESP.O. BOX 38 - I.Z. KALAA KEBIRA - 4060 KALAA KEBIRA - TUNISIA	TUNISIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0X2.0X0.2 ML PRE- FILLED SYRINGE	08/02/2023

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627	NDA/MAL/HDP/1 0456	UNIMED LABORATORIES	OMAB UGANDA LIMITED	ENOXAMED 4000 IU ANTI-XA /0.4 ML	ENOXAPARIN SODIUM	4000 IU ANTI-XA /0.4 ML (EQUIVALENT TO 40 MG PER 0.4 ML)	UNIMED LABORATORIESP.O. BOX 38 - I.Z. KALAA KEBIRA - 4060 KALAA KEBIRA - TUNISIA	TUNISIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0X2.0X0.4 ML PRE- FILLED SYRINGE	08/02/2023
628	NDA/MAL/HDP/1 0457	UNIMED LABORATORIES	OMAB UGANDA LIMITED	ENOXAMED 6000 IU ANTI-XA /0.6 ML	ENOXAPARIN SODIUM	6000 IU ANTI-XA /0.6 ML (EQUIVALENT TO 60 MG PER 0.6 ML)	UNIMED LABORATORIESP.O. BOX 38 - I.Z. KALAA KEBIRA - 4060 KALAA KEBIRA - TUNISIA	TUNISIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0X2.0X0.4 ML PRE- FILLED SYRINGE	08/02/2023
629	NDA/MAL/HDP/1 0458	UNIMED LABORATORIES	OMAB UGANDA LIMITED	ENOXAMED 8000 IU ANTI-XA /0.8 ML	ENOXAPARIN SODIUM	8000 IU ANTI-XA /0.8 ML (EQUIVALENT TO 80 MG PER 0.8 ML)	UNIMED LABORATORIESP.O. BOX 38 - I.Z. KALAA KEBIRA - 4060 KALAA KEBIRA - TUNISIA	TUNISIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0X2.0X0.4 ML PRE- FILLED SYRINGE	08/02/2023

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630	NDA/MAL/HDP/1 0459	UNIMED LABORATORIES	OMAB UGANDA LIMITED	PARAMED	PARACETAMOL	1G/100ML	UNIMED LABORATORIES P.O. BOX 38 - I.Z. KALAA KEBIRA - 4060 KALAA KEBIRA - TUNISIA	TUNISIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X6.0X1.0X100.0 ML BAG	08/02/2023
631	NDA/MAL/HDP/1 0460	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	AERIALLERG 5MG	DESLORATIDINE	5 MG	PHARMA INTERNATIONAL CO. LTD AL QASTAL AIRPORT ROAD, P.O. BOX 334 AL JUBAIHA 11941, AMAAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023
632	NDA/MAL/HDP/1 0461	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	AERIALLERG 0.5MG/ML	DESLORATIDINE	0.5MG/ML	PHARMA INTERNATIONAL CO. LTD AL QASTAL AIRPORT ROAD, P.O. BOX 334 AL JUBAIHA 11941, AMAAN	JORDAN	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X125.0 ML BOTTLE	08/02/2023

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633	NDA/MAL/HDP/1 0462	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
634	NDA/MAL/HDP/1 0463	FAES FARMA S.A	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DISFOR	METHOCARBAMOL	500 MG	FAES FARMA SAMAXIMO AGUIRRE 14. 48940 LEIOA – SPAIN	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	08/02/2023
635	NDA/MAL/HDP/1 0464	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN 4 FLU TABLETS	DIPHENHYDRAMINE + PARACETAMOL + PSEUDOEPHEDRINE	12.5MG + 500MG + 22.5MG	SPECGX LLC100 LOUIS LATZER DRIVE, GREENVILLE, ILLINOIS, 62246 - UNITED STATES OF AMERICA JOHNSON & JOHNSON (PTY) LTD241 MAIN ROAD, RETREAT, 7945, CAPE TOWN	UNITED STATES SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X12.0 TABLET BLISTER	08/02/2023

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636	NDA/MAL/HDP/1 0466	ARCELIA LIFE SCIENCES LTD.	NOVOMED HEALTHCARE 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
637	NDA/MAL/HDP/1 0468	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CORTIRIV-100	HYDROCORTISON E SODIUM SUCCINATE	100 MG/VIAL	EAST AFRICAN (INDIA) OVERSEASPLOT 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
638	NDA/MAL/HDP/1 047	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EXOFEN 180MG	FEXOFENADINE	180MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTDP.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL- RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X15.0 TABLET BLISTER	01/07/2013

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639	NDA/MAL/HDP/1 0472	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	TRAMADOL HYDROCHLORIDE INJECTION 100 MG/2ML	TRAMADOL HYDROCHLORIDE	100 MG/2 ML	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0X2.0 ML AMPOULE	08/02/2023
640	NDA/MAL/HDP/1 0473	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	POLYMOL SUSPENSION 125MG/5ML.	PARACETAMOL	125MG/5ML.	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE, 1.0X60.0ML BOTTLE	08/02/2023
641	NDA/MAL/HDP/1 0474	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	POLYMOL EXTRA	PARACETAMOL + CAFFEINE	500 MG + 30 MG	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/02/2023

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642	NDA/MAL/HDP/1 0477	CENTURION LABORATORIES PVT. LTD.	SHREEJI PHARMACEUTICAL S LIMITED	PENACAM	PIROXICAM	20 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	08/02/2023
643	NDA/MAL/HDP/1 0483	NVS KENYA LTD	SURGIPHARM (U) LIMITED	PATIZRA	RANIBIZUMAB	10 MG/ML	NOVARTIS PHARMA STEIN AG STERILE OPERATIONS SOLID OPERATIONSNOVAR TIS PHARMA STEIN AG SCHAFFHAUSER STRA SSE, 4332 STEIN - SWITZERLAND	SWITZERLAND	PARENTERAL ORDINARY VIALS	1.0X1.0X0.23 ML VIAL	08/02/2023
644	NDA/MAL/HDP/1 0484	INDIANA OPHTHALMICS	SWASTIK PHARMACEUTICAL LTD	TETROP	TETRACYCLINE HYDROCHLORIDE	1%W/W	INDIANA OPHTHALMICS 135, 136, 137, GIDC ESTATE, WADHWAN- 363035	INDIA	OPHTHALMIC OINTMENTS	1.0X1.0X5.0 G TUBE	08/02/2023

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645	NDA/MAL/HDP/1 0485	ESKAYEF PHARMACEUTICAL S LTD.	SWASTIK PHARMACEUTICAL LTD	RIVAROX 15	RIVAROXABAN	15 MG	ESKAYEF BANGLADESH LTD- 400, TONGI INDUSTRIAL AREA, SQUIB ROAD TONGI- GAZIPUR BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	08/02/2023
646	NDA/MAL/HDP/1 0486	ESKAYEF PHARMACEUTICAL S LTD.	SWASTIK PHARMACEUTICAL LTD	RIVAROX 20	RIVAROXABAN	20 MG	ESKAYEF BANGLADESH LTD- 400, TONGI INDUSTRIAL AREA, SQUIB ROAD TONGI- GAZIPUR BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	08/02/2023
647	NDA/MAL/HDP/1 0488	ESKAYEF PHARMACEUTICAL S LTD.	SWASTIK PHARMACEUTICAL LTD	GTN 2.6 SR	DILUTED NITROGLYCERIN	2.6 MG	ESKAYEF BANGLADESH LTD- 400, TONGI INDUSTRIAL AREA, SQUIB ROAD TONGI- GAZIPUR BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	08/02/2023

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648	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
649	NDA/MAL/HDP/10492	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	DOLUTEGRAVIR SODIUM TABLETS 50 MG	DOLUTEGRAVIR SODIUM	50 MG	MACLEODS PHARMACEUTICALS LIMITED, UNIT II PLOT 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
650	NDA/MAL/HDP/10493	CENTURION LABORATORIES PVT. LTD.	SHREEJI PHARMACEUTICALS LIMITED	ROUNOX	TRAMADOL HYDROCHLORIDE	50 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIOTECH PARK, MANJUSAR, TALSAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	08/02/2023

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651	NDA/MAL/HDP/1 0496	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	IRIS SYRUP	DES Loratadine	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
652	NDA/MAL/HDP/1 050	INTAS PHARMACEUTICAL S LIMITED	NORVIK ENTERPRISES LIMITED	AMTAS-10	AMLODIPINE	10MG	INTAS PHARMACEUTICALS LTD PLOT 457/458, SARKHEJ BAVLA HIGHWAY MATODA 382 210 TAL: SANAND, AHMEDABAD, INDIA INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI- 248197, DEHRADUN (UTTARAKHAND)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER, 10.0X10.0 TABLET BLISTER	01/07/2013
653	NDA/MAL/HDP/1 0503	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	HI-ALFA SR 10	ALFUZOSIN HYDROCHLORIDE	10MG	AUROBINDO PHARMA LIMITED UNIT 3 PLOT NO. 313, 314, BACHUPALLY, RR DIST. 500090	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023

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654	NDA/MAL/HDP/1 0505	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	OPTOR EYE DROPS	KETOROLAC TROMETHAMINE	0.5%W/V	ABACUS PARENTERAL DRUGS LIMITED PLOT 114, BLOCK 191, KINGA	UGANDA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML BOTTLE	08/02/2023
655	NDA/MAL/HDP/1 0507	AUROLAB	SWASTIK PHARMACEUTICAL LTD	TOB - DEX	TOBRAMYCIN SULFATE + DEXAMETHASON E SODIUM PHOSPHATE	0.3%W/V + 0.1%W/V	AUROLAB .NO. 1, SIVAGANGAI MAIN ROAD, VEERAPANJANI, MADURAI 1 - 625 020	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	08/02/2023
656	NDA/MAL/HDP/1 0508	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	FIMABUTE-100	CEFIXIME TRIHYDRATE	100MG/5ML	BRAWN LABORATORIES LIMITED 13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X60.0 ML BOTTLE	08/02/2023

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657	NDA/MAL/HDP/1 0511	VRUSHIK INVESTMENT (U) LTD.	SHREEJI PHARMACEUTICAL S LIMITED	METO	METOCLOPRAMI DE 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
658	NDA/MAL/HDP/1 0519	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 CIMAHI SELATAN, KOTA CIMAHI 40553 INDONESIA	INDONESIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	08/02/2023
659	NDA/MAL/HDP/1 052	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	MICLOGEN	MICONAZOLE NITRATE+CLOBET ASOLE PROPIONATE+GE NTAMICIN SULPHATE	2.0%W/W+0.05% W/W+0.1W/W	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2013

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660	NDA/MAL/HDP/1 0523	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICAL S 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
661	NDA/MAL/HDP/1 053	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOXIN-125 DT	AMOXICILLIN	125MG	MILAN LABORATORIES (INDIA) PVT LTD .PLOTS 63,67,87,35,36,64,6 5, 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, 1.0X10.0X1 0.0 TABLET BLISTER	01/07/2013
662	NDA/MAL/HDP/1 0530	ZOTA HEALTHCARE LTD	HARLEYS UGANDA LIMITED	COXZOTA 120	ETORICOXIB	120MG	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	08/02/2023

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663	NDA/MAL/HDP/1 0531	GLAXOSMITHKLINE LIMITED-	UNITED HEALTHCARE DISTRIBUTORS LTD	ENO CALCIUM ANTACID TABLETS	CALCIUM CARBONATE	500MG	GLAXOSMITHKLINE LIMITEDLIKONI ROAD, INDUSTRIAL AREA, P.O. BOX 78392-00507, VIWANDANI, NAIROBI GLAXOSMITHKLINE CONSUMER HEALTHCARE HOLDINGS (US) LLC320 SOUTH BROADWAY ST. LOUIS, MISSOURI, 63102 - UNITED	KENYA UNITED STATES	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X2.0X10 .0 TABLET BLISTER	08/02/2023
664	NDA/MAL/HDP/1 0532	ALKEM LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	TAXIM-O	CEFIXIME TRIHYDRATE	400MG	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X5.0 CAPSULE BLISTER	08/02/2023
665	NDA/MAL/HDP/1 0535	FERRER INTERNATIONAL, S.A.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	ANGINOVAG	DEQUALINIUM CHLORIDE + TYROTHRICIN + B GLYCYRRHETINIC 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

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666	NDA/MAL/HDP/1 0536	KLM LABORATORIES PVT. LTD.	REDDYS PHARMA LIMITED	MUPISOFT OINTMENT	MUPIROCIN	2.0% W/W	CURETECH SKINCAREPLOT NO. 33 & 34, PHASE IV, BHATOLI KALAN, BADDI DISTT. SOLAN (HP) 173205	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X5.0 G TUBE, 1.0X1.0X15.0 G TUBE	08/02/2023
667	NDA/MAL/HDP/1 0537	KLM LABORATORIES PVT. LTD.	REDDYS PHARMA LIMITED	NIOSOL OINTMENT	CLOBETASOL PROPIONATE	0.05%W/W	CURETECH SKINCAREPLOT NO. 33 & 34, PHASE IV, BHATOLI KALAN, BADDI DISTT. SOLAN (HP) 173205	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X30.0 G TUBE	08/02/2023
668	NDA/MAL/HDP/1 0538	KLM LABORATORIES PVT. LTD.	REDDYS PHARMA LIMITED	SUDIF CREAM	FUSIDIC ACID	2.0 %W/W	CURETECH SKINCAREPLOT NO. 33 & 34, PHASE IV, BHATOLI KALAN, BADDI DISTT. SOLAN (HP) 173205	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X10.0 G TUBE	08/02/2023

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669	NDA/MAL/HDP/1 0539	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
670	NDA/MAL/HDP/1 054	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AZ-250	AZITHROMYCIN	250MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X6.0 CAPSULE BLISTER	01/07/2011
671	NDA/MAL/HDP/1 0540	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICAL S LTD	ATAZANAVIR AND RITONAVIR TABLETS	ATAZANAVIR SULFATE + RITONAVIR	300MG + 100MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE	08/02/2023

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672	NDA/MAL/HDP/1 0544	AUROLAB	SWASTIK PHARMACEUTICAL LTD	ATROP	ATROPINE SULFATE	1%W/V	AUROLAB LIMITEDNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU INDIA	BRAZIL	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	08/02/2023
673	NDA/MAL/HDP/1 0545	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	BRAMOL	PARACETAMOL	10MG/ML	BROOKES PHARMA (PRIVATE) LIMITED58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML VIAL	08/02/2023
674	NDA/MAL/HDP/1 0551	SANJAR PHARMA LLP.	MOTI PHARMA (UGANDA) LIMITED	ADRENLIN	ADRENALINE ACID TARTRATE	1MG	SANJAR PHARMA LLPSURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0X1.0 MG AMPOULE	08/02/2023

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675	NDA/MAL/HDP/1 0552	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
676	NDA/MAL/HDP/1 0553	ACINO AG.	LABOREX UGANDA LIMITED	TITANAFIL 5	TADALAFIL	5MG	PHARMACTIVE ILAC SAN. VE TIC. A.S.CERKEZKOY ORGANIZE SANAYI BOLGESI KARAAGAC MAH. FATIH BULV. NO: 32 KAPAKLI/TEKIRDAG - 2820133250 - TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	08/02/2023
677	NDA/MAL/HDP/1 0554	ACINO AG	LABOREX UGANDA LIMITED	TITANAFIL 20	TADALAFIL	20MG	PHARMACTIVE ILAC SAN. VE TIC. A.S.CERKEZKOY ORGANIZE SANAYI BOLGESI KARAAGAC MAH. FATIH BULV. NO: 32 KAPAKLI/TEKIRDAG - 2820133250 - TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	08/02/2023

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678	NDA/MAL/HDP/1 0557	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	LOFNAC-50	DICLOFENAC SODIUM	50MG	BLISS GVS PHARMA LIMITED10,11 & 12,DEWAN UDYOG NAGAR,ALIYALI,PAL GHAR,MAHARASHTR A 401404,INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	08/02/2023
679	NDA/MAL/HDP/1 0558	KLM LABORATORIES PVT. LTD.	REDDYS PHARMA LIMITED	NEOCLEAN GEL	CLINDAMYCIN PHOSPHATE + NICOTINAMIDE	1.0 %W/W + 4.0%W/W	CURETECH SKINCAREPLOT NO. 33 & 34, PHASE IV, BHATOLI KALAN, BADDI DISTT. SOLAN (HP) 173205	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X1.0X10.0 G TUBE	08/02/2023
680	NDA/MAL/HDP/1 0559	KLM LABORATORIES PVT. LTD.	REDDYS PHARMA LIMITED	NIOSALIC OINTMENT	CLOBETASOL PROPIONATE + SALICYLIC ACID	0.05%W/W + 3.00W/W	CURETECH SKINCAREPLOT NO. 33 & 34, PHASE IV, BHATOLI KALAN, BADDI DISTT. SOLAN (HP) 173205	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X30.0 G TUBE, 1.0X1.0X20.0 G TUBE	08/02/2023

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681	NDA/MAL/HDP/1 056	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOVATE-N OINTMENT	BETAMETHASONE + NEOMYCIN	0.1%W/W + 0.5% W/W	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X15.0 G TUBE	01/07/2013
682	NDA/MAL/HDP/1 0561	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	WORIV	ALBENDAZOLE	400MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X1.0 TABLET BLISTER	08/02/2023
683	NDA/MAL/HDP/1 0562	EAST AFRICAN (INDIA) OVERSEAS	ROYAL PHARMA 2011 LIMITED	ACESON-P	ACECLOFENAC + PARACETAMOL	100MG + 500MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	08/02/2023

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684	NDA/MAL/HDP/1 0565	AUROLAB	SWASTIK PHARMACEUTICAL LTD	PILO	PILOCARPINE NITRATE	2%W/V	AUROLAB .NO. 1, SIVAGANGAI MAIN ROAD, VEERAPANJANI, MADURAI 1 - 625 020	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	08/02/2023
685	NDA/MAL/HDP/1 0566	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROCARPINE	PILOCARPINE NITRATE	0.5%W/V	AUROLAB .NO. 1, SIVAGANGAI MAIN ROAD, VEERAPANJANI, MADURAI 1 - 625 020	INDIA	OPHTHALMIC DROPS	1.0X5.0X1.0 ML VIAL	08/02/2023
686	NDA/MAL/HDP/1 0567	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CELMAC 200	CELECOXIB	200MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	08/02/2023

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687	NDA/MAL/HDP/1 0568	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	AMADAY PL 5/4	AMLODIPINE BESILATE + PERINDOPRIL ERBUMINE	5 MG + 4 MG	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023
688	NDA/MAL/HDP/1 0569	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	AMADAY PL 5/8	AMLODIPINE BESILATE + PERINDOPRIL ERBUMINE	5MG + 8MG	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023
689	NDA/MAL/HDP/1 057	NECTAR LIFSCIENCES LTD	SUPER MEDIC LTD	FIXINECT-200MG	CEFIXIME	200MG	NECTAR LIFE SCIENCES LTD-VILL. BHATOLIKALAN, ADJOINING JHARMJRI, E.P.I.P TEL. NALAGARH, DISTT. SOLAN, H.P.-173205 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2013

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690	NDA/MAL/HDP/1 0570	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	AMADAY PL 10/4	AMLODIPINE BESILATE + PERINDOPRIL ERBUMINE	10 MG + 4 MG	NALAGARH, DISTT. SOLAN, H.P.-173205 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023
691	NDA/MAL/HDP/1 0571	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	AMADAY PL 10/8	AMLODIPINE BESILATE + PERINDOPRIL ERBUMINE	10MG + 8MG	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023
692	NDA/MAL/HDP/1 0572	MEGA LIFSCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	NAT-B FORTE	THIAMINE MONONITRATE (VITAMIN B1) + PYRIDOXINE HYDROCHLORIDE (VITAMIN B6) + METHYLCOBALA MIN (VITAMIN B12) + FOLIC ACID + D-ALPHA- TOCOPHEROL ACETATE + VITAMIN A + VITAMIN D3 + COPPER	100 MG + 200 MG + 500 MCG + 200 MCG + 200 IU + 5000 IU + 400 IU + 1.0 MG + 0.20 MG + 15.0 MG	MEGA LIFSCIENCES PUBLIC CO. LTDPLANT 1; 384 MOO 4, SOI 6, BANGPOO INDUSTRIAL ESTATE, PATTANA 3 ROAD, PHRAEKSA, MUEANG, SAMUTPRAKARN 10280 THAILAND	THAILAND	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	08/02/2023

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693	NDA/MAL/HDP/1 0578	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	OCORTIN	HYDROCORTISON E	1%W/W	KREMOINT PHARMA PVT LTD. B-8, ADDITIONAL AMBERNATH M.I.D.C, OPP. ANAND NAGIAR POLICE CHECK POST, AMBERNATH (E), DIST. THANE.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	08/02/2023
694	NDA/MAL/HDP/1 0579	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	BENZYL BENZOATE APPLICATION BP	BENZYL BENZOATE	25%W/V	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	TOPICAL EXTERNAL EMULSIONS	1.0X100.0 ML BOTTLE	08/02/2023
695	NDA/MAL/HDP/1 0597	MEDISEL(K) LTD	SUPER MEDIC LTD	GABANERVE	GABAPENTIN + METHYLCOBALA MIN	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

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696	NDA/MAL/HDP/1 0600	MEDISEL(K) LTD	AIVEEN (U) LIMITED	OSTEOCERIN	GLUCOSAMINE SULPHATE POTASSIUM CHLORIDE + METHL SULPHONYL METHANE (MSM) + DIACEREIN	750MG + 250MG + 50MG	CORONA REMEDIES PVT. LTDVILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	15/02/2023
697	NDA/MAL/HDP/1 0604	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	PIPERATAZ 4.5	PIPERACILLIN + TAZOBACTAM	4 G + 0.5 G	UNI MEDICOLABSUNI MEDICOLABS, PLOT NO. 21-22, PHARMACITY, SELAQUI, DEHRADUN - 248011	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X4.5 G VIAL	15/02/2023
698	NDA/MAL/HDP/1 0606	MEDISEL(K) LTD	AIVEEN (U) LIMITED	EMADON SYRUP	ONDANSETRON HYDROCHLORIDE	2MG/5ML	CORONA REMEDIES PVT. LTDVILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X30.0 ML BOTTLE	15/02/2023

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699	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
700	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
701	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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702	NDA/MAL/HDP/1 0615	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	LEVOZIN 5	LEVOCETIRIZINE DIHYDROCHLORID E	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
703	NDA/MAL/HDP/1 0616	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
704	NDA/MAL/HDP/1 0617	COSMOS LTD.	ASTRA PHARMA (U) LIMITED	GLYSIT 10	DAPAGLIFLOZIN	10MG	COSMOS LTD..RANGWE ROAD OFF, LUNA LUNGA ROAD, INDUSTRIAL AREA - NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	15/02/2023

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705	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
706	NDA/MAL/HDP/10619	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	DEXIREN	DEKXETOPROFEN 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
707	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

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708	NDA/MAL/HDP/1 0621	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	PENIREN	PHENOXYMETHYL PENICILLIN POTASSIUM	250MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	15/02/2023
709	NDA/MAL/HDP/1 0622	CENTURION LABORATORIES PVT. LTD.	SHREEJI PHARMACEUTICAL S LIMITED	PANTOPRAM 40	PANTOPRAZOLE SODIUM SESQUIHYDRATE	40 MG	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
710	NDA/MAL/HDP/1 0623	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	STERIREN	CHLORHEXIDINE GLUCONATE	5% W/V	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X5.0 L CONTAINER	15/02/2023

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711	NDA/MAL/HDP/1 0625	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	ESOGRESS 40	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40 MG	STANFORD LABORATORIES PRIVATE LIMITED (A SUBSIDIARY COMPANY OF LA RENON HEALTHCARE PRIVATE LIMITED)8, INDUSTRIAL AREA, MEHATPUR - 174315, HIMACHAL PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
712	NDA/MAL/HDP/1 0631	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICAL S LTD	RYALTRIS	OLOPATADINE HYDROCHLORIDE + MOMETASONE FUROATE	665 MCG/25 MCG	GLENMARK PHARMACEUTICALS LIMITED-UNIT 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
713	NDA/MAL/HDP/1 0634	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROFLU-CARE	PARACETAMOL + CAFFEINE + CHLORPHENIRAM INE MALEATE + PHENYLEPHRINE HYDROCHLORIDE	500MG + 30MG + 2MG + 10MG	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X6.0 TABLET BLISTER, 1.0X50.0X4.0 TABLET BLISTER,	15/02/2023

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714	NDA/MAL/HDP/1 0637	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	SETRIZIN	CETIRIZINE	10MG	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	15/02/2023
715	NDA/MAL/HDP/1 0640	FAES FARMA S.A	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DISTEM	METHOCARBAMO L + PARACETAMOL	380 MG + 300 MG	FAES FARMA SAMAXIMO AGUIRRE 14. 48940 LEIOA – SPAIN	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	15/02/2023
716	NDA/MAL/HDP/1 0649	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	ESOCID 40	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

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717	NDA/MAL/HDP/1 065	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	SLIPIZEM-5	DIAZEPAM	5MG	BLISS GVS PHARMA LIMITEDNO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	RECTAL SYSTEMIC ADULT SUPPOSITORIES	1.0X5.0 SUPPOSITORY BLISTER	01/07/2007
718	NDA/MAL/HDP/1 0652	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	Z-OFLOX 200	OFLOXACIN	200MG	ZOTA HEATHCARE LIMITEDPLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NEAR SACHIN RAILWAY STATION, SACHIN, CITY: SURAT, DIST: SURAT, GUJARAT STATE - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	15/02/2023
719	NDA/MAL/HDP/1 0653	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	COXZOTA-60	ETORICOXIB	60MG	ZOTA HEATHCARE LIMITEDPLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NEAR SACHIN RAILWAY STATION, SACHIN, CITY: SURAT, DIST: SURAT, GUJARAT STATE - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

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720	NDA/MAL/HDP/1 0654	ALTHEA PHARMA PVT LTD.	JOINT MEDICAL STORE (UPMB - UCMB)	COMPOUND SODIUM LACTATE INTRAVENOUS INFUSION	SODIUM LACTATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE + CALCIUM CHLORIDE	0.320%W/V + 0.600%W/V + 0.040%W/V + 0.027%W/V	ALTHEA PHARMA PRIVATE LIMITEDWORKS: PLOT NO. 374, SHED NO. 'E', ALPHA INDL. PARK, ATHIAWAD, DABHEL, NANI DAMAN - 396210 (U.T.), INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	15/02/2023
721	NDA/MAL/HDP/1 0660	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	AZITZOZ-250	AZITHROMYCIN DIHYDRATE	250MG	ZOTA HEATHCARE LIMITEDPLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NEAR SACHIN RAILWAY STATION, SACHIN, CITY: SURAT, DIST: SURAT, GUJARAT STATE - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	15/02/2023
722	NDA/MAL/HDP/1 0661	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	LIVOTA-750	LEVOFLOXACIN HEMIHYDRATE	750MG	ZOTA HEATHCARE LIMITEDPLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NEAR SACHIN RAILWAY STATION, SACHIN, CITY: SURAT, DIST: SURAT, GUJARAT STATE - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	15/02/2023

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723	NDA/MAL/HDP/1 0662	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	TOMOZA	MOSAPRIDE CITRATE DIHYDRATE	5MG	ZOTA HEATHCARE LIMITEDPLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NEAR SACHIN RAILWAY STATION, SACHIN, CITY: SURAT, DIST: SURAT, GUJARAT STATE - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
724	NDA/MAL/HDP/1 0663	FERRER INTERNATIONAL, S.A.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TRAMAPA 37.5 MG/325 MG	TRAMADOL HYDROCHLORIDE + PARACETAMOL	37.5 MG/325 MG	FERRER INTERNATIONAL, S.AC/ JOAN BUSCALLA, 1-9 08173 SANT CUGAT DEL VALLES,	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	15/02/2023
725	NDA/MAL/HDP/1 0664	FDC LTD	AIVEEN (U) LIMITED	OCUDORT-T	DORZOLAMIDE HYDROCHLORIDE + TIMOLOL MALEATE	(20 MG + 5 MG)/ML	FDC LIMITED, WALUJ .PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	15/02/2023

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726	NDA/MAL/HDP/1 0668	LUPIN LIMITED	AIVEEN (U) LIMITED	DOLUTEGRAVIR SODIUM/LAMIVU DINE/TENOFOVIR DISOPROXIL FUMERATE 50MG/300MG/30 0MG	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFVIR 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
727	NDA/MAL/HDP/1 067	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	IBUPARA	IBUPROFEN+PAR ACETAMOL	200MG+ 250MG/10ML	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2010
728	NDA/MAL/HDP/1 0673	EAST AFRICAN (INDIA) OVERSEAS	ROYAL PHARMA 2011 LIMITED	CETARIV	CETIRIZINE HYDROCHLORIDE	5MG/5ML	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE	15/02/2023

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729	NDA/MAL/HDP/1 0678	KESAR PHARMA	ABACUS PHARMA (AFRICA) LIMITED	ARTELUM	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	KESAR PHARMA PVT LTD PLOT SURVEY NO. 50/2. VILLAGE BILSHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X24.0 TABLET BLISTER	15/02/2023
730	NDA/MAL/HDP/1 0679	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	PG-75	PREGABALIN	75 MG	ZOTA HEALTHCARE LIMITED PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY STATION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER	15/02/2023
731	NDA/MAL/HDP/1 0688	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	UROKA	DUTASTERIDE	0.5 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	1.0X3.0X10.0 CAPSULE BLISTER	15/02/2023

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732	NDA/MAL/HDP/1 0689	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	LOSARZED-100	LOSARTAN POTASSIUM	100 MG	ZOTA HEALTHCARE LIMITED PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY STATION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
733	NDA/MAL/HDP/1 069	CIRON DRUGS & PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	K-ONE INJECTION	PHYTOMENADIO NE	10MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X1.0 ML AMPOULE	01/07/2014
734	NDA/MAL/HDP/1 0690	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	PROTAC-40	PANTOPRAZOLE SODIUM	40 MG	SUNRISE INTERNATIONAL LABS LTD PLOT NO. 100, LANE-5, SECTOR-II, PHASE-II, IDA, CHERLAPALLY INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

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735	NDA/MAL/HDP/1 0691	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEUROGLOPENTI N 400 MG	GABAPENTIN	400MG	GLOBAL NAPI PHARMACEUTICALS- 2ND INDUSTRIAL ZONE, ST 18, 6TH OCTOBER CITY	EGYPT	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	15/02/2023
736	NDA/MAL/HDP/1 0692	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEUROGLOPENTI N 300 MG	GABAPENTIN	300MG	GLOBAL NAPI PHARMACEUTICALS- 2ND INDUSTRIAL ZONE, ST 18, 6TH OCTOBER CITY	EGYPT	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	15/02/2023
737	NDA/MAL/HDP/1 0696	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	CELEBIB CAPSULES 200MG	CELECOXIB	200MG	MACLEODS PHARMACEUTICALS LIMITED, UNIT VIVILLAGE THEDA, KHARUNI LODHI MAJRA RD, TEHSIL BADDI N2, DISTRICT SOLAN, HIMACHAL PRADESH-174101	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	15/02/2023

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738	NDA/MAL/HDP/1 0697	BHARAT SERUMS & VACCINES LTD.	ABACUS PHARMA (AFRICA) LIMITED	ASPORELIX	CETRORELIX ACETATE	0.25MG	BHARAT SERUM AND VACCINES LIMITEDPLOT NO. K- 27 ADDITIONAL M.I.D.C INDIA	INDIA	PARENTERAL ORDINARY I V VIALS	1.0X0.25 MG VIAL + 1*1ML GLASS AMPOULE OF WFI	15/02/2023
739	NDA/MAL/HDP/1 0706	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	NTSUGA 500	METFORMIN HYDROCHLORIDE	500 MG	BIOMATRIX HEALTHCARE PRIVATE LIMITEDSURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
740	NDA/MAL/HDP/1 0707	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	ZOPIMAC 3	ESZOPICLONE	3MG	MACLEODS PHARMACEUTICALS LIMITED, UNIT VIVILLAGE THEDA, KHARUNI LODHI MAJRA RD, TEHSIL BADDI N2, DISTRICT SOLAN, HIMACHAL PRADESH-174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X100.0 TABLET CONTAINER	15/02/2023

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741	NDA/MAL/HDP/1 0708	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	CAFENOL	ACETYLSALICYLIC ACID + CAFFEINE	375MG + 25MG	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO. LR 209/6554, MOGADISHU ROAD INDUSTRIAL AREA, NAIROBI KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X8.0X20.0 TABLET BLISTER	15/02/2023
742	NDA/MAL/HDP/1 0709	CADILA HEALTHCARE LIMITED "ZYDUS TOWER" -	ABACUS PHARMA (AFRICA) LIMITED	VINGLYN M 50/850	VILDAGLIPTIN + METFORMIN HYDROCHLORIDE	50 MG + 850 MG	EAST AFRICAN (INDIA) 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
743	NDA/MAL/HDP/1 0710	CADILA HEALTHCARE LIMITED;	ABACUS PHARMA (AFRICA) LIMITED	OXALGIN GEL	DICLOFENAC DIETHYLAMINE+ METHYL SALICYLATE + VIRGIN LINSEED OIL + CAPSAICIN + RACEMETHOL	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, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X1.0X30.0 G TUBE	15/02/2023

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744	NDA/MAL/HDP/1 0712	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
745	NDA/MAL/HDP/1 0715	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	VILDARIL M 50/500	VILDAGLIPTIN + METFORMIN HYDROCHLORIDE	50 MG + 500MG	AJANTA PHARMA LIMITEDPLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT- 392130	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
746	NDA/MAL/HDP/1 0716	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	VILDARIL M 50/850	VILDAGLIPTIN + METFORMIN HYDROCHLORIDE	50 MG + 850 MG	AJANTA PHARMA LIMITEDPLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT- 392130	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

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747	NDA/MAL/HDP/1 0717	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	VILDARIL M 50/1000	VILDAGLIPTIN + METFORMIN HYDROCHLORIDE	50 MG + 1000 MG	AJANTA PHARMA LIMITEDPLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT- 392130	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
748	NDA/MAL/HDP/1 0719	HETERO LABS LTD	AIVEEN (U) LIMITED	GOAB 5	SOLIFENACIN SUCCINATE	5 MG	M/S. ANNORA PHARMA PRIVATE LIMITEDSY. NO. 261, ANNARAM VILLAGE, GUMMADIDALA MANDAL, SANGAREDDY DISTRICT, TELENGANA STATE – 502313, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
749	NDA/MAL/HDP/1 072	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CO-ANGINET 80/12.5MG	VALSARTAN + HYDROCHLOROT HIAZIDE	80MG + 12.5MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD .57 UBAYBIN MUAATH STREET AL RAGEEM- SAHAB, AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013

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750	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
751	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
752	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

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753	NDA/MAL/HDP/1 0724	MERIDIAN ENTERPRISES PRIVATE LIMITED.	VIDA AFRICA LTD	MONIZOL 3	MICONAZOLE NITARATE	400MG	MERIDIAN ENTERPRISES PVT. LTD-PLOT NO. 418, G.I.D.C.,KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	VAGINAL SUPPOSITORIES	1X1X3 PESSARY SACHET	20/09/2023
754	NDA/MAL/HDP/1 0725	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BESICOR 2.5	BISOPROLOL FUMARATE	2.5MG	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
755	NDA/MAL/HDP/1 0726	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BESICOR 5	BISOPROLOL FUMARATE	5MG	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

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756	NDA/MAL/HDP/1 0727	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BESICOR 10	BISOPROLOL FUMARATE	10MG	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
757	NDA/MAL/HDP/1 0728	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	RAPI-COOL	CHOLINE SALICYLATE + LIDOCAINE HYDROCHLORIDE	8.70% W/W + 2.00% W/W	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X10.0 G TUBE	15/02/2023
758	NDA/MAL/HDP/1 0729	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	BRISCORIL	SALBUTAMOL SULPHATE + BROMHEXINE HYDROCHLORIDE + GUAIFENESIN	(1MG + 2MG + 50MG) PER 5ML	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	15/02/2023

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759	NDA/MAL/HDP/1 074	NECTAR LIFESCIENCES LTD	SUPER MEDIC LTD	CEFJAXIT	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
760	NDA/MAL/HDP/1 0742	CADILA HEALTHCARE LIMITED "ZYDUS TOWER" -	ABACUS PHARMA (AFRICA) LIMITED	VINGLYN	VILDAGLIPTIN	50 MG	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
761	NDA/MAL/HDP/1 0743	CADILA HEALTHCARE LIMITED "ZYDUS TOWER" -	ABACUS PHARMA (AFRICA) LIMITED	VINGLYN M 50/500	VILDAGLIPTIN + METFORMIN HYDROCHLORIDE	50 MG + 500 MG	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

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762	NDA/MAL/HDP/1 0748	KESAR PHARMA	VEERAM HEALTHCARE (U) LIMITED	LULI CREAM	LULICONAZOLE	1% W/W	KESAR PHARMA PVT LTD PLOT SURVEY NO. 50/2. VILLAGE BILSHWARPURA CHHATRAL - 382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X10.0 G TUBE	15/02/2023
763	NDA/MAL/HDP/1 0750	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	RESTOCIN PLUS	PARACETAMOL + DEXTROMETHOR PHAN HYDROBROMIDE + PHENYLEPHRINE HYDROCHLORIDE + CHORPHENIRAMI NE MALEATE	500 MG + 15 MG + 10 MG + 2 MG	LINCOLN PHARMACEUTICALS LTD 10, 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
764	NDA/MAL/HDP/1 0753	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	HISTALIN 8	BETAHISTINE DIHYDROCHLORID E	8 MG	LINCOLN PHARMACEUTICALS LTD 10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

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765	NDA/MAL/HDP/1 0754	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	HISTALIN 16	BETAHISTINE DIHYDROCHLORID E	16 MG	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
766	NDA/MAL/HDP/1 0755	NEXT WAVE (INDIA)	DAVIMED PHARMA LIMITED	ZADYCINE-250	AZITHROMYCIN DIHYDRATE	250 MG	NEXT WAVERAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	15/02/2023
767	NDA/MAL/HDP/1 0756	NEXT WAVE (INDIA)	DAVIMED PHARMA LIMITED	DAVIGRA 100	SILDENAFIL CITRATE	100 MG	NEXT WAVERAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X1.0 TABLET BLISTER	15/02/2023

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768	NDA/MAL/HDP/1 0757	NEXT WAVE (INDIA)	DAVIMED PHARMA LIMITED	ZADYCINE-500	AZITHROMYCIN DIHYDRATE	500 MG	NEXT WAVERAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	15/02/2023
769	NDA/MAL/HDP/1 0758	NEXT WAVE (INDIA)	DAVIMED PHARMA LIMITED	DAVIZOLE	ALBENDAZOLE	400 MG	NEXT WAVERAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X1.0 TABLET BLISTER	15/02/2023
770	NDA/MAL/HDP/1 076	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNICAST 4MG	MONTELUKAST SODIUM	4MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTDP.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL- RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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771	NDA/MAL/HDP/1 0760	TORQUE PHORCEAUTICALS 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
772	NDA/MAL/HDP/1 0763	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROCORT	TRIAMCINOLONE ACETONIDE	40 MG/ML	AUROLAB LIMITEDNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0X1.0 ML VIAL	15/02/2023
773	NDA/MAL/HDP/1 0764	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

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774	NDA/MAL/HDP/1 0765	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HEXGABALIN 75	PREGABALIN	75MG	GLOBAL NAPI PHARMACEUTICALS- 2ND INDUSTRIAL ZONE, ST 18, 6TH OCTOBER CITY	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	15/02/2023
775	NDA/MAL/HDP/1 0766	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TRAMA-50	TRAMADOL HYDROCHLORIDE	50MG	CACHET PHARMACEUTICAL PVT LTD.VILLAGE- THANA, NEAR BADDI, TEHSIL_NALAGARH, DIST. SOLAN, HIMACHAL PRADESH- 173205	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	15/02/2023
776	NDA/MAL/HDP/1 0768	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	NEBUNTA 5	NEBIVOLOL HYDROCHLORIDE	5 MG	AJANTA PHARMA LIMITEDPLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT- 392130	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

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777	NDA/MAL/HDP/1 0769	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMOXIREN-500	AMOXICILLIN TRIHYDRATE	500MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER, 1.0X1000.0 CAPSULE CONTAINER	15/02/2023
778	NDA/MAL/HDP/1 0776	CENTAUR PHARMACEUTICAL S PVT. LTD.	GITTOES PHARMACEUTICAL S LIMITED	LEEFLOX	LEVOFLOXACIN HEMIHYDRATE	0.5%W/V	CENTAUR PHARMACEUTICALS PVT. LTD (PLANT 1) PLOT 3,5B, 2C TIVIM INDUSTRIAL ESTATE, KARASVADA, MAPUSA, GOA 403526	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	15/02/2023
779	NDA/MAL/HDP/1 078	MICRO LABS LTD	LABOREX UGANDA LIMITED	LEVOBACT INFUSION	LEVOFLOXACIN HEMIHYDRATE	500MG	AHLCON PARENTERALS (INDIA) LTD SP-917- 918, PHASE-III BHIWADI-301019, ALWAR, RAJASTHAN	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2013

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780	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
781	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
782	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

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783	NDA/MAL/HDP/1 0806	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	LOSARZED-50	LOSARTAN POTASSIUM	50MG	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	03/05/2023
784	NDA/MAL/HDP/1 0807	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	RESTOCIN PLUS	PARACETAMOL + DEXTROMETHOR PHAN HYDROBROMIDE + CHLORPHENAMIN E MALEATE + PHENYLEPHRINE HYDROCHLORIDE	(250MG + 10MG + 2MG + 5MG) PER 5ML	LINCOLN PHARMACEUTICALS LTD .,10,12,13, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ-382721 TA: KALOL, DIST. GHANDINAGAR, GUJARAT	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	03/05/2023
785	NDA/MAL/HDP/1 0808	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	ROSUNA-10	ROSUVASTATIN CALCIUM	ROSUNA-10	ZOTA HEALTHCARE LIMITEDPLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY SATTION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	03/05/2023

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786	NDA/MAL/HDP/1 0816	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S 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
787	NDA/MAL/HDP/1 0818	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	LINFLOX	OFLOXACIN	0.3 % W/V	LINCOLN PHARMACEUTICALS LTD .,.10,12,13, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ-382721 TA: KALOL, DIST. GHANDINAGAR, GUJARAT	INDIA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML BOTTLE	03/05/2023
788	NDA/MAL/HDP/1 082	DAWA LIMITED	SUPER MEDIC LTD	DACOF PAEDIATRIC	DIPHENHYDRAMINE HYDROCHLORIDE + SODIUM CITRATE + MENTHOL	75MG + 28.5MG + 0.55MG	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2013

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789	NDA/MAL/HDP/1 0822	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
790	NDA/MAL/HDP/1 0823	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (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
791	NDA/MAL/HDP/1 0824	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (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

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792	NDA/MAL/HDP/1 0825	NOVARTIS OVERSEAS INVESTMENT	SURGIPHARM (U) LIMITED	UPERIO 50MG	SACUBITRIL + VALSARTAN	24.3MG + 25.7MG	NOVARTIS FARMA S.P.A.-NOVARTIS FARMA S.P.A. VIA PROVINCIALE SCHITO 131, 80058 TORRE ANNUNZIATA, ITALY	ITALY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	06/06/2023
793	NDA/MAL/HDP/1 0826	NOVARTIS OVERSEAS INVESTMENT	SURGIPHARM (U) LIMITED	UPERIO 100MG	SACUBITRIL + VALSARTAN	48.6MG +51.4MG	NOVARTIS FARMA S.P.A.-NOVARTIS FARMA S.P.A. VIA PROVINCIALE SCHITO 131, 80058 TORRE ANNUNZIATA, ITALY	ITALY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	06/06/2023
794	NDA/MAL/HDP/1 0827	NOVARTIS OVERSEAS INVESTMENT	SURGIPHARM (U) LIMITED	UPERIO 200MG	SACUBITRIL + VALSARTAN	97.2MG + 102.8MG	NOVARTIS FARMA S.P.A.-NOVARTIS FARMA S.P.A. VIA PROVINCIALE SCHITO 131, 80058 TORRE ANNUNZIATA, ITALY	ITALY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER	06/06/2023

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795	NDA/MAL/HDP/1 0828	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	FENOTOR 200	FENOFIBRATE	200MG	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
796	NDA/MAL/HDP/1 0829	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	FENOTOR 67	FENOFIBRATE	67 MG	TORRENT PHARMACEUTICALS LIMITED PLOT NO. Z104-106, DAHEJ SEZ PART II, TALUKA: VAGRA, DIST.: BHARUCH-392130, GUJARAT- INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	06/06/2023
797	NDA/MAL/HDP/1 083	GALPHA LABORATORIES LTD	DAWASANA PHARMACEUTICALS LTD	CHOCOFER SYRUP	IRON + FOLIC ACID	50MG + 0.5MG /5ML	GALPHA LABORATORIES LIMITED VILLAGE "A" THANA BADDI, TEHSIL BADDI SOLAN HIMACHAL PRADESH-173 205 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2013

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798	NDA/MAL/HDP/1 0830	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	MUSCUREL	THIOLCHICOSI DE	8 MG	BILIM ILAC SAN.VE TIC.A.SGEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY	TURKEY	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	06/06/2023
799	NDA/MAL/HDP/1 0831	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LASTAVIN 80	VALSARTAN	80 MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	19/06/2023
800	NDA/MAL/HDP/1 0832	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	LASTAVIN 160	VALSARTAN	160MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	06/06/2023

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801	NDA/MAL/HDP/1 0833	AUROBINDO PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	MOLNAFLU	MOLNUPIRAVIR	200MG	AUROBINDO PHARMA LIMITED, UNIT - XV PLOT NO. 17A, E BONANGI (V), PARAWADA (M), VISAKHAPATNAM DISTRICT, ANDHRA PRADESH. PIN: 531021 AUROBINDO PHARMA LIMITED UNIT 3 PLOT NO. 313, 314, BACHUPALLY, RR DIST. 500090	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X40.0 CAPSULE BOTTLE	06/06/2023
802	NDA/MAL/HDP/1 0834	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	PANSIPTIN 100	SITAGLIPTIN HYDROCHLORIDE	100MG	SAG MANUFACTURING S.LCARRETERA NACIONAL 1 KM 36, SAN AGUSTIN DEL GUADALIX, 28750, SPAIN	SPAIN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER, 1.0X2.0X14 .0 TABLET BLISTER	06/06/2023
803	NDA/MAL/HDP/1 0835	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	PANSIPTIN 50	SITAGLIPTIN HYDROCHLORIDE	50MG	SAG MANUFACTURING S.LCARRETERA NACIONAL 1 KM 36, SAN AGUSTIN DEL GUADALIX, 28750, SPAIN	SPAIN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X18.0 TABLET BLISTER, 1.0X2.0X14 .0 TABLET BLISTER	06/06/2023

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804	NDA/MAL/HDP/1 0836	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	PANSIPTIN 25	SITAGLIPTIN HYDROCHLORIDE	25MG	SAG MANUFACTURING S.LCARRETERA NACIONAL 1 KM 36, SAN AGUSTIN DEL GUADALIX, 28750, SPAIN	SPAIN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X16.0 TABLET BLISTER,1.0X2.0X14 .0 TABLET BLISTER	06/06/2023
805	NDA/MAL/HDP/1 0838	SHANGHAI DESANO BIO- PHARMACEUTICAL CO., LTD	TATA UGANDA LIMITED	DOLUTEGRAVIR TABLETS 50MG	DOLUTEGRAVIR SODIUM	50MG	SHANGHAI DESANO BIO- PHARMACEUTICAL CO., LTD1479, ZHANGHENG ROAD, CHINA (SHANGHAI) PILOT FREE TRADE ZONE, SHANGHAI 201203 - CHINA	CHINA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	06/06/2023
806	NDA/MAL/HDP/1 0839	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	ZEEDERM	ZINC OXIDE	15%W/W	STEDMAN PHARMACEUTICALS PVT. LTD.C-4, SIDCO PHARMACEUTICALS COMPLEX, ALATHUR, THIRUPORUR- 603 110, TAMIL NADU INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	06/06/2023

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807	NDA/MAL/HDP/1 084	DAWA LIMITED	SUPER MEDIC LTD	DAWA-CPM	CHLORPHENIRAM INE MALEATE	4MG	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2013
808	NDA/MAL/HDP/1 0841	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (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
809	NDA/MAL/HDP/1 0842	WOCKHARDT LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	EMROK	LEVONADIFLOXAC IN	800 MG / 100ML	WOCKHARDT LIMITED BIOTECH PARK, H-14/2, M.I.D.C, WALUJ, AURANGABAD - 431136, INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML VIAL	06/06/2023

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810	NDA/MAL/HDP/1 0851	DEVA HOLDING A.S	SHREEJI PHARMACEUTICAL S LIMITED	LOSAPRES PLUS 50 MG / 12.5 MG	LOSARTAN POTASSIUM + HYDROCHLOROT HIAZIDE	50 MG + 12.5 MG	DEVA HOLDING A.S (CERKEZKOY PRODUCTION SITE)CERKEZKOY ORGANIZE SANAYI BOLGESI. KARAAGAC MAH. ATATURK CAD. NO: 32 59510 KAPAKLI/TEKIRDAG/ TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	03/05/2023
811	NDA/MAL/HDP/1 086	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	SYNOGEN TABLETS	DIACEREIN + METHYL SULPHONYL METHANE + GLUCOSAMINE SULPHATE	50MG +250MG + 750MG	NEM LABORATORIES LIMITED133 KRISHNA IND. ESTATE, VASAI (E), THANE – 401 210, MAHARASHTRA – INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2012
812	NDA/MAL/HDP/1 087	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOCYCLINE	TETRACYCLINE	3%W/W	AGOG PHARMA LTD.PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/2013

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813	NDA/MAL/HDP/1 0873	MARCYRL PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TORSAMOLEX 10MG	TORSEMIDE	10 MG	MARCYRL PHARMACEUTICAL INDUSTRIES WESTERN EXTEENSION-PARTS NUMBER 5/6/7/8/9/10/11/12- BLOCK 20005, EL OBOUR CITY	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	17/08/2023
814	NDA/MAL/HDP/1 0874	: ALKEM LABORATORIES LIMITEDV	ABACUS PHARMA (AFRICA) LIMITED	PAN IV	PANTOPRAZOLE SODIUM	40MG	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X40.0 MG VIAL (+ 10 ML OF 0.9%W/V SODIUM CHLORIDE INJECTION, LDPE AMPOULE)	17/08/2023
815	NDA/MAL/HDP/1 0877	CRATUS PHARMA PVT. LTD. 7,	ABACUS PHARMA (AFRICA) LIMITED	RABEGUARD IV	RABEPRAZOLE SODIUM	20 MG/VIAL	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	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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816	NDA/MAL/HDP/1 0878	LUPIN LIMITED-	AIVEEN (U) LIMITED	LINEZOLID 600 MG TABLETS	LINEZOLID	600MG	LUPIN LTD198-202, NEW INDUSTRIAL AREA NO. 2, MANDIDEEP, BHOPAL-462 046, DIST. RAISEN, MADIA PRADESH INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	17/08/2023
817	NDA/MAL/HDP/1 0879	LUPIN LIMITED-	AIVEEN (U) LIMITED	ISONIAZID TABLETS 300MG	ISONIAZID	300MG	LUPIN LIMITED A- 28/1 MIDC CHIKALTHANA AURANGABAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	17/08/2023
818	NDA/MAL/HDP/1 088	GALPHA LABORATORIES LTD	DAWASANA PHARMACEUTICAL S 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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819	NDA/MAL/HDP/1 0880	TABROS PHARMA	HEALTHCARE LTD.	HEMSAMIC CAPSULE	TRANEXAMIC ACID	500MG	TABROS PHARMAL- 20/B SECTOR 22 FB INDUSTRIAL AREA KARACHI PAKISTAN	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	24/07/2023
820	NDA/MAL/HDP/1 0881	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
821	NDA/MAL/HDP/1 0882	BHARAT SERUMS & VACCINES LTD.	ABACUS PHARMA (AFRICA) LIMITED	FOLIGRAF 1200 IU	RECOMBINANT - HUMAN FOLLICLE STIMULATING HORMONE (R- HFSH)	1200IU/VIAL (MULTIDOSE)	BHARAT SERUM AND VACCINES LIMITEDPLOT NO. K- 27 ADDITIONAL M.I.D.C INDIA	INDIA	PARENTERAL ORDINARY DRY AMPOULES	1.0X1.0 VIAL 1 PREFILLED SYRINGE OF DILUENT + 15 DISPOSABLE SYRINGES]	17/08/2023

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822	NDA/MAL/HDP/1 0883	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	DAPAGLIFLOZIN 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
823	NDA/MAL/HDP/1 0884	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	MALOTEM 80/480MG	ARTEMETHER + LUMEFANTRINE	80 MG + 480 MG	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X6.0 TABLET BLISTER	17/08/2023
824	NDA/MAL/HDP/1 0885	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	NEBIMAC 10	NEBIVOLOL HYDROCHLORIDE	10MG	MACLEODS PHARMACEUTICALS LIMITED (BLOCK -N1) BLOCK N1, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, HIMACHAL PRADESH -174101,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X7.0 TABLET BLISTER	17/08/2023

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825	NDA/MAL/HDP/1 0888	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
826	NDA/MAL/HDP/1 0889	WORLD MEDICINE Ä°LAÄ± SAN. VE TIC. A.Äž.	GOODMAN INTERNATIONAL LTD	PIRETIKOL PLUS	PARACETAMOL + CHLORPHENIRAM INE 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/INSTANB UL, TURKEY	TURKEY	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	16/04/2024
827	NDA/MAL/HDP/1 0890	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,1.0X10 0.0 TABLET CONTAINER,1.0X50 0.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	17/08/2023

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828	NDA/MAL/HDP/1 0894	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
829	NDA/MAL/HDP/1 0896	REYOUNG PHARMACEUTICAL CO LTD	BIOGEN PHARMA LIMITED	AMPIGEN	AMPICILLIN SODIUM + CLOXACILLIN SODIUM	(250MG + 250MG)VIAL	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X0.5 G VIAL	17/08/2023
830	NDA/MAL/HDP/1 0897	HILTON PHARMA (PVT) LTD	BOOTS PHARMACEUTICAL S LIMITED	DAPA	DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE	5MG	HILTON PHARMACEUTICALS (PVT) LIMITEDPLOT NO. 13-14, SECTOR 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X14.0 TABLET BLISTER	17/08/2023

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831	NDA/MAL/HDP/1 0898	HILTON PHARMA (PVT) LTD	BOOTS PHARMACEUTICAL S LIMITED	ROLIP EZE TABLETS	ROSUVASTATIN CALCIUM + EZETIMIBE	20MG +10MG	HILTON PHARMACEUTICALS (PVT) LIMITED PLOT NO. 13-14, SECTOR 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	17/08/2023
832	NDA/MAL/HDP/1 0900	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	TRAMADOL DENK	TRAMADOL HYDROCHLORIDE	100MG/2 ML	SOLUPHARM GMBH INDUSTRIESTRASSE 3, 34212 MELSUNGEN	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X2.0 ML AMPOULE	17/08/2023
833	NDA/MAL/HDP/1 0903	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	BIDSIPTIN	VILDAGLIPTIN	50MG	SAG MANUFACTURING S.LCARRETERA NACIONAL 1 KM 36, SAN AGUSTIN DEL GUADALIX, 28750, SPAIN	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023

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834	NDA/MAL/HDP/1 0904	MEGA LIFSCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	UROKA PLUS	DUTASTERIDE + TAMSULOSIN HYDROCHLORIDE	0.5MG + 0.4MG	SAG MANUFACTURING S.LCARRETERA NACIONAL 1 KM 36, SAN AGUSTIN DEL GUADALIX, 28750, SPAIN	SPAIN	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	17/08/2023
835	NDA/MAL/HDP/1 0908	BDR PHARMACEUTICAL S 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
836	NDA/MAL/HDP/1 0909	NEXT WAVE (INDIA)	DAVIMED PHARMA LIMITED	CADZOLE	CLOTRIMAZOLE	1% W/W	NEXT WAVERAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	17/08/2023

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837	NDA/MAL/HDP/1 0910	NEXT WAVE (INDIA)	DAVIMED PHARMA LIMITED	DAVI-IBU	IBUPROFEN	200MG	NEXT WAVERAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	17/08/2023
838	NDA/MAL/HDP/1 0911	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
839	NDA/MAL/HDP/1 0912	NEXT WAVE (INDIA)	DAVIMED PHARMA LIMITED	FLUZINE	CETIRIZINE DIHYDROCHLORID E	10MG	NEXT WAVERAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	17/08/2023

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840	NDA/MAL/HDP/1 0914	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
841	NDA/MAL/HDP/1 0915	DAVIMED PHARMA LIMITED	DAVIMED PHARMA LIMITED	DAVICEF 1 G	CEFTRIAZONE SODIUM	1G/VIAL	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X10.0 ML VIAL	17/08/2023
842	NDA/MAL/HDP/1 0916	DAVIMED PHARMA LIMITED	DAVIMED PHARMA LIMITED	CEFOTEC	CEFOTAXIME SODIUM	1G/VIAL	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	PARENTERAL RETARD DRY VIALS	1.0X1.0X1.0 G VIAL	17/08/2023

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843	NDA/MAL/HDP/1 0917	DAVIMED PHARMA LIMITED	DAVIMED PHARMA LIMITED	CEFTRIAZONE	CEFTRIAZONE SODIUM	1G/VIAL	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X25.0X1.0X1.0 G VIAL	17/08/2023
844	NDA/MAL/HDP/1 0918	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	ESUPRONE	ESOMEPRAZOLE SODIUM	40 MG/VIAL	BLISS INDASI LIFESCIENCE PRIVATE LIMITEDPLOT 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
845	NDA/MAL/HDP/1 0920	ACINO AG.	LABOREX UGANDA LIMITED	PARACONICA™ PLUS 500 MG/150 MG	PARACETAMOL + IBUPROFEN	500 MG + 150 MG	SIGMA LABORATORIES PRIVATE LIMITED6, 7, 8 TIVIM INDUSTRIAL ESTATE, TIVIM, MAPUSA 403526, GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	17/08/2023

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846	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
847	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
848	NDA/MAL/HDP/10924	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	METOPRIX 10	METOCLOPRAMIDE	10 MG	BIOMATRIX HEALTHCARE PRIVATE LIMITEDSURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	17/08/2023

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849	NDA/MAL/HDP/1 0925	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	HERPIRAX 200	ACICLOVIR	200 MG	BIOMATRIX HEALTHCARE PRIVATE LIMITEDSURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023
850	NDA/MAL/HDP/1 0926	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	ACELEVO 500	LEVOFLOXACIN HEMIHYDRATE	500 MG	BIOMATRIX HEALTHCARE PRIVATE LIMITEDSURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	17/08/2023
851	NDA/MAL/HDP/1 0927	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	ACELEVO 750	LEVOFLOXACIN HEMIHYDRATE	750MG	BIOMATRIX HEALTHCARE PRIVATE LIMITEDSURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	17/08/2023

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852	NDA/MAL/HDP/1 0928	FAROMED LIFESCIENCES LLP	METRO PHARMACEUTICAL S LIMITED	FIX-A	CEFIXIME TRIHYDRATE	100MG/5ML	THE ACME LABORATORIES LIMITEDDHULIVITA, DHAMRAI, DHAKA - 1350, BANGLADESH	BANGLADESH	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X75.0 ML BOTTLE	17/08/2023
853	NDA/MAL/HDP/1 0930	RATNATRIS PHARMARMACEUT ICALS PVT. LTD	JEET PHARMACEUTICAL S 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
854	NDA/MAL/HDP/1 0931	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	UNIDROL 10	ALFUZOSIN HYDROCHLORIDE	10 MG	UNICHEM LABORATORIES LTDUNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023

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855	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
856	NDA/MAL/HDP/10933	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	P-ALAXIN	DIHYDROARTEMISININ + PIPERAQUINE PHOSPHATE	20 MG + 160 MG	BLISS GVS PHARMA LIMITED10,11 & 12,DEWAN UDYOG NAGAR,ALIYALI,PAL GHAR,MAHARASHTRA 401404,INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X3.0 TABLET BLISTER,1.0X2.0X3.0 TABLET BLISTER	17/08/2023
857	NDA/MAL/HDP/10934	FAROMED LIFSCIENCES 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

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858	NDA/MAL/HDP/1 0935	FAROMED LIFESCIENCES LLP	METRO PHARMACEUTICAL S LIMITED	SUPERPIME 1G IM/IV INJECTION	CEFEPIME HYDROCHLORIDE	1 G/VIAL	THE ACME LABORATORIES LIMITEDDHULIVITA, DHAMRAI, DHAKA - 1350, BANGLADESH	BANGLADESH	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	17/08/2023
859	NDA/MAL/HDP/1 0938	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	ATORKEY 80	ATORVASTATIN CALCIUM TRIHYDRATE	80 MG	AUROBINDO PHARMA LIMITED, UNIT - XV PLOT NO. 17A, E BONANGI (V), PARAWADA (M), VISAKHAPATNAM DISTRICT, ANDHRA PRADESH. PIN: 531021	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023
860	NDA/MAL/HDP/1 094	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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861	NDA/MAL/HDP/1 0940	BRAWN LABORATORIES LTD	PLANET PHARMACEUTICAL S UGANDA LTD	MASTIC-LC	MONTELUKAST SODIUM + LEVOCETIRIZINE DIHYDROCHLORID E	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
862	NDA/MAL/HDP/1 0944	TORRENT PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S LTD.	TORLEVA 500MG	LEVETIRACETAM	500MG	TORRENT PHARMACEUTICALS LTD .,INDRAD - 382721, TAL: KADI, CITY - INDRAD, DIST. MEHSANA, GUJARAT STATE - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023
863	NDA/MAL/HDP/1 0945	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	XYLOPIL-2%	LIDOCAINE HYDROCHLORIDE	20MG/ML	PSYCHOTROPICS INDIA LTD PLOT NO. 12 & 12A, INDUSTRIAL PARK-II, PHASE-1, VILLAGE SALEMPUR, MEHDOOD-2 HARIDWAR-249403, UTTARAKHAND INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X30.0 ML VIAL (CLEAR GLASS VIAL)	17/08/2023

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864	NDA/MAL/HDP/1 0946	MACLEODS PHARMACEUTICAL S LTD	AIVEEN (U) LIMITED	MONTEMAC-10	MONTELUKAST SODIUM	10MG	MACLEODS PHARMACEUTICALS LIMITED, UNIT VIVILLAGE THEDA, KHARUNI LODHI MAJRA RD, TEHSIL BADDI N2, DISTRICT SOLAN, HIMACHAL PRADESH-174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023
865	NDA/MAL/HDP/1 0947	MACLEODS PHARMACEUTICAL S LTD	AIVEEN (U) LIMITED	OLMESAR H	OLMESARTAN MEDOXOMIL + HYDROCHLOROT HIAZIDE	20 MG + 12.5 MG	MACLEODS PHARMACEUTICALS LIMITED, UNIT VIVILLAGE THEDA, KHARUNI LODHI MAJRA RD, TEHSIL BADDI N2, DISTRICT SOLAN, HIMACHAL PRADESH-174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	17/08/2023
866	NDA/MAL/HDP/1 0948	WALLACE PHARMACEUTICAL S PVT. LTD	STAR PHARMACEUTICAL S LTD	FLUCOLD	PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + CHLORPHENAMIN E MALEATE	500 MG + 10 MG + 2 MG	WALLACE PHARMACEUTICALS PVT LTDBHATIAN, NALAGARH, DIST. SOLAN HP 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X5.0X10.0 TABLET BLISTER	17/08/2023

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867	NDA/MAL/HDP/1 0949	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	CLAMOXIN-375 TABLETS	AMOXICILLIN SODIUM + POTASSIUM CLAVULANATE	250MG + 125 MG	MEDOPHARM PVT LIMITEDNO. 50 KAYARAMBEDU VILLAGE, GUDUVANCHERY- 603202	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	17/08/2023
868	NDA/MAL/HDP/1 095	MICRO LABS LTD	LABOREX UGANDA LIMITED	EROSTINE-20	EBASTINE	20MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2012
869	NDA/MAL/HDP/1 0950	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICAL S LTD	DICORATE ER 500	DIVALPROEX SODIUM	500 MG	SUN PHARMA LABORATORIES LIMITED6-9, EPIP, KARTHOLI, BARI BRAHMANA, JAMMU - 181133 (JAMMU AND KASHMIR) - INDIA	INDIA	ORAL SOLID RETARD COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER	17/08/2023

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870	NDA/MAL/HDP/1 0952	MINAPHARM PHARMACEUTICAL & CHEMICAL INDUSTRIES	SWASTIK PHARMACEUTICAL LTD	HYDROQUINE	HYDROXYCHLORO QUINE 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
871	NDA/MAL/HDP/1 0953	KOPRAN LIMITED	TATA UGANDA LIMITED	LOKIT HP	CLARITHROMYCIN + TINIDAZOLE + OMEPRAZOLE	250 MG + 500 MG + 20 MG	KOPRAN LIMITEDVILLAGE - SAVROLI (KHOPOLI), TALUKA - KHALAPUR, DIST. RAIGAD 410202, MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY COMBINATION PACK COATED TABLETS	1.0X7.0X1.0X1.0X6. 0 TABLE STRIP (EACH STRIP CONTAINS 2 TABLETS OF CLARITHROMYCIN + 2 TABLETS OF TINIDAZOLE + 2 CAPSULES OF OMEPRAZOLE)	17/08/2023
872	NDA/MAL/HDP/1 0954	RENATA LIMITED	UHAI PHARMACY	FUROCEF®	CEFUROXIME AXETIL	500MG	RAJENDRAPUR POTENT PRODUCT FACILITY (RPPF), RENATA LIMITEDNOYAPARA, BHAWAL MIRZAPUR, RAJENDRAPUR, GAZIPUR 1700 - BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X6.0 TABLET BLISTER	17/08/2023

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873	NDA/MAL/HDP/1 0956	RENATA LIMITED	UHAI PHARMACY	ZITHRIN	AZITHROMYCIN	500MG	RENATA LIMITED RAJENDRAPUR GENERAL FACILITY, NOYAPARA BHAWAL MIRZAPUR RAJENDRAPUR GAZIPUR, 1700 BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X5.0 TABLET BLISTER	17/08/2023
874	NDA/MAL/HDP/1 0957	ORCHIDIA PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CO-AVAZIR	TOBRAMYCIN + DEXAMETHASON E	(3 MG + 1 MG)/ML	ORCHIDIA PHARMACEUTICAL INDUSTRIESAL OBOUR CITY INDUSTRIAL ZONE, AREA 14, 15 - PLOT NO. 12011 - CAIRO - EGYPT	EGYPT	OPHTHALMIC SUSPENSIONS	1.0X1.0X5.0 ML BOTTLE	17/08/2023
875	NDA/MAL/HDP/1 0958	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

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876	NDA/MAL/HDP/1 0959	MACLEODS PHARMACEUTICAL S 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
877	NDA/MAL/HDP/1 096	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ARTEMETHER	ARTEMETHER	80MG/ML	SANJAR PHARMA LLP HIMATNAGAR- VIJOPUR HIGHWAY, DEDHROTA HIMATNAGAR 383 220, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE,1.0X1.0X 8.0X1.0 ML AMPOULE	01/07/2014
878	NDA/MAL/HDP/1 0960	AXA PARENTERALS LTD	VITACARE LIMITED	AXADEX D5	GLUCOSE ANHYDROUS	5% W/V	AXA PARENTERALS LTD PLOT NO. 936, 937 & 939, VILLAGE KISHANPUR, JAMALPUR ROORKEE 247667, DIST. HARIDWAR, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES	1.0X100.0 ML BOTTLE	17/08/2023

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879	NDA/MAL/HDP/1 0961	ADWIA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LEPTROGINE 25MG	LAMOTRIGINE	25 MG	ADWIA S.A.E.1ST INDUSTRIAL ZONE A1, 10TH OF RAMADAN CITY, EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023
880	NDA/MAL/HDP/1 0962	MYLAN LABORATORIES LIMITED-	KIMSY MEDS LTD	DARUNAVIR/RITO NAVIR TABLETS 400 MG/50 MG	DARUNAVIR ETHANOLATE + RITONAVIR	400 MG + 50 MG	MYLAN LABORATORIES LTD .F/4 & F/12, MALEGAON MIDC, SINNAR, NASHIK-422 113, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X60.0 TABLET CONTAINER	17/08/2023
881	NDA/MAL/HDP/1 0964	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AZIREN	AZITHROMYCIN DIHYDRATE	500MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	17/08/2023

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882	NDA/MAL/HDP/1 0965	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	MPHETAS-500	MYCOPHENOLAT E MOFETIL	500MG	INTAS PHARMACEUTICALS LTD ..PLOT NO. 457- 458 VILL MATODA BAVLA ROAD TA SANAND DIST AHMEDABAD PIN- 382 210 GUJARART STATE	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	17/08/2023
883	NDA/MAL/HDP/1 0966	EUGIA PHARMA SPECIALITIES LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	SKYTINIB 12.5	SUNITINIB MALATE	12.5 MG	EUGIA PHARMA SPECIALITIES LIMITEDSURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X7.0 CAPSULE BLISTER	17/08/2023
884	NDA/MAL/HDP/1 0967	EUGIA PHARMA SPECIALITIES LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	SKYTINIB 25	SUNITINIB MALATE	25 MG	EUGIA PHARMA SPECIALITIES LIMITEDSURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X7.0 CAPSULE BLISTER	17/08/2023

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885	NDA/MAL/HDP/1 0968	HALEWOOD LABORATORIES PVT. LTD.	AIVEEN (U) LIMITED	ELECTRORUSH POWDER ORS BP	SODIUM CHLORIDE + POTASSIUM CHLORIDE + TRISODIUM CITRATE DIHYDRATE + DEXTROSE ANHYDROUS	2.60 G + 1.50 G + 2.90 G + 13.50 G	HALEWOOD LABORATORIES PVT. LIMITED319, PHASE - II, GIDC, VATVA, AHMEDABAD - 382445, GUJARAT	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X10.0X20.5 G SACHET	17/08/2023
886	NDA/MAL/HDP/1 0969	FDC LTD	AIVEEN (U) LIMITED	VITCOFOL	FERROUS FUMARATE + FOLIC ACID + CYANOCOBALAMI N	(100MG + 0.5MG + 5MCG)/5ML	FDC LIMITED, WALUJ .PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	17/08/2023
887	NDA/MAL/HDP/1 0971	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

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888	NDA/MAL/HDP/1 0972	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (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), TSIIC, 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
889	NDA/MAL/HDP/1 0973	SWISS PARENTERALS LTD.	SHREEJI PHARMACEUTICAL S 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
890	NDA/MAL/HDP/1 0974	EUGIA PHARMA SPECIALITIES LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	SKYTINIB 50	SUNITINIB MALATE	50 MG	EUGIA PHARMA SPECIALITIES LIMITEDSURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X7.0 CAPSULE BLISTER	17/08/2023

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891	NDA/MAL/HDP/1 0975	VERVE HUMAN CARE LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	BUPIVER-H	BUPIVACAINE HYDROCHLORIDE	5MG/ML	VERVE HUMAN CARE LABORATORIESPLOT NO. 15A PHARMACITY, SELAQUI, DEHRADUN, UTTARAKHAND, 248011, INDIA.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X4.0 ML AMPOULE	17/08/2023
892	NDA/MAL/HDP/1 0976	SAGA LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	PARAGESIC	DICLOFENAC SODIUM + PARACETAMOL + CHLORZOXAZONE	50 MG + 325 MG + 250 MG	SAGA LABORATORIES .198/2 & 198/3, CHACHRAWADI, VASNA NO. CLARIS LIFE SCIENCE, TA SANAND, DIST. DIST: AHMEDABAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER	17/08/2023
893	NDA/MAL/HDP/1 0978	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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894	NDA/MAL/HDP/1 0980	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MEFENEC PLUS	MEFENAMIC ACID + DICYCLOMINE HYDROCHLORIDE	250 MG + 20 MG	RAVIAN LIFE SCIENCE PVT. LIMITED PLOT NO. 34, SECTOR: 8A, SIDCUL, IIE, HARIDWAR - 249403, UTTARAKHAND	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023
895	NDA/MAL/HDP/1 0982	COMED CHEMICALS LTD.	LEGIT MEDEQ 2007 LIMITED	RAPCO-DSR	RABEPRAZOLE SODIUM + DOMPERIDONE	20 MG + 30 MG	COMED CHEMICALS LTD (UNIT-III)VILL: DASSOMATRA BADDI, NALAGARGH ROAD DISTRICT: SOLAN, PIN.173205 HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	17/08/2023
896	NDA/MAL/HDP/1 0983	AGIO PHARMACEUTICAL S LTD	ROYAL PHARMA 2011 LIMITED	ENALAPRIL-AGIO TABLET	ENALAPRIL MALEATE	5MG	AGIO PHARMACEUTICALS LIMITED.T- 81, 82, MIDC, BHOSARI, PUNE - 411 026 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	17/08/2023

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897	NDA/MAL/HDP/1 0984	AGIO PHARMACEUTICAL S LTD	ROYAL PHARMA 2011 LIMITED	ENALAPRIL-AGIO TABLET	ENALAPRIL MALEATE	10MG	AGIO PHARMACEUTICALS LIMITED.T- 81, 82, MIDC, BHOSARI, PUNE - 411 026 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	17/08/2023
898	NDA/MAL/HDP/1 0985	APEX LABORATORIES PRIVATE LIMITED	NORVIK ENTERPRISES LIMITED	ZINCOVIT DROPS	VITAMIN A (AS PALMITATE) + RRR -ALPHA- TOCOPHERYL ACETATE + COLECALCIFEROL + THIAMINE HYDROCHLORIDE + RIBOFLAVIN SODIUM PHOSPHATE + PYRIDOXINE HYDROCHLORIDE + ASCORBIC ACID + DEXPANTHENOL	(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
899	NDA/MAL/HDP/1 0986	THE SEARLE COMPANY LIMITED	SURGIPHARM (U) LIMITED	JENTIN MET	SITAGLIPTIN PHOSPHATE MONOHYDRATE + METFORMIN HYDROCHLORIDE	50 MG + 1000 MG	SEARLE PAKISTAN LTD..F-319, S.I.T.E., OPP. KESC POWER STATION, KARACHI	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	17/08/2023

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900	NDA/MAL/HDP/1 0987	LUPIN LIMITED-	AIVEEN (U) LIMITED	LAMIVUDINE AND TENOFIVIR DISOPROXIL FUMARATE TABLETS 300MG AND 300 MG	LAMIVUDINE + TENOFIVIR DISOPROXIL FUMARATE	300 MG + 300 MG	LUPIN LTD PLOT NO. 6A, SECTOR 17, SPECIAL ECONOMIC ZONE, MIHAN, NAGPUR 441108, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	17/08/2023
901	NDA/MAL/HDP/1 0988	Y.S.P. INDUSTRIES (M) SDN. BHD.	ROYAL PHARMA 2011 LIMITED	LACTUL	LACTULOSE	670MG/ML	Y.S.P INDUSTRIES (M) SDN BHN.LOT 3, 5 & 7, JALAN P/7, SECTION 13, KAWASAN PENDUSTRIAN BANDAR BARU BANGI, 43000, KAJANG, SELANGOR, MALAYSIA	MALAYSIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE (AMBER PET BOTTLE)	17/08/2023
902	NDA/MAL/HDP/1 0989	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	BINFIN 5	FINASTERIDE	5MG	HETERO LABS LIMITED (UNIT III)...22-110, I.D.A, JEEDIMETLA, HYDERABAD-500 055, ANDHRA PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER	17/08/2023

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903	NDA/MAL/HDP/1099	GLENMARK PHARMACEUTICALS 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
904	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
905	NDA/MAL/HDP/10994	DINLAS PHARMA EPZ LIMITED	AFRICURE PHARMACEUTICALS U LIMITED	PARADOL	PARACETAMOL	500MG	DINLAS PHARMA EPZ LIMITED PLOT NO. LR 7149/121, MOMBASA ROAD, SYOKIMAU	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	17/08/2023

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906	NDA/MAL/HDP/1 0998	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	MOCIN	MOXIFLOXACIN HYDROCHLORIDE	400MG/100ML	ABACUS PARENTERAL DRUGS LIMITED PLOT 114, BLOCK 191, KINGA	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	17/08/2023
907	NDA/MAL/HDP/1 0999	MARCYRL PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	URICODROP	FEBUXOSTAT	80MG	MARCYRL PHARMACEUTICAL INDUSTRIES WESTERN EXTENSION-PARTS NUMBER 5/6/7/8/9/10/11/12- BLOCK 20005, EL BOUR CITY	EGYPT	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023
908	NDA/MAL/HDP/1 100	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOVIR SKIN CREAM	ACICLOVIR	5% W/W	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE,1.0X5.0 G TUBE	01/07/2013

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909	NDA/MAL/HDP/1 1000	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	SINUTAB SINUS PAIN NON- DROWSY	PARACETAMOL + PSEUDOEPHEDRI NE HYDROCHLORIDE	500 + 30 MG	JOHNSON & JOHNSON (PTY) LTD241 MAIN ROAD, RETREAT, 7945, CAPE TOWN	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	17/08/2023
910	NDA/MAL/HDP/1 1001	UNISON PHARMACEUTICAL S PVT. LTD.	HARLEYS UGANDA LIMITED	AKILOS-CR	ACECLOFENAC	200MG	UNISON PHARMACEUTICALS PRIVATE LIMITED – UNIT 1UNIT I, C/6, STEEL TOWN, OPP. NOVA PETRO, MORAIYA, TA. SANAND, DIST.: AHMEDABAD - 382213, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	17/08/2023
911	NDA/MAL/HDP/1 1003	MEGA LIFSCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	BAROLE	RABEPRAZOLE	20MG	NAPROD LIFE SCIENCES PVT. LTDG- 17/1, MIDC TARAPUR IND. AREA, BOISAR, 401506 MAHARASHTRA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 MG VIAL	17/08/2023

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912	NDA/MAL/HDP/1 1004	FAROMED LIFESCIENCES LLP	METRO PHARMACEUTICAL S LIMITED	FAST 125	PARACETAMOL	125MG	THE ACME LABORATORIES LIMITEDDHULIVITA, DHAMRAI, DHAKA - 1350, BANGLADESH	BANGLADESH	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY STRIP	17/08/2023
913	NDA/MAL/HDP/1 1012	COSMOS LTD.	ASTRA PHARMA (U) LIMITED	CEMET 400	CIMETIDINE	400MG	COSMOS LTD..RANGWE ROAD OFF, LUNA LUNGA ROAD, INDUSTRIAL AREA - NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997
914	NDA/MAL/HDP/1 1015	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	HYDROCORTISON E CREAM BP	HYDROCORTISON E ACETATE	1% W/W	CIRON DRUGS PHARMACEUTICALS PRIVATE LIMITEDPLOT NO. 35- 37, 43-45, CFC-B, DEWAN UDHYOG NAGAR, ALIYALI, PALGHAR " " " 401404, MAHARASHTRA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	12/13/2023

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915	NDA/MAL/HDP/1 1016	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	LEDOBOOK 15	LENALIDOMIDE	15MG	EUGIA PHARMA SPECIALITIES LIMITEDSURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X7.0 CAPSULE BLISTER	12/13/2023
916	NDA/MAL/HDP/1 1017	AUROBINDO	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	LEDOBOOK 25	LENALIDOMIDE	25MG	EUGIA PHARMA SPECIALITIES LIMITEDSURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X7.0 CAPSULE BLISTER	12/13/2023
917	NDA/MAL/HDP/1 1018	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	MEDWIN	MEDROXYPROGE STERONE	150MG/ML	EUGIA PHARMA SPECIALITIES LIMITEDSURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0X1.0 ML PRE FILLED SYRINGE	12/13/2023

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918	NDA/MAL/HDP/1 1019	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	LEDOBOOK 5	LENALIDOMIDE	5MG	EUGIA PHARMA SPECIALITIES LIMITEDSURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X7.0 CAPSULE BLISTER	12/13/2023
919	NDA/MAL/HDP/1 102	MATRIX UGANDA LTD	ROYAL PHARMA 2011 LIMITED	OVUREX	CLOMIPHENE	50MG	Y.S.P INDUSTRIES (M) SDN BDH LOT 3,5 & 7 P/7 SECTION 13 KAWASAN PERINDUSTRIAN BANDAR BARU BANGI 43000 KAJANG SELANGOR DARUL EHSAN	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1.0X10 .0 TABLET BLISTER	01/07/2011
920	NDA/MAL/HDP/1 1020	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	IBUPLUS	IBUPROFEN + PARACETAMOL	100MG/125MG	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X60.0 ML BOTTLE	12/13/2023

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921	NDA/MAL/HDP/1 1021	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	INTAFERON	IRON SUCROSE	100MG/5ML.	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X5.0 ML AMPOULE	12/13/2023
922	NDA/MAL/HDP/1 1022	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CEFIXIME QUIX DISPERSIBLE TABLETS 200MG	CEFIXIME TRIHYDRATE	200MG	M/S SCOTT-EDIL ADVANCE RESEARCH LABORATORIES AND EDUCATION LIMITEDHILL-TOP, INDUSTRIAL AREA, BHATOLI KALAN, BADDI, DISTT. SOLAN (HP) - 173205, INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X10.0 TABLET BLISTER	12/13/2023
923	NDA/MAL/HDP/1 1023	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	MOXVID	AMOXICILLIN TRIHYDRATE	125 MG/5 ML	M/S SCOTT-EDIL ADVANCE RESEARCH LABORATORIES AND EDUCATION LIMITEDHILL-TOP, INDUSTRIAL AREA, BHATOLI KALAN, BADDI, DISTT. SOLAN (HP) - 173205, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X100.0 ML CONTAINER	12/13/2023

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924	NDA/MAL/HDP/1 1024	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LTD	CLONAPIN-2	CLONAZEPAM	2MG	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023
925	NDA/MAL/HDP/1 1025	LINCOLN PHARMACEUTICAL S LIMITED	METRO PHARMACEUTICAL S LTD	DYGYL	METRONIDAZOLE BENZOATE	125MG/5ML	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	12/13/2023
926	NDA/MAL/HDP/1 1026	LINCOLN PHARMACEUTICAL S LIMITED	METRO PHARMACEUTICAL S LTD	TELMISIN	TELMISARTAN	40 MG	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023

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927	NDA/MAL/HDP/1 1027	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	CEFIMCZ-400	CEFIXIME	400 MG	ZEISS PHARMA LIMITEDIGC,SIDCO, PHASE II, SAMBA, JAMMU - 184121,(J&K)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	12/13/2023
928	NDA/MAL/HDP/1 1028	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	APLENE 50	PREGABALIN	50MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	12/13/2023
929	NDA/MAL/HDP/1 1029	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	APLENE 75	PREGABALIN	75MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	12/13/2023

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930	NDA/MAL/HDP/1 103	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOCIN CREAM	NEOMYCIN SULPHATE	0.5% W/W	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2014
931	NDA/MAL/HDP/1 1030	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
932	NDA/MAL/HDP/1 1031	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

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933	NDA/MAL/HDP/1032	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	NIZACARD 1000	RANOLAZINE	1000MG	HETERO LABS PRIVATE LIMITED UNIT IISURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) JEEDIMETLA, HYDERABAD-500 055, TELANGANA STATE	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023
934	NDA/MAL/HDP/1033	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
935	NDA/MAL/HDP/1034	ARCELIA LIFE SCIENCES LTD.	PLUTO PHARMACEUTICALS LIMITED	ARCELIA® ESOMEPRAZOLE TABLETS 40 MG	ESOMEPRAZOLE MAGNESIUM DIHYDRATE	40 MG	ASSOCIATED BIOTECH VILLAGE: 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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936	NDA/MAL/HDP/1 1035	ARCELIA LIFE SCIENCES LTD.	PLUTO PHARMACEUTICAL S 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
937	NDA/MAL/HDP/1 1036	ARCELIA LIFE SCIENCES LTD.	PLUTO PHARMACEUTICAL S LIMITED	DROCELIA	DROTAVERINE HYDROCHLORIDE	40 MG/2 ML	SANJAR PHARMA LLPSURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1X1X5X2X0 ML AMPOULE	12/13/2023
938	NDA/MAL/HDP/1 1037	FERRER INTERNATIONAL, S.A.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DISLEP 25	LEVOSULPIRIDE	25MG	DOPPEL FARMACEUTICI SRL,VIA VOLTURNO 48-20089 QUINTO DE STAMPI, ROZZANO (MI)	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X20.0 TABLET BLISTER	12/13/2023

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939	NDA/MAL/HDP/1 1038	AUROBINDO	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DELOHIST 5	DES Loratadine	5MG	AUROBINDO PHARMA LIMITED, UNIT - XV PLOT NO. 17A, E BONANGI (V), PARAWADA (M), VISAKHAPATNAM DISTRICT, ANDHRA PRADESH. PIN: 531021	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023
940	NDA/MAL/HDP/1 1039	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	LIGNOCAIN	LIDOCAINE	20 MG/ML	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X30.0 ML VIAL	12/13/2023
941	NDA/MAL/HDP/1 104	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	LIPIDUCE 10	ATORVASTATIN	10MG	HOVID BERHAD, LOT 56442, 7 1/2 MILES JALAN IPOH/CHEMOR 31200, CHEMOR PERAK	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X3.0 TABLET BLISTER	01/07/2014

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942	NDA/MAL/HDP/1 1041	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICAL S LIMITED	ROMYCIN	AZITHROMYCIN DIHYDRATE	500MG	NABIQASIM INDUSTRIES (PVT) LTD .17/24 KORANGI INDUSTRIAL AREA KORANGI KARACHI	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X3.0 TABLET BLISTER	12/13/2023
943	NDA/MAL/HDP/1 1042	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	MOVFOR	MOLNUPIRAVIR	200MG	HETERO LABS LIMITED (UNIT V)SY. NO. 439, 440, 441 & 458, POLEPALLY VILLAGE, JADCHERLA MANDAL MAHABOBNAGAR DISTRICT, PIN-509 301, TELANGANA, INDIA	INDIA	ORAL SOLID RETARD OTHER CAPSULES	1.0X40.0 CAPSULE CONTAINER, 1.0X4.0X10.0 CAPSULE BLISTER	12/13/2023
944	NDA/MAL/HDP/1 1043	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DIAZAC 5	DAPAGLIFLOZIN	5MG	AJANTA PHARMA LIMITEDPLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT- 392130	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023

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945	NDA/MAL/HDP/1 1044	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
946	NDA/MAL/HDP/1 1047	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	MURAXAL -10	ALFUZOSIN HYDROCHLORIDE	10MG	MICRO LABS LIMITED, HOSURNO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA	INDIA	ORAL SOLID RETARD TABLETS	1.0X1.0X10.0 TABLET BLISTER	12/13/2023
947	NDA/MAL/HDP/1 1048	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	APRETUDE 600 MG	CABOTEGRAVIR	200MG/ML	GLAXO OPERATIONS UK LIMITEDHARMIRE ROAD, BARNARD CASTLE, DURHAM, DL 12 8DT - UNITED KINGDOM	UNITED KINGDOM	PARENTERAL ORDINARY VIALS	1.0X25.0X3.0 ML VIAL, 1.0X5.0X3.0 ML VIAL	12/13/2023

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948	NDA/MAL/HDP/1 1049	NEXT WAVE (INDIA)	DAVIMED PHARMA LIMITED	XYM-KID	SIMETHICONE + DILL OIL + FENNEL OIL	40MG + 0.005ML + 0.0007ML	NEXT WAVERAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X15.0 ML BOTTLE	12/13/2023
949	NDA/MAL/HDP/1 1050	SURGE LABORATORIES (PVT) LTD,	JEET PHARMACEUTICAL S 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
950	NDA/MAL/HDP/1 1051	SURGE LABORATORIES (PVT) LTD,	JEET PHARMACEUTICAL S 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

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951	NDA/MAL/HDP/1 1052	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AKO-PAS	ACECLOFENAC + PARACETAMOL + SERRATIOPEPTID ASE	100 MG + 325 MG + 15 MG	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	12/13/2023
952	NDA/MAL/HDP/1 1053	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	OLODINE	OLOPATADINE HYDROCHLORIDE	0.1% W/V	ABACUS PARENTERAL DRUGS LIMITEDPLOT 114, BLOCK 191, KINGA	UGANDA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML CONTAINER	12/13/2023
953	NDA/MAL/HDP/1 1054	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	TORA	TOBRAMYCIN SULPHATE	0.3% W/V	ABACUS PARENTERAL DRUGS LIMITEDPLOT 114, BLOCK 191, KINGA	UGANDA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML CONTAINER	12/13/2023

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954	NDA/MAL/HDP/1 1055	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	TORA-D	TOBRAMYCIN SULPHATE + DEXAMETHASON E SODIUM PHOSPHATE	0.3%W/V + 0.1%W/V	ABACUS PARENTERAL DRUGS LIMITEDPLOT 114, BLOCK 191, KINGA	UGANDA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML CONTAINER	12/13/2023
955	NDA/MAL/HDP/1 1056	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	VOLDIC Â® 1% EMULGEL	DICLOFENAC DIETHYLAMINE	1%W/W	PHARMA INTERNATIONAL COMPANY ,,AL- QASTAL AREA, AIRPORT ROAD, P.O. BOX 334 AL JUBAIHA, 11941, AMMAN - JORDAN	JORDAN	TOPICAL EXTERNAL GELS AND SOLS	1.0X1.0X30.0 G TUBE	12/13/2023
956	NDA/MAL/HDP/1 1057	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	SHELTRIZINE	CETIRIZINE HYDROCHLORIDE	10MG	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO. LR 209/6554, MOGADISHU ROAD INDUSTRIAL AREA, NAIROBI KENYA	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	12/13/2023

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957	NDA/MAL/HDP/1 1058	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	EXYT-200	ALBENDAZOLE	200MG/5ML	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X10.0 ML BOTTLE	12/13/2023
958	NDA/MAL/HDP/1 1059	AURA LIFECARE PVT. LTD.	REDDYS PHARMA LIMITED	AURADERM-0.05	CLOBETASOL	0.05%W/W	AURA LIFECARE PRIVATE LIMITEDSURVEY NO. 254/14/1, JAROD- SAVLI ROAD, P.O. KARACHIYA, 391 520, TAL. SAVLI, DIST. VADODARA - INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X10.0 G TUBE, 1.0X1.0X15.0 G TUBE	12/13/2023
959	NDA/MAL/HDP/1 106	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

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960	NDA/MAL/HDP/1 1060	WORLD MEDICINE S.A. SAN. VE TIC. A.Ž.	GOODMAN INTERNATIONAL LTD	ROXIPIME	CEFEPIME HYDROCHLORIDE	1G/VIAL	PHARMAVISION SAN. VE TIC. A.S.DAVUTPASA CAD. NO: 145 ZEYINBURNU / ISTANBUL - TURKEY	TURKEY	PARENTERAL RETARD DRY VIALS	1.0X1.0X1.0 G VIAL	12/13/2023
961	NDA/MAL/HDP/1 1061	MIDASCARE PHARMACEUTICAL S PRIVATE LIMITED,	ABACUS PHARMA (AFRICA) LIMITED	MISTDRESS	LIDOCAINE + CETRIMIDE	1%W/W + 0.10%W/W	MIDAS CARE PHARMACEUTICALS PVT LTD.B-16 MIDC, WALUJ AURANGABAD 431136, MAHARASHTRA, INDIA	INDIA	TOPICAL EXTERNAL SPRAYS WITHOUT GAS	1.0X100.0 ML CANNISTER	12/13/2023
962	NDA/MAL/HDP/1 1062	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	GAVISIL	ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE	250MG + 250MG + 50MG	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X200.0 ML BOTTLE	12/13/2023

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963	NDA/MAL/HDP/1 1063	PHARMA BAVARIA INTERNACIONAL(P BI) PORTUGUAL	GOODMAN INTERNATIONAL LTD	COMBOFUSIV	PARACETAMOL + IBUPROFEN	10MG/ML + 3MG/ML	S.M. FARMACEUTICI S.R.L.ZONA INDUSTRIALE, 85050 TITO (PZ)	ITALY	PARENTERAL ORDINARY VIALS	1.0X10.0X100.0 ML VIAL	12/13/2023
964	NDA/MAL/HDP/1 1064	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	ISONIAZID DISPERSIBLE TABLETS 100 MG	ISONIAZID	100 MG	OXALIS LABS LIMITEDVILLAGE THEDA, P.O LODHIMAJRA, TEHSIL BADDI DIST: SOLAN (H.P.) PIN CODE: 174101 - INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET STRIP	12/13/2023
965	NDA/MAL/HDP/1 1065	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	AROX	MOXIFLOXACIN HYDROCHLORIDE	0.5% W/V	JAMJOOM PHARMACEUTICALS COMPANYPLOT 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

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966	NDA/MAL/HDP/1 1066	MACARTHYS LABORATORIES LTD	LABOREX UGANDA LIMITED	COLISTIMETHATE SODIUM 1 MIU	COLISTIMETHATE SODIUM	1MU/VIAL	ALTAN PHARMACEUTICALS S.A.AVDA. DE LA CONSTITUCION 198 - 199, POLIGONO INDUSTRIAL MONTE BOYAL, CASARRUBIOS DE MONTE, 45950 TOLEDO - SPAIN	SPAIN	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X1.0 MU VIAL	12/13/2023
967	NDA/MAL/HDP/1 1067	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (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
968	NDA/MAL/HDP/1 1068	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	LEVAUR 500	LEVETIRACETAM	500MG	AUROBINDO PHARMA LIMITED, UNIT - XV PLOT NO. 17A, E BONANGI (V), PARAWADA (M), VISAKHAPATNAM DISTRICT, ANDHRA PRADESH. PIN: 531021	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023

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969	NDA/MAL/HDP/1069	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	LEVAUR 1000	LEVETIRACETAM	1000MG	AUROBINDO PHARMA LIMITED, UNIT - XV PLOT NO. 17A, E BONANGI (V), PARAWADA (M), VISAKHAPATNAM DISTRICT, ANDHRA PRADESH. PIN: 531021	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023
970	NDA/MAL/HDP/107	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
971	NDA/MAL/HDP/1070	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	JITRIT-5	TOFACINIB	5MG	MICRO LABS LIMITED, HOSURNO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X15.0 TABLET BLISTER	12/13/2023

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972	NDA/MAL/HDP/1 1071	MYLAN PHARMACEUTICAL S PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	OGIVRIĀ,,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
973	NDA/MAL/HDP/1 1072	MEDOPHARM	NUGEN PHARMACEUTICAL S UGANDA LIMITED	NUNINE	QUININE SULFATE	300MG	MEDOPHARMNO. 34B, INDUSTRIAL AREA, MALUR- 563160, KARNATAKA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	12/13/2023
974	NDA/MAL/HDP/1 1074	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	FAMYTEC	MISOPROSTOL	200MCG	MYLAN LABORATORIES LIMITEDPLOT 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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975	NDA/MAL/HDP/1 1075	HEALTH LINK PHARMACY LTD	HEALTH LINK PHARMACY LIMITED	ROLXIN OD	DIHYDROARTEMI SININ + PIPERAQUINE PHOSPHATE	120 MG + 960 MG	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN " 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	12/13/2023
976	NDA/MAL/HDP/1 1076	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	G-COSPEA®	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
977	NDA/MAL/HDP/1 1078	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	B-LACT	LACTULOSE	3.35GM/5ML	FRESENIUS KABI AUSTRIA GMBHESTERMANN STRASSE 17, A-4020 LINZ	AUSTRIA	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	02/02/2024

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978	NDA/MAL/HDP/1 1079	MEDOPHARM	PLANET PHARMACEUTICAL S UGANDA LTD	MIRAFOLIC	FOLIC ACID	5MG	MEDOPHARMNO. 34B, INDUSTRIAL AREA, MALUR- 563160, KARNATAKA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X100.0X10.0 TABLET BLISTER, 1.0X10.0X10.0 TABLET BLISTER, 1.0X50.0X10.0 TABLET BLISTER	02/02/2024
979	NDA/MAL/HDP/1 1080	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	OLMAT-AMH	OLMESARTAN MEDOXOMIL + AMLODIPINE BESILATE + HYDROCHLOROT HIAZIDE	20MG + 5MG + 12.5MG	MICRO LABS LIMITED, HOSURNO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/02/2024
980	NDA/MAL/HDP/1 1081	INFUGEN PHARMA PVT. LTD.	GITTOES PHARMACEUTICAL S 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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981	NDA/MAL/HDP/1 1082	UNITED PHARMACEUTICAL S MANUFACTURING LIMITED COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VIVAZAC PLUS	IRBESARTAN + HYDROCHLOROT HIAZIDE	150 MG + 12.5 MG	UNITED PHARMACEUTICALS MANUFACTURING LIMITED COMPANYAL- RAGEEM, SAHAB, P.O. BOX 60, AMMAN 11591 - JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/02/2024
982	NDA/MAL/HDP/1 1083	ASPIRO PHARMA LIMITED.	AIVEEN (U) LIMITED	CANDIVOR 200 MG/VIAL	VORICONAZOLE	200MG	ASPIRO PHARMA LIMITEDSY. NO. 321, BIOTECH PARK, PHASE-III, KARKAPATLA, MARKOOK MANDAL, SIDDIPET DISTRICT- 502 281, TELANGANA, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X200.0 MG VIAL	02/02/2024
983	NDA/MAL/HDP/1 1084	MEGA LIFSCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	INVEL FORTE L	METRONIDAZOLE + MICONAZOLE NITRATE + LIDOCAINE	750 MG + 200 MG + 100 MG	BLISS GVS PHARMA LTD PLOT NO. 11, SURVEY NO. 38/1, DEWAN UDYOG NAGAR, ALIYALI, PALGHAR, MAHARASHTRA 401404, INDIA	INDIA	VAGINAL SUPPOSITORIES	1.0X1.0X7.0 SUPPOSITORY STRIP, 1.0X2.0X7.0 SUPPOSITORY STRIP	02/02/2024

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984	NDA/MAL/HDP/1 1085	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EMITINO INJECTION	ONDANSETRON HYDROCHLORIDE	4MG/2ML	SAKAR HEALTHCARE PVT LTDBLOCK NO. 10-13, NR. M.N DESAI PETRO PUMP, SARKHEJ-BAVLA ROAD, CHANGODAR, DIST: AHMEDABAD- 382213, GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0X2.0 ML AMPOULE	02/02/2024
985	NDA/MAL/HDP/1 1086	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	ERYBRU 500	ERYTHROMYCIN STEARATE	500MG	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	02/02/2024
986	NDA/MAL/HDP/1 1088	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	DARUNAVIR 400 MG	DARUNAVIR	400MG	LAURUS LABS LTD (UNIT 2)PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTAM, ANDRA PRADESH,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X60.0 TABLET BOTTLE	02/02/2024

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987	NDA/MAL/HDP/1 109	DAWA LIMITED	SUPER MEDIC LTD	DAWA-CPM	CHLORPHENIRAM INE MALEATE	2MG/5ML	DAWA PHARMACEUTICALS LIMITEDPLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2014
988	NDA/MAL/HDP/1 1090	LES LABORATOIRES SERVIER	HARLEYS UGANDA LIMITED	DIAMICRON MR 60 MG	GLICLAZIDE	60MG	LES LABORATOIRES SERVIER INDUSTRIE (LSI)905 ROUTE DE SARAN 45520 GIDY - FRANCE	FRANCE	ORAL SOLID RETARD TABLETS	1.0X2.0X15.0 TABLET BLISTER	02/02/2024
989	NDA/MAL/HDP/1 1094	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	FETNAL 500	CEFUROXIME AXETIL	500MG	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	02/02/2024

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990	NDA/MAL/HDP/1 1098	VERVE HUMAN CARE LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	ADEVER	ADRENALINE ACID TARTRATE	1MG/ML	VERVE HUMAN CARE LABORATORIES PLOT NO. 15A PHARMACITY, SELAQUI, DEHRADUN, UTTARAKHAND, 248011, INDIA.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	02/02/2024
991	NDA/MAL/HDP/1 1101	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	CLARITHROMYCIN 500 MG	CLARITHROMYCIN	500MG	SANDOZ S.R.LSTR. LIVEZENI NR. 7A 540472 TARGU- MURES ROMANIA	ROMANIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	02/02/2024
992	NDA/MAL/HDP/1 1102	ENCORE HEALTHCARE PVT. LTD.	REDDYS PHARMA LIMITED	ONTADEX 50MG	TRAMADOL HYDROCHLORIDE	50MG	ENCORE HEALTHCARE PVT LTDD-5, MIDC AREA, PAITHAN- 431148, DIST. AURANGABAD, MAHARASHTRA - INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	02/02/2024

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993	NDA/MAL/HDP/1103	CACHET PHARMACEUTICALS 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
994	NDA/MAL/HDP/1104	CACHET PHARMACEUTICALS 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
995	NDA/MAL/HDP/1105	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD.	HEALTHCARE LTD.	TELOSIN	TAMSULOSIN HYDROCHLORIDE	0.4MG	AL FAZAL PHARMA INDUSTRIES (PVT) LTD PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	02/02/2024

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996	NDA/MAL/HDP/1 1106	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 LIMITEDHILL-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
997	NDA/MAL/HDP/1 1107	ZIM LABORATORIES LTD	GITTOES PHARMACEUTICAL S 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
998	NDA/MAL/HDP/1 1109	LEBEN LABORATORIES PVT. LTD	MALIX PHARMA (U) LIMITED	BETALEB-N CREAM	BETAMETHASONE VALERATE + NEOMYCIN SULPHATE	0.1%W/W + 0.5%W/W	LEBEN LABORATORIES PVT LTD .L-14 PHASE III MIDC AKOLA 444 104	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	02/02/2024

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999	NDA/MAL/HDP/111	DAWA LIMITED	SUPER MEDIC LTD	FAST-ACT GEL	DICLOFENAC DIETHYLAMINE + METHYL SALICYLATE + LINSEED OIL + MENTHOL CRYSTALS	1.16%W/W + 10%W/W + 3%W/W + 5%W/W	DAWA PHARMACEUTICALS LIMITEDPLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE	01/07/2013
1000	NDA/MAL/HDP/1110	SAGA LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	GLIBEMET 500/2.5	METFORMIN HYDROCHLORIDE + GLIBENCLAMIDE	500 MG + 2.5 MG	SAGA LABORATORIES .198/2 & 198/3, CHACHRAWADI, VASNA NO. CLARIS LIFE SCIENCE, TA SANAND, DIST. DIST: AHMEDABAD	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	02/02/2024
1001	NDA/MAL/HDP/1111	RUSAN PHARMA LTD.	NORVIK ENTERPRISES LIMITED	ADDNOK	BUPRENORPHINE HYDROCHLORIDE	8MG	RUSAN PHARMA LTDKHASRA NO. 122MI, CENTRAL HOPE TOWN, BEHIND PHARMA CITY, SELAQUI, DEHRADUN- 248197, UTTARAKHAND, INDIARUSAN PHARMA LIMITEDPLOT NO. 59 - 65, SECTOR II, KANDLA SPECIAL ECONOMIC ZONE, GANDHIDHAM	INDIA	ORAL SOLID ORDINARY SUBLINGUAL TABLETS	1.0X1.0X7.0 TABLET BLISTER, 1.0X4.0X7.0 TABLET BLISTER	02/02/2024

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1002	NDA/MAL/HDP/1 1112	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	BETASONE	BETAMETHASONE VALERATE	0.1%W/W	HOVID BERHAD (IPOH SITE)121, JALAN TUNKU ABDUL RAHMAN 30010 IPOH PERAK	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	02/02/2024
1003	NDA/MAL/HDP/1 1113	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	ATRONA-20	ATORVASTATIN CALCIUM	20MG	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
1004	NDA/MAL/HDP/1 1117	FAROMED LIFESCIENCES LLP	METRO PHARMACEUTICAL S LIMITED	FAST 250 SUPPOSITORY	PARACETAMOL	250MG	THE ACME LABORATORIES LIMITEDDHULIVITA, DHAMRAI, DHAKA - 1350, BANGLADESH	BANGLADESH	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY STRIP	02/02/2024

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1005	NDA/MAL/HDP/1118	LUPIN LIMITED-	AIVEEN (U) LIMITED	MOXIFLOXACIN	MOXIFLOXACIN HYDROCHLORIDE	400 MG	LUPIN LIMITEDUNIT-2, PLOT NO. M-2 & M-2-A, SPECIAL ECONOMIC ZONE, PHASE II, MISC. ZONE, APPAREL PARK, DIST. DHAR - M.P. PITHAMPUR, 454775, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	02/02/2024
1006	NDA/MAL/HDP/1119	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
1007	NDA/MAL/HDP/1120	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 TELEGANA (STATE)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X6.0X7.0 TABLET BLISTER	02/02/2024

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1008	NDA/MAL/HDP/1 1128	ATCO LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BETAMET-N	BETAMETHASONE AS VALERATE + NEOMYCIN SULPHATE	0.1% W/W + 0.5% W/W	ATCO LABORATORIES LIMITED-B-18, S.I.T.E, KARACHI - 74700	PAKISTAN	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X15.0 G TUBE	12/13/2023
1009	NDA/MAL/HDP/1 1129	EAST AFRICAN (INDIA) OVERSEAS	ABACUS PHARMA (AFRICA) LIMITED	PARARIV-I	IBUPROFEN + PARACETAMOL	100 MG + 162.5 MG	EAST AFRICAN (INDIA) OVERSEAS- PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	12/13/2023
1010	NDA/MAL/HDP/1 113	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	ALCID-YELLOW	MULTI- INGREDIENT	MULTI- INGREDIENT	TORQUE PHARMACEUTICALS PVT LTDISAAPUR P.O DAPPAR 140056 INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X400.0 ML BOTTLE,1.0X160.0 ML BOTTLE	01/07/1997

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1011	NDA/MAL/HDP/1 1130	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	VINGLYN M 50/1000	VILDAGLIPTIN + METFORMIN HYDROCHLORIDE	50 MG + 1000 MG	EAST AFRICAN (INDIA) OVERSEAS- PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023
1012	NDA/MAL/HDP/1 1135	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
1013	NDA/MAL/HDP/1 1136	KESAR PHARMA	ABACUS PHARMA (AFRICA) LIMITED	ALZOL	ALBENDAZOLE	400 MG	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILSHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X1.0 TABLET BLISTER	12/13/2023

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1014	NDA/MAL/HDP/1137	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	DARUNIVIR AND RITONIVIR TABLETS	DARUNAVIR ETHANOLATE + RITONAVIR	800 MG + 100 MG	HETERO LABS PRIVATE LIMITED UNIT III-SURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) JEEDIMETLA, HYDERABAD-500 055, TELANGANA STATE,	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET CONTAINER,1.0X18 0.0 TABLET CONTAINER	12/13/2023
1015	NDA/MAL/HDP/1138	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
1016	NDA/MAL/HDP/1139	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	EMTRICITABINE AND TENOFOVIR ALAFENAMIDE TABLETS	EMTRICITABINE + TENOFOVIR ALAFENAMIDE	200 MG + 25 MG	LAURUS LABS LTD (UNIT 2)-PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTAM, ANDRA PRADESH,	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE	12/13/2023

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1017	NDA/MAL/HDP/1114	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	TRANGEL ULTRA	DICLOFENAC/METHYL SALICYLATE/MEN THOL/CAPSICUM 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
1018	NDA/MAL/HDP/1140	SINOVAC BIOTECH CO LTD	BHL HEALTHCARE LIMITED	HEALIVE (JUNIOR USE)	INACTIVATED HEPATITIS A VIRUS ANTIGEN, TZ84 STRAIN PRODUCED IN HUMAN DIPLOID (2BS) CELLS ADSORBED ON ALUMINIUM HYDROXIDE	250 IU/1.0 ML	SINOVAC BIOTECH COMPANY LIMITED - CHANGPING SITE- NO. 15, ZHITONG ROAD, CHANGPING DISTRICT, BEIJING, 102200 - CHINA	CHINA	PARENTERAL ORDINARY VIALS	1.0X1.0X0.5 ML VIAL,1.0X1.0X0.5 ML PRE- FILLED SYRINGE	12/13/2023
1019	NDA/MAL/HDP/1141	SINOVAC BIOTECH CO LTD	BHL HEALTHCARE LIMITED	HEALIVE (ADULT USE)	INACTIVATED HEPATITIS A VIRUS ANTIGEN, TZ84 STRAIN PRODUCED IN HUMAN DIPLOID (2BS) CELLS ADSORBED ON ALUMINIUM HYDROXIDE	250 IU/1.0 ML	SINOVAC BIOTECH COMPANY LIMITED - CHANGPING SITE- NO. 15, ZHITONG ROAD, CHANGPING DISTRICT, BEIJING, 102200 - CHINA	CHINA	PARENTERAL ORDINARY VIALS	1.0X1.0X1.0 ML VIAL,1.0X1.0X1.0 ML PRE- FILLED SYRINGE	12/13/2023

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1020	NDA/MAL/HDP/11142	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
1021	NDA/MAL/HDP/11143	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
1022	NDA/MAL/HDP/11144	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	EFAVIRENZ, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS	EFAVIRENZ + LAMIVUDINE + TENOFOVIR 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

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1023	NDA/MAL/HDP/1 1145	NEXT WAVE (INDIA)	DAVIMED PHARMA LIMITED	CADZOLE-V	CLOTRIMAZOLE	100 MG	NEXT WAVE- RAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	VAGINAL TABLETS	1.0X1.0X6.0 TABLET STRIP	12/13/2023
1024	NDA/MAL/HDP/1 1147	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	MEMTIN 10	MEMANTINE HYDROCHLORIDE	10 MG	UNICHEM LABORATORIES LTD- UNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023
1025	NDA/MAL/HDP/1 1148	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	CONAZ CREAM	KETOCONAZOLE	2% W/W	ATCO LABORATORIES LIMITED-B-18, S.I.T.E, KARACHI - 74700	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X1.0X10.0 G TUBE	12/13/2023

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1026	NDA/MAL/HDP/1149	JAMJOOM PHARMACEUTICALS COMPANY	MU PHARMA CO - SMC LIMITED	LICAN	LULICONAZOLE	1% W/W	JAMJOOM PHARMACEUTICALS COMPANY - PLOT NO: ME1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 - KINGDOM OF SAUDI ARABIA	SAUDI ARABIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	12/13/2023
1027	NDA/MAL/HDP/1150	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	LABCLAV 625MG TABLETS	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500 MG + 125 MG	LABORATORY & ALLIED LTD -PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, NEXT TO LIBRA HOUSE, MOMBASA ROAD- NAIROBI - KENYA	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER,1.0X2.0X7.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	12/13/2023
1028	NDA/MAL/HDP/1151	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

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1029	NDA/MAL/HDP/1 1152	BAROQUE PHARMACEUTICAL S PVT LTD	JEET PHARMACEUTICAL S LIMITED	COCEL	CELECOXIB	200 MG	BAROQUE PHARMACEUTICAL PVT LTD-192/2 & 3, SOKHADA, 388620, TA: KHAMHAT DIST. ANANT (GUJARAT)	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	12/13/2023
1030	NDA/MAL/HDP/1 1153	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	XAFARIV 15	RIVAROXABAN	15 MG	MYLAN LABORATORIES LIMITED-NO. H-12 & H-13, MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD - 431 136, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	12/13/2023
1031	NDA/MAL/HDP/1 1154	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	XAFARIV 20	RIVAROXABAN	20 MG	MYLAN LABORATORIES LIMITED-NO. H-12 & H-13, MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD - 431 136, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	12/13/2023

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1032	NDA/MAL/HDP/11155	IDA FOUNDATYION	KIMSY MEDS LTD	BENZATHINE BENZYL PENICILLIN 1.2MIU	BENZATHINE BENZYL PENICILLIN	1.2 MIU	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X15.0 ML VIAL	12/13/2023
1033	NDA/MAL/HDP/11156	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
1034	NDA/MAL/HDP/11157	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

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1035	NDA/MAL/HDP/1 1158	MARCYRL PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TORSAMOLEX 20MG	TORSEMIDE	20MG	MARCYRL PHARMACEUTICAL INDUSTRIES WESTERN EXTEENSION-PARTS NUMBER 5/6/7/8/9/10/11/12- BLOCK 20005, EL OBOUR CITY	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	02/02/2024
1036	NDA/MAL/HDP/1 1159	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TIBAN 20	TENEGLIPTIN HYDROBROMIDE HYDRATE	20MG	AJANTA PHARMA LIMITEDB-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD MAHARASHTRA STATE INDIA 431 128	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/02/2024
1037	NDA/MAL/HDP/1 1160	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	ROSUNA-5	ROSUVASTATIN CALCIUM	5MG	ZOTA HEATHCARE LIMITEDPLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NEAR SACHIN RAILWAY STATION, SACHIN, CITY: SURAT, DIST: SURAT, GUJARAT STATE - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/02/2024

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1038	NDA/MAL/HDP/1161	CACHET PHARMACEUTICALS PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EMITINO-8 INJECTION	ONDANSETRON HYDROCHLORIDE	8MG/4ML	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN " 248011 (U.K), INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0X4.0 ML AMPOULE	02/02/2024
1039	NDA/MAL/HDP/1162	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICALS LTD)	TATA UGANDA LIMITED	RABZOL	RABEPRAZOLE SODIUM	20MG	NAPROD LIFE SCIENCES PVT. LTDG-17/1, MIDC TARAPUR IND. AREA, BOISAR, 401506 MAHARASHTRA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X20.0 MG VIAL, 1.0X1.0X20.0 G VIAL	02/02/2024
1040	NDA/MAL/HDP/1163	UNIMED LABORATORIES.	OMAB UGANDA LIMITED	CIPROJECT	CIPROFLOXACIN	200MG	UNIMED LABORATORIES P.O. BOX 38 - I.Z. KALAA KEBIRA - 4060 KALAA KEBIRA - TUNISIA	TUNISIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X100.0 ML BAG	02/02/2024

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1041	NDA/MAL/HDP/1164	IDA FOUNDATYION	KIMSY MEDS LTD	BENZATHINE BENZYL PENICILLIN 5MIU	BENZATHINE BENZYL PENICILLIN	5 MIU	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X15.0 ML VIAL	12/13/2023
1042	NDA/MAL/HDP/1165	IDA FOUNDATYION	KIMSY MEDS LTD	BENZATHINE BENZYL PENICILLIN 1MIU	BENZATHINE BENZYL PENICILLIN	1MIU	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X15.0 ML VIAL	12/13/2023
1043	NDA/MAL/HDP/1166	GLOBELA PHARMA PVT. LTD.	ROYAL PHARMA 2011 LIMITED	PYLOGLOB KIT	CLARITHROMYCIN + OMEPRAZOLE + TINIDAZOLE	250 MG + 20 MG + 500 MG	GLOBELA PHARMA PVT.LTD.357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY COMBINATION PACK COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	21/02/2024

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1044	NDA/MAL/HDP/1 1167	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	XAGULANT 2.5	APIXABAN	2.5 MG	MYLAN LABORATORIES LIMITED-NO. H-12 & H-13, MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD - 431 136, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	12/13/2023
1045	NDA/MAL/HDP/1 1168	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	XAGULANT 5	APIXABAN	5 MG	MYLAN LABORATORIES LIMITED-NO. H-12 & H-13, MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD - 431 136, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	12/13/2023
1046	NDA/MAL/HDP/1 1169	IDA FOUNDATYION	KIMSY MEDS LTD	DICLOFENAC SODIUM	DICLOFENAC SODIUM	75MG/3ML	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X3.0 ML AMPOULE	12/13/2023

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1047	NDA/MAL/HDP/117	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	TETRACYCLINE EYE OINTMENT USP 1%	TETRACYCLINE	1%W/W	NEM LABORATORIES LIMITED133 KRISHNA IND. ESTATE, VASAI (E), THANE – 401 210, MAHARASHTRA – INDIA	INDIA	OPHTHALMIC OINTMENTS	1.0X20.0X3.5 G TUBE	01/07/2013
1048	NDA/MAL/HDP/1170	JEVIANA HEALTH CARE LLP,	MARVIN PHARMA LIMITED	MARIPRAZOLE	OMEPRAZOLE SODIUM	40 MG/VIAL	SANJAR PHARMACEUTICALS LIMITED-SURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X40.0 MG VIAL + 1*10 ML, WATER FOR INJECTION IN LDPE AMPOULE	12/13/2023
1049	NDA/MAL/HDP/1171	BIOMATRIX HEALTHCARE PVT LTD.-	MEDIWORLD PHARMA AFRICA LTD	PRIMECIP	CIPROFLOXACIN HYDROCHLORIDE	500 MG	BIOMATRIX HEALTHCARE PRIVATE LIMITED-SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	12/13/2023

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1050	NDA/MAL/HDP/1 1172	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	GLANTRIM	DORZOLAMIDE HYDROCHLORIDE + TIMOLOL MALEATE	2%W/V + 0.5%W/V	ATCO LABORATORIES LIMITEDB-18, S.I.T.E, KARACHI - 74700	PAKISTAN	OPHTHALMIC LIQUIDS	1.0X1.0X5.0 ML BOTTLE	02/02/2024
1051	NDA/MAL/HDP/1 1173	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	WINOLAP 0.1	OLOPATADINE HYDROCHLORIDE	0.1%W/V	ATCO LABORATORIES LIMITEDB-18, S.I.T.E, KARACHI - 74700	PAKISTAN	OPHTHALMIC LIQUIDS	1.0X1.0X5.0 ML BOTTLE	02/02/2024
1052	NDA/MAL/HDP/1 1174	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	WINOLAP 0.2%	OLOPATADINE HYDROCHLORIDE	0.2%W/V	ATCO LABORATORIES LIMITEDB-18, S.I.T.E, KARACHI - 74700	PAKISTAN	OPHTHALMIC LIQUIDS	1.0X1.0X2.5 ML BOTTLE	02/02/2024

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1053	NDA/MAL/HDP/1175	ADWIA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	URIPAN XR	OXYBUTYNIN HYDROCHLORIDE	10MG	ADWIA S.A.E.1ST INDUSTRIAL ZONE A1, 10TH OF RAMADAN CITY, EGYPT	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/02/2024
1054	NDA/MAL/HDP/1176	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BORTEBIN	BORTEZOMIB	3.5MG	EUGIA PHARMA SPECIALITIES LIMITED SURVEY 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
1055	NDA/MAL/HDP/1177	ADWIA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LEPTROGINE 200 MG	LAMOTRIGINE	200MG	ADWIA S.A.E.1ST INDUSTRIAL ZONE A1, 10TH OF RAMADAN CITY, EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/02/2024

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1056	NDA/MAL/HDP/1178	UNIMED LABORATORIES.	OMAB UGANDA LIMITED	SYNERGIC 500	IMIPENEM + CILASTATIN	500 MG + 500 MG	UNIMED LABORATORIESP.O. BOX 38 - I.Z. KALAA KEBIRA - 4060 KALAA KEBIRA - TUNISIA	TUNISIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X20.0 ML VIAL	02/02/2024
1057	NDA/MAL/HDP/1179	UNIMED LABORATORIES.	OMAB UGANDA LIMITED	TAZOBACT 4G/500 MG	PIPERACILLIN SODIUM + TAZOBACTAM SODIUM	4G + 500MG	UNIMED LABORATORIESP.O. BOX 38 - I.Z. KALAA KEBIRA - 4060 KALAA KEBIRA - TUNISIA	TUNISIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X4.5 G VIAL	02/02/2024
1058	NDA/MAL/HDP/1118	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ELAXIM 52.5	TENECTEPLASE (RECOMBINANT TISSUE PLASMINOGEN ACTIVATOR), (TNK-T-PA)	52.5	GENNOVA BIOPHARMACEUTICALS LIMITEDBLOCK 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

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1059	NDA/MAL/HDP/1 1182	INDIANA OPHTHALMICS	SWASTIK PHARMACEUTICAL LTD	AZEECON	AZITHROMYCIN DIHYDRATE	1%W/W	INDIANA OPHTHALMICS135, 136, 137, GIDC ESTATE, WADHWAN- 363035	INDIA	OPHTHALMIC OINTMENTS	1.0X1.0X5.0 G TUBE	02/02/2024
1060	NDA/MAL/HDP/1 1189	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	CLEOBACT 150	CLINDAMYCIN HYDROCHLORIDE	150 MG	BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	12/13/2023
1061	NDA/MAL/HDP/1 1190	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	ACNEX	CLINDAMYCIN PHOSPHATE	1% W/W	NANZ MED SCIENCE PHARMA PVT. LTD- RAMPUR GHAT, PAONTA SAHIB, DISTRICT SIRMOUR- 173025, HIMACHAL PRADESH, INDIA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X15.0 G TUBE	12/13/2023

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1062	NDA/MAL/HDP/1 1191	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	FUNGIDERM	CLOTRIMAZOLE + ZINC OXIDE + DIMETHICONE	1% W/W + 1.75% W/W + 2.50% W/W	NANZ MED SCIENCE PHARMA PVT. LTD- RAMPUR GHAT, PAONTA SAHIB, DISTRICT SIRMOUR- 173025, HIMACHAL PRADESH, INDIA	INDIA	TOPICAL EXTERNAL DUSTING POWDERS	1.0X50.0 G BOTTLE	12/13/2023
1063	NDA/MAL/HDP/1 1192	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	ERINOCIN 250	ERYTHROMYCIN STEARATE	250 MG	BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	12/13/2023
1064	NDA/MAL/HDP/1 1193	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	WELGRA 100	SILDENAFIL CITRATE	100 MG	AKUMS DRUGS AND PHARMACEUTICALS- 19,20,21, SEC.6-A, IIE, SIDCUL, RANIPUR, HARIDWAR 249403, UTTARAKHAND, INDIAINDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	12/13/2023

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1065	NDA/MAL/HDP/1194	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	UNOKETRO	KETOROLAC TROMETHAMINE	30 MG/ML	AKUMS DRUGS & PHARMACEUTICALS LTD ,-2,3,4,5, SECTOR 6B, SIDCUL, I.I.E, RANIPUR, HARIDWAR-249403, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0X1.0 ML AMPOULE	12/13/2023
1066	NDA/MAL/HDP/1195	FAROMED LIFESCIENCES LLP	METRO PHARMACEUTICALS LIMITED	WINOP 60	KETOROLAC TROMETHAMINE	60MG/2ML	THE ACME LABORATORIES LIMITED-DHULIVITA, DHAMRAI, DHAKA - 1350, BANGLADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X2.0 ML AMPOULE	12/13/2023
1067	NDA/MAL/HDP/1196	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

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1068	NDA/MAL/HDP/1197	LINCOLN PHARMACEUTICALS 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
1069	NDA/MAL/HDP/1198	ARCELIA LIFE SCIENCES LTD.	NOVOMED HEALTHCARE LIMITED	GENTAMICIN SULPHATE	GENTAMICIN SULPHATE	80MG/2ML	SANJAR PHARMA LLP-SURVEY NO. 622/2/1/4, DEDHROTA, TAHIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X2.0 ML VIAL	12/13/2023
1070	NDA/MAL/HDP/1199	PRISMA PHARMACEUTICALS (UGANDA) LIMITED	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

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1071	NDA/MAL/HDP/1 1200	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	HYTAN – 80	TELMISARTAN	80MG	BAFNA PHARMACEUTICALS LIMITED UNIT II-NO. 147, MADHAVARAM RED HILLS ROAD, GRANTLYON VILLAGE, VADAKARAI POST, CHENNAI, TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023
1072	NDA/MAL/HDP/1 1201	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	HYTAN – 40	TELMISARTAN	40MG	BAFNA PHARMACEUTICALS LIMITED UNIT II-NO. 147, MADHAVARAM RED HILLS ROAD, GRANTLYON VILLAGE, VADAKARAI POST, CHENNAI, TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/13/2023
1073	NDA/MAL/HDP/1 1202	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	IRNIZET 40	IRINOTECAN HYDROCHLORIDE TRIHYDRATE	20MG/ML	EUGIA PHARMA SPECIALITIES LIMITED-SURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X2.0 ML VIAL	12/13/2023

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1074	NDA/MAL/HDP/1 1203	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	AUROPODOX 40	CEFPODOXIME PROXETIL	40MG PER 5ML	AUROBINDO PHARMA LIMITED, FORMULATIONS UNIT-VI- R7- AUROBINDO PHARMA LIMITED, FORMULATIONS UNIT-VI SY.NO.329/39 & 329/47 CHITKUL(V) PATANCHERU MANDAL, SANGA REDDY DISTTELANGANA502 307	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X100.0 ML BOTTLE	12/13/2023
1075	NDA/MAL/HDP/1 1204	KLM LABORATORIES PVT. LTD.	REDDYS PHARMA LIMITED	NIOFINE CREAM	TERBINAFINE HYDROCHLORIDE	1.0% W/W	CURETECH SKINCARE-PLOT NO. 33 & 34, PHASE IV, BHATOLI KALAN, BADDI DISTT. SOLAN (HP) 173205	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	12/13/2023
1076	NDA/MAL/HDP/1 1205	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	20M	MANNITOL	20% W/V	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED-SURVEY NO. 199 TO 201 & 208 TO 210, MF01 AND MF02 VILLAGE- VASNA CHACHARWADI, TAL. SANAND DISTRICT. AHMEDABAD-382 213	INDIA	PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES	1.0X1.0X500.0 ML BOTTLE	12/13/2023

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1077	NDA/MAL/HDP/1 1206	XL LABORATORIES PRIVATE LIMITED	ROYAL PHARMA 2011 LIMITED	FLAMO 400	IBUPROFEN	400 MG	XL LABORATORIES PRIVATE LIMITED-A- 141, EPIP INDUSTRIAL AREA, NEEMRANA, DIST. ALWAR, RAJASTHAN - 301705 (INDIA)	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X6.0X1.0X10.0 CAPSULE BLISTER	12/13/2023
1078	NDA/MAL/HDP/1 1208	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROZMET - 500	METFORMIN	500 MG	EAST AFRICAN (INDIA) OVERSEAS- PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	12/13/2023
1079	NDA/MAL/HDP/1 1209	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	RO-VIT-K 10	PHYTOMENADIO NE	10MG/ML	SANJAR PHARMACEUTICALS LIMITED-SURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0X1.0 ML AMPOULE	12/13/2023

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1080	NDA/MAL/HDP/1 122	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABCHLOR EAR DROPS	CHLORAMPHENIC OL	5%W/V	ABACUS PARENTERAL DRUGS LIMITEDBLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	OTIC DROPS	1.0X10.0 ML VIAL,1.0X5.0 ML VIAL	01/07/2013
1081	NDA/MAL/HDP/1 123	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOPAR	PARACETAMOL	500 MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER	01/07/2012
1082	NDA/MAL/HDP/1 1230	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

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1083	NDA/MAL/HDP/1 1232	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	PLERISTEM	PLERIXAFOR	24MG/1.2ML	EUGIA PHARMA SPECIALITIES LIMITEDSURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X1.2.0 ML VIAL	22/03/2024
1084	NDA/MAL/HDP/1 1233	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICAL S LTD)	PLANET PHARMACEUTICAL S UGANDA LTD	AMCARDIA-10	AMLODIPINE BESYLATE	10 MG	UNIQUE PHARMACEUTICAL LABS LIMITED. .PLOT NO. 215-219 AND 304-308, GIDC INDUSTRIAL ESTATE, PANOLI - 394 116, DIST: BHARUCH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	22/03/2024
1085	NDA/MAL/HDP/1 1234	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	MOXILEB 250 DT	AMOXICILLIN TRIHYDRATE	250MG	LEBEN LABORATORIES PVT LTD .L-14 PHASE III MIDC AKOLA 444 104	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	22/03/2024

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1086	NDA/MAL/HDP/1 1235	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	QUALITY CHEMICALS LTD	ZENTAIR 1.0MG	ENTECAVIR	1.0MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED (CIPLAQCIL)PLOT 1- 7, 1ST RING ROAD, LUZIRA INDUSTRIAL PARK	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	22/03/2024
1087	NDA/MAL/HDP/1 1236	REDDYS PHARMA LIMITED	REDDYS PHARMA LIMITED	AURATRIM-GB	BETAMETHASONE DIPROPIONATE + CLOTRIMAZOLE + GENTAMICIN SULFATE	0.05% W/W + 1.0% W/W + 0.1% W/W	AURA LIFECARE PRIVATE LIMITEDSURVEY NO. 254/14/1, JAROD- SAVLI ROAD, P.O. KARACHIYA, 391 520, TAL. SAVLI, DIST. VADODARA - INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE, 1.0X30.0 G TUBE	22/03/2024
1088	NDA/MAL/HDP/1 1237	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	PERILIN	METOCLOPRAMI DE HYDROCHLORIDE	10MG/2ML	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	22/03/2024

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1089	NDA/MAL/HDP/1 1238	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	DESLORA-5	DESLORATADINE	5MG	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	22/03/2024
1090	NDA/MAL/HDP/1 1239	NEM LABORATORIES (PVT) LTD	RENE PHARMACY LTD	TIGBODERM -G CREAM	CLOTRIMAZOLE + GENTAMICIN SULFATE + BETAMETHASONE DIPROPIONATE	1% W/W + 0.1% W/W + 0.05% W/W	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE, 1.0X30.0 G TUBE	22/03/2024
1091	NDA/MAL/HDP/1 124	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGO SCRUB	CHLORHEXIDINE GLUCONATE	4%W/V	AGOG PHARMA LTD PLOT NO.33, SECTOR II, VASAI, TALUKA INDL CO-OP ESTATE LTD, GAURAI PADA, VASAI(E) DIST. THANE INDIA	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X1.0X500.0 ML BOTTLE	01/07/2013

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1092	NDA/MAL/HDP/1 1241	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	TERBINAFINE TABLETS USP, 250 MG	TERBINAFINE HYDROCHLORIDE	250MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN “ 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/03/2024
1093	NDA/MAL/HDP/1 1242	FAROMED LIFESCIENCES LLP	METRO PHARMACEUTICAL S LIMITED	SITAP 50	SITAGLIPTIN PHOSPHATE MONOHYDRATE	50MG	ADVANCED CHEMICAL INDUSTRIES (ACI) LIMITED7, HAJEEGONJ ROAD, GOODNYL, NARAYANGONJ - 1400	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/03/2024
1094	NDA/MAL/HDP/1 1243	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	ZETIRISE	ALBENDAZOLE	200MG/5ML	SUNRISE INTERNATIONAL LABS LTD PLOT NO. 100, LANE-5, SECTOR-II, PHASE-II, IDA, CHERLAPALLY INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X10.0 ML BOTTLE	22/03/2024

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1095	NDA/MAL/HDP/1 1244	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	ESOPRALIN	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40MG	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/03/2024
1096	NDA/MAL/HDP/1 1245	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	VALPIN-200	SODIUM VALPROATE	200MG	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	22/03/2024
1097	NDA/MAL/HDP/1 1246	SCOTT-EDIL ADVANCE RESEARCH LABORATORIES & EDUCATION LTD.,	ROYAL PHARMA 2011 LIMITED	SCOFIX 400	CEFIXIME TRIHYDRATE	400MG	M/S SCOTT-EDIL ADVANCE RESEARCH LABORATORIES AND EDUCATION LIMITEDHILL-TOP, INDUSTRIAL AREA, BHATOLI KALAN, BADDI, DISTT. SOLAN (HP) - 173205, INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	22/03/2024

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1098	NDA/MAL/HDP/1 1248	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICAL S LTD	VIDAGLIN	VILDAGLIPTIN	50 MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/03/2024
1099	NDA/MAL/HDP/1 1249	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	ARH-L	ARTEMETHER + LUMEFANTRINE	(180 MG + 1080 MG)/ 60ML	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X60.0 ML BOTTLE	22/03/2024
1100	NDA/MAL/HDP/1 125	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	AUROXONE 1000	CEFTRIAZONE	1000MG	AUROBINDO PHARMA LIMITED, FORMULATIONS UNIT-VI- R7AUROBINDO PHARMA LIMITED, FORMULATIONS UNIT-VI SY.NO.329/39 & 329/47 CHITKUL(V) PATANCHERU MANDAL, SANGA REDDY DISTTELANGANA502 307	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2009

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1101	NDA/MAL/HDP/1 1250	AUROCHEM LABORATORIES(I) PVT LTD	SUPER MEDIC LTD	DOBESIL H	CALCIUM DOBESILATE MONOHYDRATE + LIDOCAINE HYDROCHLORIDE + HYDROCORTISON E ACETATE + ZINC OXIDE	0.5 % W/W + 3.0 %W/W + 0.25 % W/W + 5.0 % W/W	AUROCHEM LABORATORIES (I) PVT LTD8, PALGHAR TALUKA INDUSTRIAL CO - OPERATIVE ESTATE LIMITED PALGHAR, DISTRICT - PALGHAR, 401404	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	22/03/2024
1102	NDA/MAL/HDP/1 1252	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TELMICLAR HTZ 40/12.5	TELMISARTAN + HYDROCHLOROT HIAZIDE	40 MG + 12.5 MG	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	16/03/2024
1103	NDA/MAL/HDP/1 1253	FRESENIUS KABI MANUFACTURING S.A. (PTY) LTD	SURGIPHARM (U) LIMITED	CLINDAMYCIN FRESENIUS 600MG/4ML	CLINDAMYCIN PHOSPHATE	600MG/4ML	FRESENIUS KABI MANUFACTURING SA (PTY) LIMITED6 GIBAUD ROAD, KORSTEN, 6020, PORT ELIZABETH, SOUTH AFRICALABESFAL LABORATORIOS ALMIRO, S.A ZONA INDUSTRIAL DO LAGEDO, 3465-157 SANTIAGO DE BESTEIROS	PORTUGALSOUTH AFRICA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X4.0 ML AMPOULE	22/03/2024

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1104	NDA/MAL/HDP/1 1254	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ORIXO 400	OFLOXACIN	400MG	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	16/03/2024
1105	NDA/MAL/HDP/1 1255	MANKIND PHARM LTD	TATA UGANDA LIMITED	MAHACEF-200	CEFIXIME TRIHYDRATE	200 MG	COPMED PHARMACEUTICALS PVT LTD-UNIT II. ,PLOT 50, GONDPUR INDUSTRIAL AREA, PAONTA, SAHIB, SIRMOUR, HIMACHAL PRADESH- 173025, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	22/03/2024
1106	NDA/MAL/HDP/1 1256	BRAWN LABORATORIES LTD	TATA UGANDA LIMITED	MOXIBRU	MOXIFLOXACIN	0.5% W/V	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML BOTTLE	22/03/2024

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1107	NDA/MAL/HDP/1 1257	BRAWN LABORATORIES LTD	TATA UGANDA LIMITED	BRUCOXIA-90	ETORICOXIB	90MG	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/03/2024
1108	NDA/MAL/HDP/1 1258	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ADERAN HTZ 16/12.5	CANDESARTAN CILEXETIL + HYDROCHLOROT HIAZIDE	16 MG + 12.5 MG	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	16/03/2024
1109	NDA/MAL/HDP/1 1259	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICAL S LTD)	TATA UGANDA LIMITED	MAGNILEK	GADOPENTETATE DIMEGLUMINE	469MG/ML	UNIQUE PHARMACEUTICAL LABORATORIESPLOT NO.4, PHASE IV, GIDC, INDUSTRIAL AREA, PANOLI- 394 116, DIST: BHARUCH, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL, 1.0X10.0 ML VIAL, 1.0X15.0 ML VIAL	22/03/2024

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1110	NDA/MAL/HDP/1 1260	MANKIND PHARM LTD	TATA UGANDA LIMITED	MAHACEF-100	CEFIXIME TRIHYDRATE	100 MG	COPMED PHARMACEUTICALS PVT LTD-UNIT II. ,PLOT 50, GONDPUR INDUSTRIAL AREA, PAONTA, SAHIB, SIRMOUR, HIMACHAL PRADESH- 173025, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	22/03/2024
1111	NDA/MAL/HDP/1 1261	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	COLIHENZ	CITICOLINE SODIUM	500MG	STANFORD LABORATORIES PRIVATE LIMITED (A SUBSIDIARY COMPANY OF LA RENON HEALTHCARE PRIVATE LIMITED)8, INDUSTRIAL AREA, MEHATPUR - 174315, HIMACHAL PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	16/03/2024
1112	NDA/MAL/HDP/1 1262	AMN LIFE SCIENCE PVT LTD	VITACARE LIMITED	MOXITAM 125	AMOXICILLIN TRIHYDRATE	125MG PER 5ML	AMN LIFE SCIENCE PVT LTD67/P-1, MALAV, AREA- BHILAD, VALSAD- 396105, GUJARAT	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X60.0 ML BOTTLE	22/03/2024

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1113	NDA/MAL/HDP/1 1263	ORCHIDIA PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NORMOPROST	LATANOPROST	50MCG/ML	ORCHIDIA PHARMACEUTICAL INDUSTRIESAL OBOUR CITY INDUSTRIAL ZONE, AREA 14, 15 - PLOT NO. 12011 - CAIRO - EGYPT	EGYPT	OPHTHALMIC DROPS	1.0X1.0X3.0 ML BOTTLE	22/03/2024
1114	NDA/MAL/HDP/1 1264	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	FLAIROF	ROFLUMILAST	250MCG	HETERO LABS LIMITED (UNIT III)...22-110, I.D.A, JEEDIMETLA, HYDERABAD-500 055, ANDHRA PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X15.0 TABLET BLISTER	16/03/2024
1115	NDA/MAL/HDP/1 1265	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	NEUTAS	RECOMBINANT HUMAN GRANULOCYTE COLONY STIMULATING FACTOR	300MCG/0.5ML	INTAS PHARMACEUTICALS LTD (BIOPHARMA DIVISION)PLOT NO. 423/P/A, SARKHEJ- BAVLA HIGHWAY, MORAIYA, TALUKA SANAND, AHMEDABAD- 382213, GUJARAT	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0 ML PRE- FILLED SYRINGE	22/03/2024

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1116	NDA/MAL/HDP/1 1266	I-CARE PHARMA LTD	AIVEEN (U) LIMITED	IZ 500	AZITHROMYCIN DIHYDRATE	500MG	CORONA REMEDIES PVT. LTD.VILLAGE 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
1117	NDA/MAL/HDP/1 1267	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ASTRA PHARMA (U) LIMITED	CACHMAX-200	CEFIXIME TRIHYDRATE	200 MG	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	16/03/2024
1118	NDA/MAL/HDP/1 1269	INTAS PHARMACUITICALS LTD	NORVIK ENTERPRISES LIMITED	DOXORUBICIN INJECTION	DOXORUBICIN	2MG/ML	INTAS PHARMACEUTICALS LTD.PLOT NO. 457, 458, & 191/218P,VILLAGE: MATODA, TAL. SANAND, AHMEDABAD, GUJARAT, 382210 INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X25.0 ML VIAL	22/03/2024

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1119	NDA/MAL/HDP/1 1270	RUSAN PHARMA LTD.	NORVIK ENTERPRISES LIMITED	ADDNOK-N 2/0.5	BUPRENORPHINE HYDROCHLORIDE + NALOXONE HYDROCHLORIDE	2 MG + 0.5 MG	RUSAN PHARMA LTDKHASRA NO. 122MI, CENTRAL HOPE TOWN, BEHIND PHARMA CITY, SELAQUI, DEHRADUN- 248197, UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY SUBLINGUAL TABLETS	1.0X3.0X10.0 TABLET BLISTER, 1.0X10.0 TABLET BLISTER, 1.0X10.0X10.0 TABLET BLISTER	22/03/2024
1120	NDA/MAL/HDP/1 1271	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	DOLUTEGRAVIR SODIUM 50 MG, EMTRICITABINE 200 MG AND TENOFVIRAL AFENAMIDE 25 MG	DOLUTEGRAVIR SODIUM + EMTRICITABINE + TENOFVIR ALAFENAMIDE	50 MG + 200 MG + 25 MG	LAURUS LABS LTD (UNIT 2)PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTAM, ANDRA PRADESH,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	16/03/2024
1121	NDA/MAL/HDP/1 1273	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	ABACAVIR, DOLUTEGRAVIR AND LAMIVUDINE TABLETS	ABACAVIR SULFATE + DOLUTEGRAVIR SODIUM + LAMIVUDINE	600 MG + 50 MG + 300 MG	LAURUS LABS LTD (UNIT 2)PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTAM, 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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1122	NDA/MAL/HDP/1 1274	HILTON PHARMA (PVT) LTD	BOOTS PHARMACEUTICAL S LIMITED	DAPA 10MG	DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE	10 MG	HILTON PHARMACEUTICALS (PVT) LIMITED PLOT NO. 13-14, SECTOR 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X14.0 TABLET BLISTER	16/03/2024
1123	NDA/MAL/HDP/1 1275	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	SPIRONOLACTON E	SPIRONOLACTON E	25MG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI- 248197, DEHRADUN (UTTARAKHAND)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/03/2024
1124	NDA/MAL/HDP/1 1276	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 PATALGANGA, 410220 DISTRICT RAIGAD, MAHARASHTRA CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED (CIPLAQCIL) PLOT 1- 7, 1ST RING ROAD, LUZIRA INDUSTRIAL PARK	UGANDA INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER, 1.0X90.0 TABLET CONTAINER	16/03/2024

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1125	NDA/MAL/HDP/1 1277	SQUARE PHARMACEUTICAL S LTD	GAMA PHARMACEUTICAL S (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
1126	NDA/MAL/HDP/1 1278	AGOG PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	AGOXIN-500	AMOXICILLIN TRIHYDRATE	500MG	MILAN LABORATORIES (INDIA) PVT LTD,63,67,87,35,36, 64, 65 JAWAHAR CO- OP INDUSTRIAL ESTATE KAMOTHE, PANVEL NAVI MUMBAI	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X1.0X20.0 CAPSULE BLISTER	16/03/2024
1127	NDA/MAL/HDP/1 1279	MSN LABORATORIES PRIVATE LIMITED,	GOOD DAY PHARMACY LIMITED	SILOTRIF 8	SILODOSIN	8MG	MSN LABORATORIES LTD. PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, ZIP CODE - 502 325, ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	16/03/2024

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1128	NDA/MAL/HDP/1 128	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	BTC KIT	FLUCONAZOLE + AZITHROMYCIN + SECNIDAZOLE	150MG + 1G + 1G	LINCOLN PHARMACEUTICALS L.T.DTRIMUL ESTATE KHATRAJ 382721 GHANDINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY COMBINATION PACK TABLETS	1.0X4.0 TABLET BLISTER	01/07/2013
1129	NDA/MAL/HDP/1 1280	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BRUGENTA EYE/EAR DROPS	GENTAMICIN SULFATE	0.3%W/V	BRAWN LABORATORIES LTD .13, NIT, INDUSTRIAL AREA, FARIDABAD- 121001, HARYANA	INDIA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE	16/03/2024
1130	NDA/MAL/HDP/1 1281	WORLD MEDICINE Ä°LAÄ± SAN. VE TIC. A.Äž.	GOODMAN INTERNATIONAL LTD	SERTOGEN	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/INSTANB UL, TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	16/03/2024

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1131	NDA/MAL/HDP/1 1282	WORLD MEDICINE İLAÇ SAN. VE TİC. A.Ş.	GOODMAN INTERNATIONAL LTD	CULENTO 4MG	MONTELUKAST SODIUM	4MG	WORLD MEDICINE ILAC SAN VE TIC A.S.15 TEMMUZ MAHALLESİ, CAMI YOLU CADDESİ, NO: 50 K:4 WM PLAZA, GUNESIL- BAGCILAR/INSTANB UL, TURKEY	TURKEY	ORAL SOLID ORDINARY GRANULES	1.0X28.0 SACHET CARTON	16/03/2024
1132	NDA/MAL/HDP/1 1283	THE SEARLE COMPANY LIMITED	HEALTHCARE LTD.	VAPTOR 10MG	ROSUVASTATIN CALCIUM	10MG	SEARLE PAKISTAN LIMITED,F-319, SITE KARACHI	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	16/03/2024
1133	NDA/MAL/HDP/1 1284	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	MYDEKLA 60	DACLATASVIR DIHYDROCHLORID E	60MG	MYLAN LABORATORIES LTD .F/4 & F/12, MALEGAON MIDC, SINNAR, NASHIK-422 113, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X28.0 TABLET CONTAINER	16/03/2024

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1134	NDA/MAL/HDP/1 1285	JSC BIOCAD, SAINT PETERSBURG	ONCOPHARM (U) LTD	BEVALAST	BEVACIZUMAB	25 MG/ML	JSC BIOCAD NEUDORF, FACILITY 2BLD. 38, CONSTRUCTION 1, SVYAZI ST., STRELNA, SAINT- PETERSBURG, RUSSIA, 198515	RUSSIA	PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES	1.0X1.0X16.0 ML VIAL, 1.0X1.0X4.0 ML VIAL, 1.0X1.0X100.0 MG VIAL, 1.0X1.0X400.0 MG VIAL	22/03/2024
1135	NDA/MAL/HDP/1 1286	JSC BIOCAD	ONCOPHARM (U) LTD	ACELLBIA	RITUXIMAB	10 MG/ML	JSC BIOCAD NEUDORF, FACILITY 2BLD. 38, CONSTRUCTION 1, SVYAZI ST., STRELNA, SAINT- PETERSBURG, RUSSIA, 198515	RUSSIA	PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES	1.0X1.0X50.0 ML VIAL, 1.0X1.0X500.0 MG VIAL	22/03/2024
1136	NDA/MAL/HDP/1 1287	LABORATÁRIOS BASI	ONCOPHARM (U) LTD	MIDAZOLAM BASI	MIDAZOLAM	15 MG/3 ML	LABORATORIOS BASI - INDUSTRIA FARMACEUTICAPAR QUE INDUSTRIAL MANUEL LOURENCO FERREIRA, LOTES 8, 15 E 16, 3450-232 MORTAGUA - PORTUGAL	PORTUGAL	PARENTERAL ORDINARY AMPOULES	1.0X10.0X3.0 ML AMPOULE	22/03/2024

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1137	NDA/MAL/HDP/1 1288	MICRO LABS LIMITED	PHARMA VILLE LIMITED	PARACETAMOL BP 500MG TABLET	PARACETAMOL	500MG	MICRO LABS LIMITED, HOSURNO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	22/03/2024
1138	NDA/MAL/HDP/1 1289	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ADCCLENA 5	LENALIDOMIDE	5MG	MYLAN LABORATORIES LTD PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR - 454775; DIST; DHAR; MADHYA PRADESH;	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X14.0 CAPSULE BLISTER	16/03/2024
1139	NDA/MAL/HDP/1 1290	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ADCCLENA 10	LENALIDOMIDE	10MG	MYLAN LABORATORIES LTD PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR - 454775; DIST; DHAR; MADHYA PRADESH;	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X14.0 CAPSULE BLISTER	16/03/2024

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1140	NDA/MAL/HDP/1291	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ADCCLENA 15	LENALIDOMIDE	15MG	MYLAN LABORATORIES LTD PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR - 454775; DIST; DHAR; MADHYA PRADESH;	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X14.0 CAPSULE BLISTER	16/03/2024
1141	NDA/MAL/HDP/1293	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
1142	NDA/MAL/HDP/1294	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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1143	NDA/MAL/HDP/1 1295	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DYGLI 100	SITAGLIPTIN	100MG	BAFNA PHARMACEUTICALS LIMITED UNIT IINO. 147, MADHAVARAM RED HILLS ROAD, GRANTLYON VILLAGE, VADAKARAI POST, CHENNAI, TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/03/2024
1144	NDA/MAL/HDP/1 1296	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DYGLI-50	SITAGLIPTIN	50MG	BAFNA PHARMACEUTICALS LIMITED UNIT IINO. 147, MADHAVARAM RED HILLS ROAD, GRANTLYON VILLAGE, VADAKARAI POST, CHENNAI, TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/03/2024
1145	NDA/MAL/HDP/1 1297	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	OLMAT-AM	OLMESARTAN MEDOXOMIL + AMLODIPINE BESILATE	40MG + 5MG	MICRO LABS LIMITED, HOSURNO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/03/2024

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1146	NDA/MAL/HDP/1 1298	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	OLMAT-AM	OLMESARTAN MEDOXOMIL + AMLODIPINE BESILATE	20MG + 5MG	MICRO LABS LIMITED, HOSURNO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/03/2024
1147	NDA/MAL/HDP/1 1299	LABORATĂRIOS VITĂRIA, S.A	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TRAUSAN	CITICOLINE SODIUM	100MG/ML	FAES FARMA SAMAXIMO AGUIRRE 14. 48940 LEIOA Ă€ SPAIN	SPAIN	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X50.0 ML BOTTLE	22/03/2024
1148	NDA/MAL/HDP/1 130	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	KLARO-500	CLARITHROMYCIN TABLETS	500MG	LINCOLN PHARMACEUTICALS LIMITEDTRIMUL 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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1149	NDA/MAL/HDP/1 1309	LABORATORIOS BASI INDUSTRIA FARMACEUTICA S.A	HEAVENCENT THERAPEUTICS LIMITED	AZITHROMYCIN	AZITHROMYCIN	500MG	GUFIC BIOSCIENCES LIMITED (UNIT 2)SURVEY NO. 171, NATIONAL HIGHWAY NO. 8, NEAR GRID, AT & PO: KABILPORE, NAVSARI - 396424, GUJARAT - INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL	28/03/2024
1150	NDA/MAL/HDP/1 131	FEROZSONS LABORATORIES LTD	HEALTHCARE LTD.	XAVOR 50	LOSARTAN	50MG	FEROZSONS LABORATORIES LTDAMANGARH- NOWSHERA, (KHYBER PAKHTOONKHWA), PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2014
1151	NDA/MAL/HDP/1 132	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	M-CALZ	CALCIUM CITRATE +MAGNESIUM HYDROXIDE + ZINC SULPHATE + COLECALCIFEROL	1000MG+100MG+ 4MG+200.I.U	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2012

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1152	NDA/MAL/HDP/1 1329	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GLIMERON 4	GLIMEPIRIDE	4MG	AJANTA PHARMA LIMITED-MIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/05/2024
1153	NDA/MAL/HDP/1 1330	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S LIMITED	PREGASAFE M 75	PREGABALIN + METHYLCOBALA MIN	75 MG + 750 MCG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISION-PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	24/05/2024
1154	NDA/MAL/HDP/1 1331	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S LIMITED	ALMOTAN 12.5	ALMOTRIPTAN MALATE	12.5 MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISION-PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X6.0X1.0 TABLET BLISTER	22/05/2024

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1155	NDA/MAL/HDP/1 1332	WORLD MEDICINE İLAÇ SAN. VE TIC. A.Ş.	GOODMAN INTERNATIONAL LTD	PIRETIKOL	PARACETAMOL	250MG/5ML	WORLD MEDICINE ILAC SAN VE TIC A.S.- 15 TEMMUZ MAHALLESİ, CAMI YOLU CADDESİ, NO: 50 K:4 WM PLAZA, GUNESIL- BAGCILAR/INSTANB UL, TURKEY	TURKEY	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	24/05/2024
1156	NDA/MAL/HDP/1 1333	MERIDIAN ENTERPRISES PRIVATE LIMITED.	VIDA AFRICA LTD	NASO-FLO	SODIUM CHLORIDE	0.9%W/V	MERIDIAN ENTERPRISES PVT. LTD--PLOT NO. 418, G.I.D.C.,KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	NASAL SYSTEMIC DROPS	1.0X1.0X20.0 ML BOTTLE	22/05/2024
1157	NDA/MAL/HDP/1 1334	MERIDIAN ENTERPRISES PRIVATE LIMITED.	VIDA AFRICA LTD	ZORIN ADULT	XYLOMETAZOLINE HYDROCHLORIDE	0.1% W/V	MERIDIAN ENTERPRISES PVT. LTD--PLOT NO. 418, G.I.D.C.,KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	NASAL SYSTEMIC DROPS	1.0X1.0X10.0 ML BOTTLE	24/05/2024

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1158	NDA/MAL/HDP/1 1335	MERIDIAN ENTERPRISES PRIVATE LIMITED.	VIDA AFRICA LTD	ZORIN PAEDIATRIC	XYLOMETAZOLINE HYDROCHLORIDE	0.05% W/V	MERIDIAN ENTERPRISES PVT. LTD--PLOT NO. 418, G.I.D.C.,KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	NASAL SYSTEMIC DROPS	1.0X1.0X10.0 ML BOTTLE	22/05/2024
1159	NDA/MAL/HDP/1 1336	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	TOLSIN 0.4	TAMSULOSIN HYDROCHLORIDE	0.4 MG	MICRO LABS LIMITED, HOSUR- NO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	22/05/2024
1160	NDA/MAL/HDP/1 1337	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROCID	MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE	(250 MG + 250 MG)/5 ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N- 119, N-113 MIDC TARAPUR BOISAR DIST. THANE 401506 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	24/05/2024

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1161	NDA/MAL/HDP/1 1338	MIDASCARE PHARMACEUTICAL S PRIVATE LIMITED,	ABACUS PHARMA (AFRICA) LIMITED	RELISPRAY DR	DICLOFENAC DIETHYLAMINE + METHYL SALICYLATE + LEVOMENTHOL	01.16 % W/W + 10.00 % W/W + 5% W/W	MIDAS CARE PHARMACEUTICALS PVT LTD.-B-16 MIDC, WALUJ AURANGABAD 431136, MAHARASHTRA, INDIA	INDIA	TOPICAL EXTERNAL PRESSURISED AEROSOLS	1.0X55.0 G CANNISTER	24/05/2024
1162	NDA/MAL/HDP/1 134	FEROZSONS LABORATORIES LTD	HEALTHCARE LTD.	XAVOR DIU	LOSARTAN AND HYDROCHLORTHI AZIDE	50/12.5MG	FEROZSONS LABORATORIES LTDAMANGARH- NOWSHERA, (KHYBER PAKHTOONKHWA), PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2013
1163	NDA/MAL/HDP/1 1342	SHREEJI CARE LIMITED	SHREEJI CARE LIMITED	DICLOFENAC	DICLOFENAC SODIUM	50MG	GLOBELA PHARMA PVT.LTD.-357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	22/05/2024

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1164	NDA/MAL/HDP/1 1351	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LOTEL	LOTEPREDNOL ETABONATE	0.5%W/W	AJANTA PHARMA LIMITED-MIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	OPHTHALMIC GELS/SOLS	1.0X1.0X5.0 ML BOTTLE	22/05/2024
1165	NDA/MAL/HDP/1 1352	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BRINZOX	BRINZOLAMIDE	1.0% W/V	AJANTA PHARMA LIMITED-MIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	OPHTHALMIC SUSPENSIONS	1.0X1.0X5.0 ML BOTTLE	22/05/2024
1166	NDA/MAL/HDP/1 1353	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BETOACT	BEPOTASTINE BESILATE	1.5% W/V	AJANTA PHARMA LIMITED-MIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	22/05/2024

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1167	NDA/MAL/HDP/1 1354	ARCELIA LIFE SCIENCES LTD.	NOVOMED HEALTHCARE LIMITED	TRANEXAMIC ACID TABLETS BP 500 MG	TRANEXAMIC ACID	500MG	ASSOCIATED BIOTECH-VILLAGE: KISHANPURA, GUGUMAJRA ROAD, BADDI THE: NALAGARH HIMACHAL PRADESH 174101 - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	22/05/2024
1168	NDA/MAL/HDP/1 1355	EMCURE PHARMACEUTICAL S LTD -	HARLEYS UGANDA LIMITED	MOLENA-200	MOLNUPIRAVIR	200MG	EMCURE PHARMACEUTICALS LIMITED-PLOT NO. P- 2. ITBT PARK, PHASE II, MIDC, HINJWADI PUNE 411057, MHARASHTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X40.0 CAPSULE CONTAINER	22/05/2024
1169	NDA/MAL/HDP/1 1357	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	DOVPRELA	PRETOMANID	200MG	MYLAN LABORATORIES LIMITED-NO. H-12 & H-13, MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD - 431 136, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X26.0 TABLET CONTAINER	24/05/2024

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1170	NDA/MAL/HDP/1 1358	BHARAT SERUMS & VACCINES LTD.	ABACUS PHARMA (AFRICA) LIMITED	EVAFACT	DIENOGEST	2MG	NAARI PHARMA PRIVATE LIMITED- PLOT NO. 14-16 &55- 57, SECTOR-5, IIE, PANTNAGAR, RUDRAPUR-263153, DIST. U.S. NAGAR, UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	24/05/2024
1171	NDA/MAL/HDP/1 1359	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	HALOSCOT 5	HALOPERIDOL	5MG	M/S SCOTT-EDIL PHARMACIA LTD -56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	22/05/2024
1172	NDA/MAL/HDP/1 136	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOSCAB APPLICATION	BENZYL BENZOATE	25%W/W	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL EMULSIONS	1.0X1.0X100.0 ML BOTTLE	01/07/2013

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1173	NDA/MAL/HDP/1 1360	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	HALOSCOT 10	HALOPERIDOL	10MG	M/S SCOTT-EDIL PHARMACIA LTD -56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	22/05/2024
1174	NDA/MAL/HDP/1 1361	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ETORIB 90	ETORICOXIB	90MG	PINNACLE LIFE SCIENCE PVT LTD- KHASRA NO. 1328- 1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	24/05/2024
1175	NDA/MAL/HDP/1 1362	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ETORIB 120	ETORICOXIB	120MG	PINNACLE LIFE SCIENCE PVT LTD- KHASRA NO. 1328- 1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	24/05/2024

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1176	NDA/MAL/HDP/1 1363	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ETORIB 60	ETORICOXIB	60MG	PINNACLE LIFE SCIENCE PVT LTD- KHASRA NO. 1328- 1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	24/05/2024
1177	NDA/MAL/HDP/1 1364	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	DESLOSCOT-5	DESLORATADINE	5MG	M/S SCOTT-EDIL PHARMACIA LTD -56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	24/05/2024
1178	NDA/MAL/HDP/1 1365	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	EFAVIRENZ, LAMIVUDINE AND TENOFIVIR DISOPROXIL FUMARATE 400/300/300 MG TABLET	EFAVIRENZ + LAMIVUDINE + TENOFIVIR DISOPROXIL FUMARATE	400MG + 300MG + 300MG	CIPLA LIMITED-PLOT NO. A-42 (UNIT-II), MIDC, PATALGANGA - 410220, DISTRICT: RAIGAD, MAHARASHTRA - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER,1.0X90. 0 TABLET CONTAINER	24/05/2024

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1179	NDA/MAL/HDP/1 1366	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	SCOZINC-20 DT	ZINC SULPHATE MONOHYDRATE	20MG	M/S SCOTT-EDIL PHARMACIA LTD -56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	24/05/2024
1180	NDA/MAL/HDP/1 1367	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	ACLOHERP 200	ACICLOVIR	200 MG	AUROBINDO PHARMA LIMITED, UNIT - XV-PLOT NO. 17A, E BONANGI (V), PARAWADA (M), VISAKHAPATNAM DISTRICT, ANDHRA PRADESH. PIN: 531021	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X5.0 TABLET BLISTER	22/05/2024
1181	NDA/MAL/HDP/1 1368	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	ACLOHERP 400	ACICLOVIR	400MG	AUROBINDO PHARMA LIMITED, UNIT - XV-PLOT NO. 17A, E BONANGI (V), PARAWADA (M), VISAKHAPATNAM DISTRICT, ANDHRA PRADESH. PIN: 531021	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X5.0 TABLET BLISTER	22/05/2024

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1182	NDA/MAL/HDP/1 1369	EUGIA PHARMA SPECIALITIES LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TAMFONY 20	TAMOXIFEN CITRATE	20MG	EUGIA PHARMA SPECIALITIES LIMITED-SURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	22/05/2024
1183	NDA/MAL/HDP/1 1370	GAMA PHARMACEUTICAL S (U) LIMITED	GAMA PHARMACEUTICAL S (U) LIMITED	GYNO-DAKTAZOL OVULES	MICONAZOLE NITRATE	400MG	JERUSALEM PHARMACEUTICALS CO. LTD-AL-BIREH RAMALLAH INDUSTRIAL ZONE, AL-BIREH NABLUS ROAD, P.O. BOX: 3570 PALESTINE	PALESTINE	VAGINAL SUPPOSITORIES	1.0X1.0X3.0 OVULE BLISTER	22/05/2024
1184	NDA/MAL/HDP/1 1371	NVS KENYA LTD	SURGIPHARM (U) LIMITED	PAGENAX 120 MG/ML	BROLUCIZUMAB	120 MG/ML	NOVARTIS PHARMA STEIN AG STERILE OPERATIONS SOLID OPERATIONS- NOVARTIS PHARMA STEIN AG SCHAFFHAUSERSTRA SSE, 4332 STEIN - SWITZERLAND NOVARTIS PHARMA AG-LICHTSTRASSE 35 - 4056 BASEL, SWITZERLAND	SWITZERLAND	PARENTERAL ORDINARY VIALS	1.0X1.0X1.0 ML VIAL + 1*1 FILTER NEEDLE	22/05/2024

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1185	NDA/MAL/HDP/1 1372	BIOSIMILARS NEWCO LIMITED	KIMSY MEDS LTD	OGIVRI	TRASTUZUMAB	150MG/VIAL	BIOCON BIOLOGICS LIMITED-SPECIAL ECONOMIC ZONE, PLOT NO. 2, 3, 4 & 5, PHASE - IV, BOMMASANDRA- JIGANI LINK ROAD, BOMMASANDRA POST, BENGALURU - 560099, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X15.0 ML VIAL	22/05/2024
1186	NDA/MAL/HDP/1 1373	HEALTH LINK PHARMACY LTD	HEALTH LINK PHARMACY LIMITED	ROYOMOL 500	PARACETAMOL	500 MG	INNOVA CAPTAB PVT. LTD-1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	22/05/2024
1187	NDA/MAL/HDP/1 1376	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	UNIFEN 10	BACLOFEN	10 MG	UNICHEM LABORATORIES LTD- UNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/05/2024

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1188	NDA/MAL/HDP/1 1378	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	UNIFEN 20	BACLOFEN	20MG	UNICHEM LABORATORIES LTD- UNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/05/2024
1189	NDA/MAL/HDP/1 138	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGO-CALAMINE	CALAMINE	15%W/W	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	TOPICAL EXTERNAL LOTIONS	1.0X1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2013
1190	NDA/MAL/HDP/1 1380	RATNAMANI HEALTHCARE PVT. LTD	JEET PHARMACEUTICAL S LIMITED	RATNAQUIN	QUININE DIHYDROCHLORID E	300MG/ML	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 VIALS	1.0X1.0X10.0X2.0 ML VIAL	22/05/2024

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1191	NDA/MAL/HDP/1 1385	BETA DRUGS LTD	PHARMACINE UGANDA LIMITED	ADCARB 450MG/45ML	CARBOPLATIN	10 MG/ML	BETA DRUGS LIMITED-KHURUNI- LOHIMAJRA ROAD THE: BADDI, DISTT: SOLAN (H.P) - INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X45.0 ML VIAL	22/05/2024
1192	NDA/MAL/HDP/1 1389	OMNICALS PHARMA PVT. LTD	GITTOES PHARMACEUTICAL S LIMITED	OMIZINC 20	ZINC SULFATE MONOHYDRATE	20MG	THE ACME LABORATORIES LIMITED-DHULIVITA, DHAMRAI, DHAKA - 1350, BANGLADESH	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X5.0X10 .0 TABLET BLISTER	22/05/2024
1193	NDA/MAL/HDP/1 139	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOVATE	BETAMETHASONE	0.1%W/W	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2012

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1194	NDA/MAL/HDP/1 1399	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DOLOGAN DENK	PARACETAMOL + IBUPROFEN + CAFFEINE	250 MG + 200 MG + 50 MG	ARTESAN PHARMA GMBH & CO. KG- WENDLANDSTR.1, 29439, LUCHOW	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	24/05/2024
1195	NDA/MAL/HDP/1 140	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOVATE-N	BETAMETHASONE +NEOMYCIN SULPHATE	0.1%W/W+0.5%W /W	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2013
1196	NDA/MAL/HDP/1 1401	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	ARTESUNATE AMODIAQUINE BILAYER TABLETS 50MG/135MG			MICRO LABS LTD,- PLOT S-155 TO S- 159, VERNA IND. ESTATE, PHASE III, VERNA-GOA-403722	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X25.0X3.0 TABLET BLISTER	22/05/2024

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1197	NDA/MAL/HDP/1 1402	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	ARTESUNATE AMODIAQUINE BILAYER TABLETS 25MG/67.25MG	ARTESUNATE + AMODIAQUINE HYDROCHLORIDE	25MG/67.25MG	MICRO LABS LTD,- PLOT S-155 TO S- 159, VERNA IND. ESTATE, PHASE III, VERNA-GOA-403722	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X25.0X3.0 TABLET BLISTER	22/05/2024
1198	NDA/MAL/HDP/1 1405	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	ARTESUNATE AMODIAQUINE BILAYER TABLETS 100MG/270MG	ARTESUNATE + AMODIAQUINE HYDROCHLORIDE	100MG + 270MG	MICRO LABS LTD,- PLOT S-155 TO S- 159, VERNA IND. ESTATE, PHASE III, VERNA-GOA-403722	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X25.0X3.0 TABLET BLISTER	22/05/2024
1199	NDA/MAL/HDP/1 1412	LG CHEM, LTD.	MM PARTNERS LOGISTICS LIMITED	EUPOLIO	INACTIVATED POLIOVIRUS TYPE 1 (SABIN STRAIN) + INACTIVATED POLIOVIRUS TYPE 2 (SABIN STRAIN) + INACTIVATED POLIOVIRUS TYPE 3 (SABIN STRAIN)	5 D-ANTIGEN UNITS + 8 D- ANTIGEN UNITS + 16 D-ANTIGEN UNITS	LG CHEM LIMITED, OSONG PLANT- 151, OSONGSAENGMYEONG-RO, OSONG-EUP, HEUNGDEOK-GU, CHEONGJU-SI, HUNGCHONGBUK- DO (POSTAL CODE: 28162) - REPUBLIC OF KOREA	NORTH KOREA	PARENTERAL ORDINARY VIALS	1.0X10.0X2.5 ML VIAL,1.0X10.0X0.5 ML VIAL	24/05/2024

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1200	NDA/MAL/HDP/1 1413	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	P-ALAXIN DISPERSIBLE 40/320	DIHYDROARTEMI SININ + PIPERAQUINE PHOSPHATE	40 MG + 320 MG	BLISS GVS PHARMA LTD,-PLOT 10, SURVEY NO. 38/1, DEWAN UDYONG NAGAR ALIYALI VILLAGE TAL PALGHAR DIST. THANE - INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X3.0 TABLET BLISTER	24/05/2024
1201	NDA/MAL/HDP/1 1414	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	NEBSTYLE 5	NEBIVOLOL HYDROCHLORIDE	5MG	AUROBINDO PHARMA LIMITED UNIT 3-PLOT NO. 313, 314, BACHUPALLY, RR DIST. 500090	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/05/2024
1202	NDA/MAL/HDP/1 1415	NEXT WAVE (INDIA)	REVITAL HEALTH CARE LTD	MUPORIG	MUPIROCIN	2% W/W	NEXT WAVE- RAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P)	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X10.0 G TUBE	22/05/2024

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1203	NDA/MAL/HDP/1 142	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S 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. THANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2013
1204	NDA/MAL/HDP/1 1421	INFUGEN PHARMA PVT. LTD.	TATA UGANDA LIMITED	INFUSUNATE	ARTESUNATE	60 MG /VIAL	SANJAR PHARMACEUTICALS LIMITED-SURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X60.0 MG VIAL + 5ML CLEAR GLASS AMPOULE OF 0.9%W/V SODIUM CHLORIDE INJECTION BP + 1ML CLEAR GLASS AMPOULE OF 5.0%W/V SODIUM BICARBONATE INJECTION	22/05/2024
1205	NDA/MAL/HDP/1 1422	BIOMATRIX HEALTHCARE PVT LTD.-	MEDIWORLD PHARMA AFRICA LTD	CLEOBACT 300	CLINDAMYCIN HYDROCHLORIDE	300 MG	BIOMATRIX HEALTHCARE PRIVATE LIMITED- SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	22/05/2024

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1206	NDA/MAL/HDP/1 1424	SERUM INSTITUTE OF INDIA PVT LTD	NORVIK ENTERPRISES LIMITED	ROTASIL - LIQUID	LIVE ATTENUATED BOVINE - HUMAN ROTAVIRUS REASSORTANT STRATIN [G1, G2, G3, G4 AND G9]	≥ 10 ^{5.6} FFU /SEROTYPE PER DOSE (2.0 ML)	SERUM INSTITUTE OF INDIA LTD -.PLOT NO. 212/2 HADAPSAR, OFF SOLI POONAWALLA ROAD, PUNE 411028 - INDIA	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X50.0X4.0 ML VIAL	22/05/2024
1207	NDA/MAL/HDP/1 1426	GLAXOSMITHKLINE BIOLOGICALS S.A.	UNITED HEALTHCARE DISTRIBUTORS LTD	MOSQUIRIX	RTS,S (PLASMODIUM FALCIPARUM AND HEPATITIS B ANTIGEN)		GLAXOSMITHKLINE BIOLOGICALS S.A- PARC DE LA NOIRE EPINE, AVENUE FLEMING 20-1300 WAVRE - BELGIUM GLAXOSMITHKLINE BIOLOGICALS-637 RUE DES AULMOIS, 59230 SAINT- AMAND-LES-EAUX	BELGIUM	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X2.0 DOSE VIAL + 1*50*1ML GLASS VIAL OF DILUENT	24/05/2024
1208	NDA/MAL/HDP/1 143	LINCOLN P'CAL'S LTD	METRO PHARMACEUTICAL S LIMITED	LOSA-H	LOSARTAN + HYDROCHLOROT HIAZIDE	50MG + 12.5MG	LINCOLN PHARMACEUTICALS LIMITEDTRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2012

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1209	NDA/MAL/HDP/1 145	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	HILAC	LACTULOSE	68%W/V	HILTON PHARMA (PVT) LTD PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2005
1210	NDA/MAL/HDP/1 1454	COSMOS LTD.	ASTRA PHARMA (U) LIMITED	HARTEZE 10	RIVAROXABAN	10MG	COSMOS LTD.- RANGWE ROAD OFF, LUNA LUNGA ROAD, INDUSTRIAL AREA - NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	31/05/2024
1211	NDA/MAL/HDP/1 1455	COSMOS LTD.	ASTRA PHARMA (U) LIMITED	HARTEZE 15	RIVAROXABAN	15MG	COSMOS LTD.- RANGWE ROAD OFF, LUNA LUNGA ROAD, INDUSTRIAL AREA - NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	31/05/2024

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1212	NDA/MAL/HDP/1 1456	COSMOS LTD.	ASTRA PHARMA (U) LIMITED	HARTEZE 20	RIVAROXABAN	20MG	COSMOS LTD.- RANGWE ROAD OFF, LUNA LUNGA ROAD, INDUSTRIAL AREA - NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	31/05/2024
1213	NDA/MAL/HDP/1 149	UNIVERSAL CORPORATION LTD	DELMAW ENTERPRISES LIMITED	NEUROBA	GABAPENTIN	300MG	UNIVERSAL CORPORATION LTD..PLOT 13777 CLUB ROAD, PAST KIKUYU	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2015
1214	NDA/MAL/HDP/1 154	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S 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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1215	NDA/MAL/HDP/1 158	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	TRAMADOL	TRAMADOL	50MG	TRIVENI FORMULATIONS LTD .PLOT NO. 52, 53,54 ALEAP INDUSTRIAL ESTATE SURAMPALLI VILLAGE GANNAVARAM MANDAL KRISHNA (DT) A.P	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2012
1216	NDA/MAL/HDP/1 160	DAFRA PHARMA LTD	MULTIPHAR UGANDA LIMITED	DAFRACLAV	AMOXYCILLIN + CLAVULANIC ACID	875MG+125MG	BILIM PHARMACEUTICALS- CERKEZKOY PLANT, 59500 CERKEZKOY, TEKIRDAG	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X2.0X5.0 TABLET BLISTER	01/07/2011
1217	NDA/MAL/HDP/1 163	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	FRUSEMIDE	FUROSEMIDE	40MG	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013

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1218	NDA/MAL/HDP/1 164	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	PIROXICAM	PIROXICAM	20MG	TRIVENI FORMULATIONS LTD .PLOT NO. 52, 53,54 ALEAP INDUSTRIAL ESTATE SURAMPALLI VILLAGE GANNAVARAM MANDAL KRISHNA (DT) A.P	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013
1219	NDA/MAL/HDP/1 166	PANACEA BIOTEC PHARMA LTD	VITACARE LIMITED	DOLZERO	TRAMADOL HYDROCHLORIDE + PARACETAMOL	37.5MG + 325MG	PANACEA BIOTEC PHARMA LIMITEDMALPURI BADDI, DISTRICT SOLAN, HIMACHAL PRADESH-173205 - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
1220	NDA/MAL/HDP/1 167	CIRON DRUGS AND PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	METOCLOPRAMID E INJECTION	METOCLOPRAMI DE	5MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD .N- 118,M.I.D.C, TARAPUR,BOISAR, DIST.THANE-401506, MAHARASHTRA,INDI A.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE	01/07/2010

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1221	NDA/MAL/HDP/1 168	DAWA LIMITED	SUPER MEDIC LTD	DAWA-CORT CREAM	HYDROCORTISON E	1%W/W	DAWA LTD BABA DOGO ROAD, RUARAKA P.O.BOX 16633-00620, NAIROBI KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2009
1222	NDA/MAL/HDP/1 169	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	NEBI 5	NEBIVOLOL HYDROCHLORIDE	5MG	ARISTO PHARMACEUTICALS PVT LTD PLOT NO.208 NEW INDUSTRIAL AREA NO.II MANDIDEEP 462046 RAISEN MADHYA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER,1.0X3.0X3. 0X10.0 TABLET BLISTER	01/07/2013
1223	NDA/MAL/HDP/1 172	CIRON DRUGS AND PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE ☒	20MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD .N- 118,M.I.D.C, TARAPUR,BOISAR, DIST.THANE-401506, MAHARASHTRA,INDI A.	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL,1.0X30.0 ML VIAL	01/07/2010

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1224	NDA/MAL/HDP/1 178	HETERO DRUGS LTD	AIVEEN (U) LIMITED	TENOFOVIR	TENOFOVIR DISOPROXIL FUMARATE	300MG	HETERO LABS LTD22- 110 IDA JEEDIMETLA HYDERABAD 500- 055 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2013
1225	NDA/MAL/HDP/1 179	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	OVITRELLE	CHORIOGONADO TROPIN ALFA	250MCG/0.5ML	MERCK SERONO S.P.A-VIA DELLE MAGNOLIE,15.70026 MODUGNO (BA).ITALY MERCK SERONO SA-1170 AUBONNE(SWITZERL AND)	ITALY, SWITZERLAND	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0 PREFILLED SYRINGE CARTON	01/07/2015
1226	NDA/MAL/HDP/1 184	DAWA LIMITED	SUPER MEDIC LTD	DACOF MUCOLYTIC	SALBUTAMOL + BROMHEXINE + GUAIPHENESIN + MENTHOL	2.0MG + 4.0MG +100MG + 1.0MG	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2013

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1227	NDA/MAL/HDP/1 185	DAWA LIMITED	SUPER MEDIC LTD	DACOF DRY	DIPHENHYDRAMINE + DEXTROMETHORPHAN + MENTHOL	12.5MG + 6.5MG + 1.10MG	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2013
1228	NDA/MAL/HDP/1 186	DAWA LIMITED	SUPER MEDIC LTD	DACOF EXPECTORANT	DIPHENHYDRAMINE HYDROCHLORIDE + AMMONIUM CHLORIDE + SODIUM CITRATE + MENTHOL	14.0MG + 135.0MG + 57.0MG + 1.10MG	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2013
1229	NDA/MAL/HDP/1 188	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	GMYCIN-80	GENTAMYCIN SULPHATE	80MG/2ML	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X2.0 ML AMPOULE	01/07/2013

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1230	NDA/MAL/HDP/1 189	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	DICLOMAX-75	DICLOFENAC SODIUM	75MG/ML	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X3.0 ML AMPOULE	01/07/2013
1231	NDA/MAL/HDP/1 196	UNIVERSAL CORPORATION LTD	DELMAW ENTERPRISES LIMITED	ACNESOL	TRETINOIN	0.05%W/W	UNIVERSAL CORPORATION LTD..PLOT 13777 CLUB ROAD, PAST KIKUYU	KENYA	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE	01/07/2012
1232	NDA/MAL/HDP/1 198	THEMIS MEDICARE LTD.	STAR PHARMACEUTICAL S LTD	MALITHER INJECTION	ARTEMETHER	80MG/ML	THEMIS MEDICARE LTD SECTOR 6A ,PLOT NO. 16,17 & 18 IIE,BHEL SIDCUL,HARIDWAR UTTARAKHAND 249403	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE	01/07/2013

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1233	NDA/MAL/HDP/1 199	THEMIS MEDICARE LTD	STAR PHARMACEUTICAL S LTD	THEMISSET 75	PALONOSETRON HYDROCHLORIDE	0.075MG/1.5ML	THEMIS MEDICARE LIMITESECTOR 6A, PLOT NO. 16 TO18, IIE, BHEL HARIDWA, UTTARAKHAND	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.5 ML VIAL	01/07/2013
1234	NDA/MAL/HDP/1 201	THEMIS MEDICARE LTD	STAR PHARMACEUTICAL S LTD	THEMISSET	PALONOSETRON HYDROCHLORIDE	0.25MG/5ML	THEMIS MEDICARE LIMITESECTOR 6A, PLOT NO. 16 TO18, IIE, BHEL HARIDWA, UTTARAKHAND	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.5 ML VIAL	01/07/2013
1235	NDA/MAL/HDP/1 204	THEMIS MEDICARE LTD	STAR PHARMACEUTICAL S LTD	DEXEM INJECTION	DEXMEDETOMIDI NE HYDROCHLORIDE	100	THEMIS MEDICARE LTDSECTOR 6A, PLOT NO. 16 TO18, IIE, BHEL HARIDWA, UTTARAKHAND	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE	01/07/2013

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1236	NDA/MAL/HDP/1 206	THE METHOLATUM CO. LTD	HARLEYS UGANDA LIMITED	DEEP RELIEF	IBUPROFEN + MENTHOL	5%W/W + 3% W/W	THE MENTHOLATUM CO. LTD. 1 REDWOOD AVE PEEL PARK CAMPUS EAST KILBRIDE	UNITED KINGDOM	TOPICAL EXTERNAL OTHER GELS/SOLS	1.0X50.0 G CONTAINER,1.0X15. 0 G CONTAINER,1.0X30. 0 G CONTAINER	01/07/2013
1237	NDA/MAL/HDP/1 208	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	VISCO LIQUID	ALGINIC ACID + MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE + SIMETHICONE	100 MG + 250 MG + 125 MG + 50 MG	ARISTO PHARMACEUTICALS PVT LTD PLOT NO.208 NEW INDUSTRIAL AREA NO.II MANDIDEEP 462046 RAISEN MADHYA PRADESH	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X200.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2011
1238	NDA/MAL/HDP/1 209	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	ARBITEL-80	TELMISARTAN	80MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011

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1239	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
1240	NDA/MAL/HDP/1214	FERRER INTERNACIONAL S.A	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NUCLEO C.M.P FORTE	CYTIDINE+URIDINE	5MG+3MG	FERRER INTERNACIONAL, S.AJOAN BUCSALA 1- 9, 08173 SANT CUGAT DEL VALLES, BARCELONA, SPAIN	SPAIN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X15.0 CAPSULE BLISTER	01/07/2013
1241	NDA/MAL/HDP/1215	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GYNANFORT VAGINAL PESSARY	METRONIDAZOLE +NEOMYCIN SULPHATE+NYSTANTIN	500MG+65,000I.U +100,000I.U	BLISS GVS PHARMA LIMITEDNO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	VAGINAL SUPPOSITORIES	1.0X10.0 TABLET BLISTER	01/07/2013

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1242	NDA/MAL/HDP/1 219	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	TORAS-DENK 5	TORASEMIDE	5MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014
1243	NDA/MAL/HDP/1 220	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	LONART	ARTEMETHER + LUMEFANTRINE	180 MG + 1080 MG	BLISS GVS PHARMA LIMITEDNO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BLISTER	01/07/2008
1244	NDA/MAL/HDP/1 223	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	WHITFIELD'S OINTMENT	BENZOIC ACID + SALICYLIC ACID	6%W/W + 3%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X25.0 G TUBE	01/07/1997

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1245	NDA/MAL/HDP/1 226	AFRICURE PHARMACEUTICAL S (INDIA) LTD	ROYAL PHARMA 2011 LIMITED	SALBUTAMOL	SALBUTAMOL	4MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9- 12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER,10.0X1 0.0 TABLET BLISTER	01/07/2005
1246	NDA/MAL/HDP/1 234	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	BISACODYL TABLETS BP	BISACODYL	5MG	MACLEODS PHARMACEUTICALS LTD.PLOT NO. 25-27 SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN (UT) - 396210, INDIA.	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2007
1247	NDA/MAL/HDP/1 242	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	TOPHEN-100	PHENYTOIN	100MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2013

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1248	NDA/MAL/HDP/1 244	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICAL S LTD	FLEXILOR SR	LORNOXICAM	16MG	GLENMARK PHARMACEUTICALS LTD .VILLAGE KISHANPURA, BADDI- NALAGARH ROAD, TEHSIL BADDI, DISTRICT SOLAN HP 173205	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
1249	NDA/MAL/HDP/1 245	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICAL S LTD	FLEXILOR P8	LORNOXICAM + PARACETAMOL	8MG + 500MG	GLENMARK PHARMACEUTICALS LTD .VILLAGE KISHANPURA, BADDI- NALAGARH ROAD, TEHSIL BADDI, DISTRICT SOLAN HP 173205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
1250	NDA/MAL/HDP/1 247	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	PROPIP	CYPROHEPTADIN E	4MG	AGOG PHARMA LTD.PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X5.0X10.0 TABLET BLISTER	01/07/2012

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1251	NDA/MAL/HDP/1 252	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	ZOY	SILDENAFIL	50MG	TORQUE PHAMACEAUTICALS PVT LTDVILL ISSAPUR P.O DAPPAR INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2013
1252	NDA/MAL/HDP/1 254	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSATRIM TABLETS	CO-TRIMOXAZOLE	480MG	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10 0.0 TABLET CONTAINER	01/07/1998
1253	NDA/MAL/HDP/1 255	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	NIFELAT RETARD	NIFEDIPINE	20MG	CIPLA LTDMIDC PATALGANGA 410 220 DIST. RAIGAD	INDIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997

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1254	NDA/MAL/HDP/1 259	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	CARDOZ- 6.25	CARVEDILOL	6.25MG	IPCA LABORATORIES LTD PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2013
1255	NDA/MAL/HDP/1 261	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	CARDOZ-12.5	CARVEDILOL	12.5MG	IPCA LABORATORIES LTD PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2013
1256	NDA/MAL/HDP/1 264	CENTAUR PHARMACEUTICAL S PRIVATE LIMITED	GITTOES PHARMACEUTICAL S LIMITED	OCUCYCLINE EYE OINTMENT	TETRACYCLINE HYDROCHLORIDE	1%W/W	CENTAUR PHARMACEUTICALS PVT LTD -PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE,1.0X3.5 G TUBE	01/07/2000

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1257	NDA/MAL/HDP/1 265	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	COMBIPLEX	VITAMIN B1 + VITAMIN B2 + NICOTINAMIDE + VITAMIN B6	1.0 MG + 1.0 MG + 15 MG + 0.5 MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2008
1258	NDA/MAL/HDP/1 275	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	NIFELAT 10 F.C TABLETS	NIFEDIPINE	10MG	REMEDICA LIMITED AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997
1259	NDA/MAL/HDP/1 278	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP	DIHYDROARTEME SININ + PIPERAQUINE PHOSPHATE	40MG +320MG	GUILIN PHARMACEUTICAL CO LTD NO.43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X9.0 TABLET BLISTER,1.0X8.0 TABLET BLISTER,1.0X25.0X1 .0X9.0 TABLET BLISTER	01/07/2013

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1260	NDA/MAL/HDP/1 282	ZEE PHARMACEUTICAL S LTD	ZEE PHARMACEUTICAL S LIMITED	LOSABERG	LOSARTAN POTASSIUM	50MG	THE MADRAS PHARMACEUTICALS. .NO. 137B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI 600096	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
1261	NDA/MAL/HDP/1 285	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANFUR-750	CEFUROXIME	750MG	SANCE LABORATORIES PRIVATE LTDPB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X750.0 MG VIAL	01/07/2012
1262	NDA/MAL/HDP/1 287	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANIX- DS 100	CEFIXIME	100MG/5ML	SANCE LABORATORIES PVT LTDVI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2014

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1263	NDA/MAL/HDP/1 290	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANIX 400 CAP	CEFIXIME	400MG	SANCE LABORATORIES PVT LTDVI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X10.0 CAPSULE BLISTER	01/07/2013
1264	NDA/MAL/HDP/1 291	BAYER SCHERING PHARMA	SURGIPHARM (U) LIMITED	ULTRAVIST-300	IOPROMIDE	300MG/ML	BAYER PHARMA A.GMULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL,1.0X100.0 ML VIAL	01/07/2012
1265	NDA/MAL/HDP/1 293	ZEE PHARMACEUTICAL S LTD	ZEE PHARMACEUTICAL S LIMITED	ZEEGRA - 100	SILDENAFIL CITRATE	100MG	THE MADRAS PHARMACEUTICALS. .NO. 137B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI 600096	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0 TABLET BLISTER	01/07/2016

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1266	NDA/MAL/HDP/1 294	BAYER SCHERING PHARMA	SURGIPHARM (U) LIMITED	ULTRAVIST 370	IOPROMIDE	370MG/ML	BAYER PHARMA A.GMULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	PARENTERAL ORDINARY VIALS	1.0X100.0 ML VIAL,1.0X50.0 ML VIAL	01/07/2012
1267	NDA/MAL/HDP/1 295	SHAIGAN PHARMACEUTICAL S (PVT) LTD	HARLEYS UGANDA LIMITED	ZEPAR	ALBENDAZOLE	200MG	SHAIGAN PHARMACEUTICALS (PVT) LTD14TH KM, ADYALA ROAD, RAWALPINDI- PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	01/07/1997
1268	NDA/MAL/HDP/1 299	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANAXONE PLUS- 1000	CEFTRIAZONE+SU LBACTAM	1000MG+500MG	SANCE LABORATORIES PRIVATE LTDPB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.5 G VIAL,1.0X50.0X1.0 VIAL CARTON	01/07/2012

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1269	NDA/MAL/HDP/1 302	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	HIPEN CAPSULES	AMOXYCILLIN	250MG	SPARSH BIO-TECH PVT. LIMITED PLOT NO. 1; SURVEY NO. 242/243/244, LAKHA BAVAD, JAMNAGAR- 361 006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1997
1270	NDA/MAL/HDP/1 303	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	FIBRAL	FINOFIBRATE	200MG	MICRO LABS LTD ..57, SIPCOT INDUSTRIAL COMPLEX, HOSUR- 635126, TAMIL NADU	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER, 1.0X10.0X1 0.0 CAPSULE BLISTER	01/07/2013
1271	NDA/MAL/HDP/1 304	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

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1272	NDA/MAL/HDP/1 307	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	ARBITEL 40	TELMISARTAN	40MG	MICRO LABS LTD ..57, SIPCOT INDUSTRIAL COMPLEX, HOSUR- 635126, TAMIL NADU	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
1273	NDA/MAL/HDP/1 312	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	SLIPIZEM- 2.5	DIAZEPAM	2.5MG	BLISS GVS PHARMA LIMITEDNO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	RECTAL SYSTEMIC PAEDIATRIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY BLISTER	01/07/2007
1274	NDA/MAL/HDP/1 319	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	ZESTAVAL 200 F.C TABLETS	ALBENDAZOLE	200MG	REMEDICA LTD AHARNON 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

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1275	NDA/MAL/HDP/1 324	MACK BROWN PHARMACEUTICAL S PVT LIMITED	SHURIK LTD	TOOTH HEAL	MULTI INGREDIENT	MULTI INGREDIENT	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X18.0 ML BOTTLE	01/07/2005
1276	NDA/MAL/HDP/1 328	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
1277	NDA/MAL/HDP/1 331	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	BETADERM N OINTMENT	BETAMETHASONE VALERATE + NEOMYCIN	0.1%W/W + 0.5%W/W	ATCO LABORATORIES PVT LTDB-18,S.I.T.E KARACHI 75700, PAKISTAN	PAKISTAN	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE,1.0X5.0 G TUBE	01/07/1997

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1278	NDA/MAL/HDP/1 335	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	PREGATAS	PREGABALIN	75MG	INTAS PHARMACEUTICALS LTDCAMP ROAD SELAQUI DEHRADUN	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2012
1279	NDA/MAL/HDP/1 337	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	FOURTS B	THIAMINE +RIBOFLAVIN + PYRIDOXINE + NICOTINAMIDE + FOLIC ACID + ASCORBIC ACID + COLECALCIFEROL + ACETYL CYSTEINE + GLYCINE + GLUTAMIC ACID + CHROMIUM + VANADIUM + ZINC + SELENIUM	10MG + 10MG + 3MG + 50MG + 1MG + 75MG + 400IU + 25MG +25MG +MG +200MCG + 100MCG + 55MG +100MCG	FOURRTS INDIA LABORATORIES PVT. LIMITEDVANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2016
1280	NDA/MAL/HDP/1 338	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	GRISEBEN 500	GRISEOFULVIN	500 MG	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016

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1281	NDA/MAL/HDP/1 341	AUROLAB	SWASTIK PHARMACEUTICAL LTD	G-FLOX	GATIFLOXACIN SESQUIHYDRATE	0.3%W/V	AUROLABNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA	INDIA	OPHTHALMIC LIQUIDS	1.0X5.0 ML VIAL	01/07/2016
1282	NDA/MAL/HDP/1 345	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SWICH-200	CEFPODOXIME	200MG	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA ALKEM LABORATORIES LTDVILLAGE – THANA, BADDI TEHSIL – NALAGARH, DIST-SOLAN (HP), INDIA – 173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2010
1283	NDA/MAL/HDP/1 347	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	ORNILOX	ORNIDAZOLE + OFLOXACIN	500MG + 200MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2010

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1284	NDA/MAL/HDP/1 348	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	VALPARIN CHRONO 500	SODIUM VALPROATE (CONTROLLED RELEASE)	500MG	TORRENT PHARMACEUTICAL LTD AHMEDABAD- MEHSANA HIGHWAY, TALUKA- KADI, DIST. MEHSANA , INDRAD-382721	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2009
1285	NDA/MAL/HDP/1 353	MEDLEY PHARMACEUTICALS LTD	EUROPA HEALTHCARE (U) LTD	KITPYLO - C	LANSOPRAZOLE + TINIDAZOLE + CLARITHROMYCIN	30MG +500MG + 250MG	MEDLEY PHARMACEUTICALS LTD, PLOT 18 & 19 SURVEY NO 378/7 & 379/ 2&3 ZARI CAUSEWAY ROAD KACHIGAM	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X7.0X1.0X6.0 TABLET BLISTER (BLISTER CONTAINS 2 CAPSULES AND 4 TABLETS)	01/07/2015
1286	NDA/MAL/HDP/1 359	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	DIFENAC-100 SR	DICLOFENAC SODIUM	100MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD PLOT M 444B STRETCHER ROAD NTINDA	UGANDA	ORAL SOLID RETARD CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/2016

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1287	NDA/MAL/HDP/1 361	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	FALCI CARE	ARTESUNATE	120MG	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*5ML OF 0.9%W/V NACL AMPOULE + 1*1ML OF 5%W/V NAHCO3 AMPOULE	01/07/2016
1288	NDA/MAL/HDP/1 362	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	BACTOCLAV-1000	AMOXICILLIN + CLAVULANATE	875 MG + 125 MG	MICRO LABS LIMITED PLOT 16 VEERASANDRA IND. AREA, ANEKAL TALUK, BANGALORE INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X6.0 TABLET STRIP	01/07/2013
1289	NDA/MAL/HDP/1 367	DAWA LIMITED	SUPER MEDIC LTD	ACEPAR	ACECLOFENAC + PARACETAMOL	100 MG + 500 MG	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2013

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1290	NDA/MAL/HDP/1 368	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	D5	GLUCOSE	5%W/V	ABACUS PARENTERAL DRUGS LIMITEDBLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE,1.0X250.0 ML BOTTLE	01/07/2010
1291	NDA/MAL/HDP/1 369	MEDIPHARM (EA) LTD	MEDIPHARM INDUSTRIES (E.A) LTD	ORALYTE CO- PACK ORANGE FLAVOUR	DT ZINC-20 + ORAL REHYDRATION SALTS (ORS)	20G	MEDIPHARM INDUSTRIES(EA) LTD PLOT 65 KAKAJJO ROAD BWEYOGERERE P.O.BOX 6218,KAMPALA,UGA NDA MEDICAMEN BIOTECH LTD.,SP- 1192 A&B PHASE IV INDUSTRIAL AREA BHIWADI 301019 DIST. ALWAR (RAJASTHAN) - INDIA AGOG PHARMA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X2.0X20.8 G SACHET + 1.0 *10.0 TABLET BLISTER	01/07/2016
1292	NDA/MAL/HDP/1 370	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	STERILIZED WATER FOR INJECTION	WATER FOR INJECTION	NEUTRAL	ABACUS PARENTERAL DRUGS LIMITEDBLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY AMPOULES	1.0X5.0 ML AMPOULE,1.0X10.0 ML AMPOULE,1.0X7.5 ML AMPOULE	01/07/2010

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1293	NDA/MAL/HDP/1 372	AXA PARENTERALS LTD	VITACARE LIMITED	RL	LACTIC ACID + SODIUM HYDROXIDE + SODIUM CHLORIDE + POTASSIUM CHLORIDE + CALCIUM CHLORIDE	(0.24 + 0.115 + 0.6 + 0.04 + 0.027)G/100ML	AXA PARENTERALS LTDKISHNPUR, JAMALPUR ROORKEE 247677	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2014
1294	NDA/MAL/HDP/1 377	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	SUPER AMP	WATER FOR INJECTION	N/A	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTDVILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0 ML AMPOULE	01/07/2014
1295	NDA/MAL/HDP/1 380	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	HYCORT CREAM	HYDROCORTISON E	1%W/W	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X30.0 G TUBE	01/07/1997

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1296	NDA/MAL/HDP/1 382	HOVID BERHAD	UNITED HEALTHCARE DISTRIBUTORS LTD	INOX CAPSULES	ITRACONAZOLE	100MG	HOVID BHDLOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1.0X7.0X4.0 CAPSULE BLISTER	01/07/2012
1297	NDA/MAL/HDP/1 383	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	KETOFEN GEL	KETOPROFEN	2.5%W/W	HOVID BHD (IPOH SITE)121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G CONTAINER	01/07/2013
1298	NDA/MAL/HDP/1 384	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

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1299	NDA/MAL/HDP/1 387	INTAS PHARMACEUTICAL S 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
1300	NDA/MAL/HDP/1 390	ASTRA ZENECA	MACNAUGHTON LIMITED	CRESTOR	ROSUVASTATIN CALCIUM	5MG	IPR PHARMACEUTICALS INC,LOT 17 INDUSTRIAL PARK PUERTO RICO, SAN ISIDRO, PUERTO RICO	PUERTO RICO	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2010
1301	NDA/MAL/HDP/1 392	ASTRA ZENECA	MACNAUGHTON LIMITED	ZOLADEX	GOSERELIN	3.6MG	ASTRA ZENECA UK LIMITEDASTRAZENE CA UK LIMITED SILK ROAD BUSINESS PARK, MACCLES FIELD,CHESHIRE SK 10 2NA,	UNITED KINGDOM	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0 PREFILLED SYRINGE CARTON	01/07/1997

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1302	NDA/MAL/HDP/1 393	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANFUR	CEFUROXIME	500MG	SANCE LABORATORIES PRIVATE LTDPB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2016
1303	NDA/MAL/HDP/1 394	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANPIME -1000	CEFEPIME	1000MG	SANCE LABORATORIES PRIVATE LTDPB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X15.0 ML VIAL	01/07/2010
1304	NDA/MAL/HDP/1 395	ASTRA ZENECA AB	MACNAUGHTON LIMITED	NEXIUM 40MG IV	ESOMEPRAZOLE	40MG/5ML	ASTRA ZENECA- KVARNBERGAGATAN 12, SE-151 SODERTALIJE	SWEDEN	PARENTERAL ORDINARY VIALS	1.0X1.0X5.0 ML VIAL,1.0X10.0X5.0 ML VIAL	01/07/2010

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1305	NDA/MAL/HDP/1 397	ASTRA ZENECA	MACNAUGHTON LIMITED	PLENDIL	FELODIPINE	10MG	ASTRAZENECA SWEDEN OPERATIONSASTRAZ ENECA SWEDEN OPERATIONS SE-151 85 SODERTALJE ASTRAZENECA PHARMACEUTICAL CO LTD.NO. 2 HUANGSHAN ROAD, WUXI, 214028, JIANGSU	CHINA SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2001
1306	NDA/MAL/HDP/1 400	MEGA LIFSCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	PANFOR SR 500	METFORMIN HYDROCHLORIDE	500MG	INVENTIA HEALTHCARE LIMITEDF-1 - F-1/1 - F75/1, ADDITIONAL AMBERNATH MIDC, AMBERNATH EAST 421506, DIST. THANE, MAHARASHTRA - INDIA	INDIA	ORAL SOLID RETARD TABLETS	1.0X5.0X20.0 TABLET BLISTER	01/07/2015
1307	NDA/MAL/HDP/1 402	MEGA LIFSCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	PANFOR SR 1000	METFORMIN HYDROCHLORIDE	1000MG	INVENTIA HEALTHCARE LIMITEDF-1 - F-1/1 - F75/1, ADDITIONAL AMBERNATH MIDC, AMBERNATH EAST 421506, DIST. THANE, MAHARASHTRA - INDIA	INDIA	ORAL SOLID RETARD TABLETS	1.0X5.0X20.0 TABLET BLISTER	01/07/2015

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1308	NDA/MAL/HDP/1 406	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	CEBAY DRY SYRUP	CEFIXIME TRIHYDRATE	50MG/5ML	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2014
1309	NDA/MAL/HDP/1 409	PHARMACTIV FZCO	JEET PHARMACEUTICAL S LIMITED	ROMYCIN	AZITHROMYCIN	200MG/5ML	NABIQASIM INDUSTRIES (PVT) LTD-17/24,KORANGI INDUSTRIAL AREA, KORANGI, KARACHI- PAKISTAN.	PAKISTAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X15.0 ML BOTTLE	01/07/2007
1310	NDA/MAL/HDP/1 411	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	CIPIUM	CHLORPHENIRAM INE	4MG	LEBEN LAB PVT LTDL4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X20.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2011

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1311	NDA/MAL/HDP/1 413	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	PODINE MOUTH WASH	POVIDONE IODINE	0.1%W/V	BETA HEALTHCARE INTERNATIONAL LTD - PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL TOPICAL LIQUIDS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE	01/07/2014
1312	NDA/MAL/HDP/1 414	UNIQUE PHARMACEUTICAL S LABORATORIES	PLANET PHARMACEUTICAL S 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
1313	NDA/MAL/HDP/1 417	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	MILICAL TABLETS	CALCIUM CITRATE + VITAMIN D3	1000MG +200 I.U	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2001

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1314	NDA/MAL/HDP/1418	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	AMINOPHYLLINE TABLETS	AMINOPHYLLINE	100MG	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR-401210, MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER	01/07/2011
1315	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
1316	NDA/MAL/HDP/1422	SHAIGAN PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	STAMIN	CETIRIZINE DIHYDROCHLORIDE	10MG	SHAIGAN PHARMACEUTICALS (PVT) LTD 14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2005

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1317	NDA/MAL/HDP/1 427	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S 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,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2011
1318	NDA/MAL/HDP/1 431	INTAS PHARMACUITICALS LTD	NORVIK ENTERPRISES LIMITED	TORTAS 10	TORSEMIDE	10MG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI- 248197,DEHRADUN UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
1319	NDA/MAL/HDP/1 433	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	NORISTERAT	NORETHISTERON E ENANTATE	200MG	BAYER PHARMA A.GMULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	PARENTERAL ORDINARY VIALS	1.0 ML PRE- FILLED SYRINGE,1.0X100.0 X1.0 ML VIAL	01/07/1997

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1320	NDA/MAL/HDP/1 436	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CONCOR 10	BISOPROLOL HEMIFUMARATE	10MG	WINTHROP PHARMACEUTICALS(PTY) LTD,315 WATLOO ROAD,WATLOO,PRE TORIA,SOUTHAFRIC A (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
1321	NDA/MAL/HDP/1 441	AXA PARENTERALS LTD	VITACARE LIMITED	SODIUM CHLORIDE	SODIUM CHLORIDE	0.9%W/V	AXA PARENTERALS LTDKISHNPUR, JAMALPUR ROORKEE 247677	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2014
1322	NDA/MAL/HDP/1 445	CADILA PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S LTD.	AXONE 1000	CEFTRIAZONE 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

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1323	NDA/MAL/HDP/1 446	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
1324	NDA/MAL/HDP/1 447	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
1325	NDA/MAL/HDP/1 449	SHAIGAN PHARMACEUTICAL S (PVT) LTD	HARLEYS UGANDA LIMITED	ZEPAR SUSPENSION	ALBENDAZOLE	200MG/5ML	SHAIGAN PHARMACEUTICALS (PVT) LTD 14TH KM, ADYALA ROAD, RAWALPINDI- PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	01/07/2000

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1326	NDA/MAL/HDP/1 450	GLAXOSMITHKLINE LIMITED LIKONI	UNITED HEALTHCARE DISTRIBUTORS LTD	VOLTAREN EMULGEL 1%	DICLOFENAC DIETHYLAMMONI UM	1%W/V	GSK CONSUMER HEALTH SAGSK CONSUMER HEALTH SA, ROUTE DE L'ETRAZ, NYON, 1260, SWITZERLAND	SWITZERLAND	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE,1.0X50.0 G TUBE	01/07/1997
1327	NDA/MAL/HDP/1 451	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN INJECTION	DICLOFENAC	25MG/ML	NOVARTIS PHARMA STEIN AGSCHAFFHARVSE TRASSE CH-4332 STEIN SWITZERLAND.	SWITZERLAND	PARENTERAL ORDINARY AMPOULES	1.0X3.0 ML AMPOULE	01/07/1997
1328	NDA/MAL/HDP/1 454	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	PAINEX	PARACETAMOL + ASPIRIN + CAFFEINE	500MG + 400MG + 50 MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X25.0X4.0 TABLET STRIP	01/07/2003

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1329	NDA/MAL/HDP/1 456	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	SUCRAFIL O GEL	SUCRALFATE + OXETACAINE	10MG + 0.2MG	FOURRTS INDIA LABORATORIES PVT. LIMITEDVANDALUR 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
1330	NDA/MAL/HDP/1 457	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICAL S LIMITED	DYSEN FORTE	SECNIDAZOLE	1000MG	NABIQASIM INDUSTRIES (PVT) LIMITED17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	01/07/2006
1331	NDA/MAL/HDP/1 458	STRIDES PHARMA SCIENCE LIMITED	DELMAW ENTERPRISES LIMITED	CLAVICIN INJECTION	AMOXICILLIN + POTASSIUM CLAVULANATE	1.2G	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.2 G VIAL	01/07/2013

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1332	NDA/MAL/HDP/1 460	VENUS REMEDIES LTD	REDDYS PHARMA LIMITED	PARIN E	ENOXAPARIN	80MG	VENUS REMEDIES LTD -UNIT II HILL TOP INDUSTRIAL ESTATE JHARMAJRI EPIP PHASE I BHATOLI KALAN BADDI (H.P)	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X10.0X2.0X0.8 ML PRE- FILLED SYRINGE	01/07/2009
1333	NDA/MAL/HDP/1 463	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
1334	NDA/MAL/HDP/1 465	NORVATIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTFAST 50MG	DICLOFENAC POTASSIUM	50MG	MIPHARM S.P.A VIA BERNARDO QUARANTA, 12- 20141, MILANO ITALY.	ITALY	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X3.0 SACHET CARTON, 9.0X1.0X3. 0X3.0 SACHET CARTON	01/07/2014

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1335	NDA/MAL/HDP/1 468	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	OCID 20	OMEPRAZOLE	20MG	S KANT HEALTHCARE LTD- PLOT NO. 1802- 1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT. EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID RETARD CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	01/07/1998
1336	NDA/MAL/HDP/1 469	VOGEN LABORATORIES LTD	BUFFALO HEALTH CARE LTD	DURAMOX 125	AMOXICILLIN	125MG/5ML	VOGEN LABORATORIES LTD70, M.HERACLEOUS STR. AYIOS ATHANASIOS INDUSTRIAL AREA, LIMASSOL, CYPRUS	CYPRUS	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2007
1337	NDA/MAL/HDP/1 474	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGODIC GEL	DICLOFENAC DIETHYLAMINE	1%W/W	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/2016

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1338	NDA/MAL/HDP/1 476	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S 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
1339	NDA/MAL/HDP/1 478	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	KAMAGRA	SILDENAFIL	50MG	AJANTA PHARMA LIMITED PAITHAN MANUFACT URING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2001
1340	NDA/MAL/HDP/1 482	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, 1.0X10.0X 10.0 DOSE VIAL + 1*10*10 DOSE AMPOULE OF NS	01/07/1997

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1341	NDA/MAL/HDP/1 485	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DICLOFEN 25	DICLOFENAC	25MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTDP.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL- RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY BLISTER	01/07/2011
1342	NDA/MAL/HDP/1 486	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AMPIMAX-1	AMPICILLIN	1G	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X1.0 G VIAL	01/07/2011
1343	NDA/MAL/HDP/1 488	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DICLO-DENK 100 RECTAL	DICLOFENAC SODIUM	100MG	HAUPT PHARMA WULFING GMBH.BETHELNER LANDSTR. 18, 31028 GRONAU	GERMANY	RECTAL SYSTEMIC ADULT SUPPOSITORIES	10.0X1.0X2.0X5.0 SUPPOSITORY STRIP,1.0X5.0 SUPPOSITORY STRIP	01/07/2000

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1344	NDA/MAL/HDP/1 492	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DICLO-DENK 75 INJECTION	DICLOFENAC SODIUM	25MG/ML	HAUPT PHARMA WULFING GMBH;- BETHELNER LANDSTR. 18, 31028 GRONAU LLEIRE, GERMANY.	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X10.0X3.0 ML AMPOULE	01/07/1998
1345	NDA/MAL/HDP/1 493	AUROBINDO PHARMA LTD UNIT VII	GITTOES PHARMACEUTICAL S LIMITED	KOACT 1000	AMOXICILLIN/CLA VULANATE POTASSIUM	875MG/125MG	AUROBINDO PHARMA LIMITED, UNIT IISURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELENGANA (STATE)	INDIA	ORAL SOLID RETARD TABLETS	1X4 TABLET BLISTER	01/07/2007
1346	NDA/MAL/HDP/1 494	FERRER INTERNACIONAL S.A	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	PEITEL 0.25%	PREDNICARBATE	0.25%W/W	FERRER INTERNACIONAL, S.AJOAN BUCSALA 1- 9, 08173 SANT CUGAT DEL VALLES, BARCELONA, SPAIN	SPAIN	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	01/07/2013

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1347	NDA/MAL/HDP/1 497	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LAEOVATE CREAM	BETAMETHASONE VALERATE	0.1%W/W	LABORATORY & ALLIED LTD-PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	01/07/1997
1348	NDA/MAL/HDP/1 499	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	PROMETHAZINE	PROMETHAZINE HYDROCHLORIDE	25MG/ML	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	CHINA INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE	01/07/2005
1349	NDA/MAL/HDP/1 500	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	ATRIPLA	EFAVIRENZ+EMTR ICITABINE + TENOFIVIR	600MG +200MG+300MG	PATHEON INCMISSISSAUGA, O N L5N 7K9 CANADA	CANADA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2008

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1350	NDA/MAL/HDP/1 503	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
1351	NDA/MAL/HDP/1 505	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	SERETIDE EVOHALER	SALMETEROL/ FLUTICASONE PROPIONATE	25/50 MCG	GLAXO WELLCOME PRODUCTIONZONE INDUSTRIELLE NO.2 23 RUE LAVOISER 27000 EVREUX	FRANCE	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X1.0 CANNISTER CARTON	01/07/2007
1352	NDA/MAL/HDP/1 508	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

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1353	NDA/MAL/HDP/1 514	JOHNSON&JOHNS ON PTY LTD	PHILLIPS PHARMACEUTICAL S (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
1354	NDA/MAL/HDP/1 516	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	URGENDOL P	TRAMADOL/ PARACETAMOL	37.5MG/ 325MG	WIN MEDICARE PVT LIMITEDMEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2011
1355	NDA/MAL/HDP/1 523	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMPIREN	AMPICILLIN	125MG/5ML	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2007

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1356	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
1357	NDA/MAL/HDP/1526	FERRER INTERNACIONAL S.A	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	GAMALATE B6	MAGNESIUM GLUTAMATE HYDROBROMIDE + AMINOBUTYRIC ACID + AMINO HYDROXYBUTYRIC ACID + VITAMIN B6	75MG + 75MG + 37MG + 37MG	FERRER INTERNATIONAL, S.A.C/JOAN BUSCALLA, 1-9.08173 SANT CUGAT DEL VALLES, BARCELONA	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2015
1358	NDA/MAL/HDP/1527	MICRO LABS LTD	LABOREX UGANDA LIMITED	BACTOCLAV	AMOXICILLIN + CLAVULANATE POTASSIUM	200MG + 28.5MG/5ML	MICRO LABS LIMITED. PLOT 16, VEERASANDRA IND. AREA, ANEKAL TALUK, BANGALORE INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X1.0X100.0 ML BOTTLE	01/07/2012

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1359	NDA/MAL/HDP/1 528	MICRO LABS LTD	LABOREX UGANDA LIMITED	BACTOCLAV-625	AMOXYCILLIN + CLAVULANATE POTASSIUM	500 MG + 125 MG	MICRO LABS LIMITED PLOT 16 VEERASANDRA IND. AREA, ANEKAL TALUK, BANGALORE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X6.0 TABLET BLISTER, 1.0X2.0X10 .0 TABLET BLISTER	01/07/2007
1360	NDA/MAL/HDP/1 529	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	PROVIRON	MESTEROLONE	25MG	BAYER WEIMAR GMBH & CO. KGDOBEREINERSTRA SSE 20 D-99427 WEIMAR, GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/1997
1361	NDA/MAL/HDP/1 532	BF BIOSCIENCES LTD	HARLEYS UGANDA LIMITED	NOVAPRESSIN	TERLIPRESSIN	1MG/VIAL	BF BIOSCIENCES LTD. -RAIWIND, PAKISTAN	PAKISTAN	PARENTERAL ORDINARY VIALS	1.0X1.0 MG VIAL	01/07/2014

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1362	NDA/MAL/HDP/1 533	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	5D	GLUCOSE	50G/L	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTDVILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE,1.0X250.0 ML BOTTLE	01/07/2007
1363	NDA/MAL/HDP/1 535	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	FORTIWIN-4	FORTIFIED PROCAINE PENICILLIN SODIUM	4 M.U	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA INJECT CARE PARENTERALS PVT LTD PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195	CHINA INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X4.0 MU VIAL,1.0X100.0X4.0 MU VIAL,1.0X10.0X4.0 MU VIAL	01/07/2011
1364	NDA/MAL/HDP/1 537	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYZOLE	ALBENDAZOLE	200MG	ELYS CHEMICAL INDUSTRIES LIMITED- ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X20.0X2.0 TABLET BLISTER	01/07/2005

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1365	NDA/MAL/HDP/1 538	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYZOLE SUSPENSION	ALBENDAZOLE	200MG	ELYS CHEMICAL INDUSTRIES LIMITED- ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	01/07/2003
1366	NDA/MAL/HDP/1 544	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S 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
1367	NDA/MAL/HDP/1 546	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	LANPRO	LANSOPRAZOLE	30MG	UNICHEM LABORATORIES LTD UNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205 UNICHEM LABORATORIES LTD PLOT NO. 15,16,17,17A & 18, PILERNE INDUSTRIAL ESTATE, PILERNE, BARDEZ, GOA- 403511	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X2.0X10.0 CAPSULE BLISTER	01/07/1999

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1368	NDA/MAL/HDP/1 551	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	CALOSHELL-500	CALCIUM CARBONATE + VITAMIN D3	1250MG + 250IU	EMCURE PHARMACEUTICALS LTDLANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2004
1369	NDA/MAL/HDP/1 553	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	VIFEX	SALBUTAMOL + BROMHEXINE + GUAIFENESIN	1MG/5ML+2MG/5 ML+50MG/5ML	EMCURE PHARMACEUTICALS LTDLANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2004
1370	NDA/MAL/HDP/1 554	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL CETIRIZINE	CETIRIZINE DIHYDROCHLORID E	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

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1371	NDA/MAL/HDP/1 555	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
1372	NDA/MAL/HDP/1 557	GLAXOSMITHKLINE	UNITED HEALTHCARE DISTRIBUTORS LTD	SYNFLORIX VACCINE	PNEUMOCOCCAL POLYSACCHARIDE SEROTYPES (1,5,6B,7F,9V,14,2 3F) + (4,18C,19F) + PROTEIN D+TETANUS TOXOID+DIPHTHER IA TOXOID CARRIER PROTEINS AND ALUMINIUM PHOSPHATE	1MCG+3MCG+13M CG+8MCG+5MCG+ 0.5MG	GLAXOSMITHKLINE BOILOGICALSS.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
1373	NDA/MAL/HDP/1 563	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	AMOXIL	AMOXYCILLIN	125MG/5ML	GLAXO WELLCOME PRODUCTION.ZONE INDUSTRIELLE DE LA PEYENNIERE 53100 MAYENNE, FRANCE	FRANCE	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

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1374	NDA/MAL/HDP/1 566	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
1375	NDA/MAL/HDP/1 569	ABBVIE (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	KALETRA	LOPINAVIR+RITO NAVIR	80MG + 20MG	AESICA PHARMACEUTICALS SRL QUEENBOROUGH KENT ME 11 5EL, UNITED KINGDOM	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X5.0X1.0X60.0 ML BOTTLE	01/07/2007
1376	NDA/MAL/HDP/1 571	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

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1377	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
1378	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
1379	NDA/MAL/HDP/1579	PT SANBE FARMA	MEDVIN PHARMA LIMITED	PLASMINEX	TRANEXAMIC ACID	100MG/ML	PT SANBE FARMA JI INDIRINO.8 KOMPLEKS INDUSTRI CIMAREME PADALARANG BANDUNG	INDONESIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X5.0 ML AMPOULE	01/07/2011

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1380	NDA/MAL/HDP/1 581	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (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
1381	NDA/MAL/HDP/1 582	LINCON PHARMCUETICALS LIMITED	METRO PHARMACEUTICAL S 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
1382	NDA/MAL/HDP/1 584	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	UCLOX	CLOXACILLIN SODIUM	500MG	UNI MEDICOLABS. 21-22 PHARMACITY SELAQUI DEHRADUN 248197	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL	01/07/2015

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1383	NDA/MAL/HDP/1 585	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	UDIHEP FORTE	URSODEOXYCHOL IC ACID	300MG	WIN-MEDICARE PRIVATE LIMITEDMEERUT- MUZAFFARNAGAR ROAD, MODIPURAM 250110 UTTAR PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2010
1384	NDA/MAL/HDP/1 588	TORRENT PHARAMACEUTICA LS LTD	KARURI PHARMACEUTICAL S LTD.	TOZAAR-H	LOSARTAN POTASSIUM + HYDROCHLOROT HIAZIDE	50MG + 12.5MG	TORRENT PHARMACEUTICALS LIMITED AHMEDABAD- MEHSANA HIGHWAY, TAL. KADI, DIST. MEHSANA, INDRAD 382 721, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP,1.0X4.0X7.0 TABLET BLISTER	01/07/2005
1385	NDA/MAL/HDP/1 589	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	CENTACID SUSPENSION	MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE+SIME THICONE	40MG+200MG+25 OMG/5ML	CENTAUR PHARMACEUTICALS PVT LTD PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE,1.0X170.0 ML BOTTLE	01/07/1997

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1386	NDA/MAL/HDP/1 591	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	CENTIPAR ELIXIR	PIPERAZINE CITRATE	750ML/5ML	CENTAUR PHARMACEUTICALS PVT LTD PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X30.0 ML BOTTLE	01/07/1997
1387	NDA/MAL/HDP/1 598	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOCIM 400	CIMETIDINE	400MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
1388	NDA/MAL/HDP/1 605	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	ASPIRIN TABLETS	ACETYL SALICYLIC ACID	300MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER	01/07/2001

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1389	NDA/MAL/HDP/1 615	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	APCALIS SX	TADALAFIL	20MG	AJANTA PHARMA LIMITED PAITHANMANUFACT URING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X2.0 TABLET BLISTER	01/07/2005
1390	NDA/MAL/HDP/1 616	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	CEZIN	CETIRIZINE	5MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. 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
1391	NDA/MAL/HDP/1 627	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	CANDID-V GEL	CLOTRIMAZOLE	2%W/W	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	VAGINAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/2004

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1392	NDA/MAL/HDP/1 629	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	CARVETAS 12.5	CARVEDILOL	12.5MG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI- 248197, DEHRADUN (UTTARAKHAND)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
1393	NDA/MAL/HDP/1 631	AUROBINDOM PHARMA LIMITED	GITTOES PHARMACEUTICAL S LIMITED	NEVIRAPINE ORAL SUSPENSION	NEVIRAPINE	50MG/5ML	AUROBINDO PHARMA LTD, UNIT III SURVEY NO. 313, 314 BACHUPALLY (VILLAGE) QUTHUBULLAPUR (MANDAL) RR DISTRICT HYDERABAD ANDHRA PRADESH 500090	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X240.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2007
1394	NDA/MAL/HDP/1 632	: 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

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1395	NDA/MAL/HDP/1 635	CADILA PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S LTD.	ORITAXIM 1000MG INJECTION	CEFOTAXIME SODIUM	1GM	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 G VIAL	01/07/1997
1396	NDA/MAL/HDP/1 636	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
1397	NDA/MAL/HDP/1 638	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FLADAZOLE	SECNIDAZOLE	500MG	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	01/07/2005

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1398	NDA/MAL/HDP/1 639	GLAXO SMITHLINE LIMITED	UNITED HEALTHCARE DISTRIBUTORS LTD	PANADOL EXTRA WITH OPTIZORB	PARACETAMOL + CAFFEINE	500MG + 65MG	GRANULES INDIA LIMITEDSY. NO. 160/A, 161/E, 162 & 174/A GAGILLAPUR VILLAGE, DUNDIGAL- GANDIMASAMMA MANDAL, MEDCHAL - MALKHAJIRI DISTRICT - 500043 TELENGANA	IRELAND INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER,1.0X100.0 TABLET CARTON	01/07/2003
1399	NDA/MAL/HDP/1 641	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	UNIENZYME C MPS	NICOTINAMIDE+S IMETHICONE+PAP AIN+FUNGAL DIASTASE+CHARC OAL	25MG+50MG+30M G+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
1400	NDA/MAL/HDP/1 646	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	BETROZOLE TABLETS	METRONIDAZOLE +DILOXANIDE	200MG+250MG	BETA HEALTHCARE INTERNATIONAL LTD - PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BLISTER	01/07/2002

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1401	NDA/MAL/HDP/1 650	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	TEGRETOL CR 200	CARBAMAZEPINE	200MG	NOVARTIS FARMA S.P.A.-VIA PROVINCIALE SCHITO 131, 80058 TORRE ANNUNZIATA, ITALY	ITALY	ORAL SOLID RETARD TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2006
1402	NDA/MAL/HDP/1 651	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	MEGATRIM SUSPENSION	CO-TRIMOXAZOLE	240MG/5ML	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED VANDALUR ROAD	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	, 1X60 ML BOTTLE	01/07/1997
1403	NDA/MAL/HDP/1 652	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	VALPARIN CHRONO 300	SODIUM VALPROATE	300MG	TORRENT PHARMACEUTICAL LTD AHMEDABAD- MEHSANA HIGHWAY, TALUKA- KADI, DIST. MEHSANA , INDRAD-382721	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2009

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1404	NDA/MAL/HDP/1 656	AIVEEN (U) LIMITED	AIVEEN (U) LIMITED	AZIGYL-500	AZITHROMYCIN	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,1.0X3.0 TABLET BLISTER	01/07/2015
1405	NDA/MAL/HDP/1 660	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOCIM-200	CIMEDITINE	200MG	AGOG PHARMA LTDPLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10 0.0X10.0 TABLET STRIP	01/07/2005
1406	NDA/MAL/HDP/1 661	ABBVIE (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	ALUVIA 100/25	LOPINAVIR/ RITONAVIR	100MG/25MG	ABBVIE DEUTSCHLAND GMBH & CO. KG.KNOLLSTASSE 50, D-67061, LUDWIGSHAFEN, GERMANY.	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2007

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1407	NDA/MAL/HDP/1 663	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	ALCID-PINK	ALUMINIUM HYDROXIDE/MAG NESIUM TRISILICATE	400MG+400MG/50 ML	TORQUE PHARMACEUTICALS PVT LTDISAAPUR P.O DAPPAR 140056 INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X400.0 ML BOTTLE,1.0X160.0 ML BOTTLE	01/07/2003
1408	NDA/MAL/HDP/1 665	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOXIN CAPSULES	AMOXICILLIN TRIHYDRATE	250MG	MILAN LABORATORIES (INDIA) PVT LTD PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTDNO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSH	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
1409	NDA/MAL/HDP/1 675	MERCK SHARP & DOHME BV	SURGIPHARM (U) LIMITED	GARDASIL	QUADRIVALENT HUMAN PAPILLOMAVIRUS RECOMBINANT VACCINE (TYPES 6, 11, 16, 18)	(20MCG+40MCG+4 0MCG+20MCG)/0. 5ML	MERK & CO. INCSUMNEYTOWN PIKE, P.O BOX 4, WEST POINT, PENNSYLVANIA, U.S. 19486, USA	UNITED STATES	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X0.5 ML PRE- FILLED SYRINGE (1 DOSE),1.0X10.0X0.5 ML VIAL (1 DOSE)	01/07/2007

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1410	NDA/MAL/HDP/1 676	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,1.0X10 00.0 CAPSULE CONTAINER,1.0X10. 0X10.0 CAPSULE BLISTER	01/07/1997
1411	NDA/MAL/HDP/1 678	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	HYDROCORTISON E SODIUM SUCCINATE	HYDROCORTISON E SODIUM SUCCINATE	100MG/VIAL	INDASI LIFESCIENCE PRIVATE LIMITED PLOT NO. 73 TO 77, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN - 396210, INDIA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X100.0 MG VIAL	01/07/2007
1412	NDA/MAL/HDP/1 679	LEBEN LABORATORIES PVT. LTD	MALIX PHARMA (U) LIMITED	CIPROLEB	CIPROFLOXACIN	500MG	LEBEN LABORATORIES PVT. LTD. PLOT NO. L-4, PHASE -III, M.I.D.C, AKOLA, 444104, MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007

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1413	NDA/MAL/HDP/1 680	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	H-CORT	HYDROCORTISON E	0.1%W/W	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997
1414	NDA/MAL/HDP/1 682	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICAL S LIMITED	TOFLOX-200	OFLOXACIN	200MG	LINCOLN PHARMACEUTICAL LIMITED TRIMAL ESTATE KHATRAJ KOLOL, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER, 1.0X10.0X1 .0X10.0 TABLET BLISTER	01/07/2005
1415	NDA/MAL/HDP/1 689	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	OMESK	OMEPRAZOLE	20MG	S.KANT HEALTHCARE LTD PLOT 1802, 1805, GIDC PHASE III VAPI 39179, GUJARAT	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	01/07/2010

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1416	NDA/MAL/HDP/1 690	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	FINALLERG	CETIRIZINE DIHYDROCHLORID E	1MG/ML	PHARMA INTERNATIONAL COMPANYMAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2004
1417	NDA/MAL/HDP/1 692	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFODOX 50MG/5ML SUSPENSION	CEFPODOXIME PROXETIL	50MG/5ML	PHARMA INTERNATIONAL CO.,AL-QASTAL AREA, AIRPORT ROAD, 11941, AMMAN	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X50.0 ML BOTTLE	01/07/2007
1418	NDA/MAL/HDP/1 693	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	OPTIMAL (0.05%) CREAM	TRETINOIN USP	0.5MG/1G	PHARMA INTERNATIONAL COMPANY .MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN	JORDAN	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	01/07/2005

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1419	NDA/MAL/HDP/1 697	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	FINALLERG	CETIRIZINE DIHYDROCHLORID E	10MG	PHARMA INTERNATIONAL COMPANYMAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2005
1420	NDA/MAL/HDP/1 698	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	AZICIP 500	AZITHROMYCIN	500MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED (CIPLAQCIL)PLOT 1- 7, 1ST RING ROAD, LUZIRA INDUSTRIAL PARK CIPLA LTD.VERNA IND. ESTATE GOA 403 722 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X1.0X3.0 TABLET BLISTER	01/07/2009
1421	NDA/MAL/HDP/1 701	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FORMIN	METFORMIN HYDROCHLORIDE	500MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014

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1422	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
1423	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
1424	NDA/MAL/HDP/1707	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	FEBRICOL TABLETS	PARACETAMOL / PSEUDOEPHEDRINE / CHLORPHENIRAMINE	500MG / 30MG / 2MG	XEPA-SOUL PATTINSON (MALAYSIA) SDN BLD 1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X2.0X10.0 TABLET BLISTER	01/07/1997

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1425	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
1426	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
1427	NDA/MAL/HDP/1711	KOPRAN LIMITED	TATA UGANDA LIMITED	AMYN-250	AMOXYCILLIN	250MG	KOPRAN LIMITED VILLAGE-SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER, 1.0X1000.0 CAPSULE CONTAINER	01/07/1997

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1428	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,1.0X30.0X18.0 TABLET BLISTER,1.0X1.0X18.0 TABLET BLISTER,1.0X30.0X6.0 TABLET	01/07/2007
1429	NDA/MAL/HDP/1715	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	MUCOLYN SYRUP	AMMONIUM CHLORIDE+CHLORPHENIRAMINE+D EXTROMETHORPHAN+BROMHEXINE	50MG+2MG+5MG+4MG	BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	01/07/2011
1430	NDA/MAL/HDP/1723	USV PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GROVIT MULTIVITAMIN DROPS	MULTI-INGREDIENT	MULTI-INGREDIENT	SAKAR HEALTHCARE PVT LTDSAKAR HEALTHCARE PVT LTD, BLOCK NO 10-13, M.N. DESA	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X15.0 ML BOTTLE	01/07/2000

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1431	NDA/MAL/HDP/1724	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	AVAMYS NASAL SPRAY	FLUTICASONE FUROATE	27.5MCG/ACTUATION	GLAXO OPERATIONS UK LTD--HARMIRE ROAD, BARNARD CASTLE, DURHAM DL128 DT UK	UNITED KINGDOM	NASAL TOPICAL SPRAYS WITHOUT GAS	1.0X120.0 METERED DOSE CANNISTER	01/07/2009
1432	NDA/MAL/HDP/1725	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	MYCORIL CREAM 1%	CLOTRIMAZOLE	1%W/W	REMEDICA LIMITED LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2000
1433	NDA/MAL/HDP/1728	ARISTO PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	DELISPRIN 75MG	ASPIRIN	75MG	ARISTO PHARMACEUTICALS PVT LTD PLOT NO 208 NEW INDUSTRIAL GREEN NO2 MANDIDEED 462046	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP, 1.0X10.0X14.0 TABLET STRIP	01/07/2007

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1434	NDA/MAL/HDP/1 730	COSMOS LTD	ASTRA PHARMA (U) LIMITED	ZITHROX	AZITHROMYCIN	500MG	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER	01/07/2008
1435	NDA/MAL/HDP/1 731	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	MEDIVEN-S OINTMENT	BETAMETHASONE VALERATE + SALICYLIC ACID	0.05%W/W + 3%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997
1436	NDA/MAL/HDP/1 732	MICRO LABS LTD	LABOREX UGANDA LIMITED	CEFEX-250	CEPHALEXIN	250MG	MICROLABS LIMITEDPLOT NO. 121-124, KIADB, BOMMASANDRA , - JIGNI LINK ROAD, ANEKUL TALUK,BANGALORE, KARNATAKA, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1999

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1437	NDA/MAL/HDP/1 734	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMOMINT	COMPOUND MAGNESIUM TRISILICATE	500MG	TIL HEALTH CAREPLOT 100, WEST, R- 5, SOUTH; SRICITY SEZ, CHERIVI, IRUHUL AM, PSOT, SATYAVED U MANDAL, CHITOOOR 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
1438	NDA/MAL/HDP/1 736	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
1439	NDA/MAL/HDP/1 739	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

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1440	NDA/MAL/HDP/1 741	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEOPRED-P	PREDNISOLONE ACETATE + NEOMYCIN SULPHATE+ POLYMYXIN-B	5MG/ML +5MG/ML + 1M I.U/ML	AMMAN PHARMACEUTICALS INDUSTRIES -KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005
1441	NDA/MAL/HDP/1 743	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
1442	NDA/MAL/HDP/1 745	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APIGEN	GENTAMYCIN SULPHATE	0.3%W/V	AMMAN PHARMACEUTICALS INDUSTRIES- AMMAN PHARMACEUTICAL INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005

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1443	NDA/MAL/HDP/1747	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	PRESARTAN H 50	LOSARTAN POTASSIUM + HYDROCHLOROT HIAZIDE	50MG + 12.5MG	IPCA LABORATORIES LTD PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER, 1.0X10.0X10.0 TABLET BLISTER	01/07/2008
1444	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
1445	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

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1446	NDA/MAL/HDP/1 751	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
1447	NDA/MAL/HDP/1 754	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
1448	NDA/MAL/HDP/1 756	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APICROM 2%	SODIUM CROMOGLYCATE	2%W/V	AMMAN PHARMACEUTICALS INDUSTRIES .-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005

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1449	NDA/MAL/HDP/1 758	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APICORT	PREDNISOLONE ACETATE	0.12%W/V	AMMAN PHARMACEUTICALS INDUSTRIES -KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005
1450	NDA/MAL/HDP/1 760	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEODEX	NEOMYCIN +DEXAMETHASO NE	0.5%W/V + 0.1%W/V	AMMAN PHARMACEUTICALS INDUSTRIES- AMMAN PHARMACEUTICAL INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OTIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005
1451	NDA/MAL/HDP/1 761	EMCURE PHARMACEUTICAL S 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

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1452	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
1453	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
1454	NDA/MAL/HDP/1764	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	FRESH BURST LISTERINE	ALCOHOL + THYMOL	95 % W/V + 12 MG	JOHNSON&JOHNSON PTY LTD..241 MAIN ROAD RETREAT 794	SOUTH AFRICA	ORAL LIQUID ORDINARY LIQUIDS	1.0X250.0 ML CONTAINER,1.0X500.0 ML CONTAINER	01/07/2006

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1455	NDA/MAL/HDP/1 766	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	COLDEASE CAPSULES	PARACETAMOL+C AFFEINE CITRATE+CHLORP HENIRAMINE MALEATE+PSEUD OEPHEDRINE HYDROCHLORIDE	400MG+30MG+4M G+30MG	RENE INDUSTRIES LIMITED PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2005
1456	NDA/MAL/HDP/1 769	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ENGERIX-B VACCINE	HEPATITIS B SURFACE ANTIGEN	10MCG/ML	GLAXOSMITHKLINE BOIOLOGICALS.S.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
1457	NDA/MAL/HDP/1 772	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S 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

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1458	NDA/MAL/HDP/1 773	MICRO LABS LTD	LABOREX UGANDA LIMITED	LEVOBACT 500	LEVOFLOXACIN HEMIHYDRATE	500MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X20.0X5.0 TABLET BLISTER,1.0X1.0X10 .0 TABLET BLISTER	01/07/2005
1459	NDA/MAL/HDP/1 777	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	NUZAC 20	FLUOXETINE	20MG	CIPLA LTD PLOT NO. L-139, VERNA, GOA 403 722 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2003
1460	NDA/MAL/HDP/1 779	BROOKES PHARMACEUTICAL LABORATORIES L	HARLEYS UGANDA LIMITED	PYODINE SOLUTION	POVIDONE IODINE	10.0G/100ML	BROOKES PHARMACEUTICALS LABORATORIES (PAKISTAN) LTD PLOT 58 SECTOR 15 KORANGI INDUSTRIAL AREA, KARACHI-PAKISTAN	PAKISTAN	TOPICAL EXTERNAL LIQUIDS	1.0X60.0 ML BOTTLE,1.0X450.0 ML BOTTLE,1.0X500.0 ML BOTTLE	01/07/1999

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1461	NDA/MAL/HDP/1 780	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
1462	NDA/MAL/HDP/1 781	ASTRAZENECA	MACNAUGHTON LIMITED	ARIMIDEX	ANASTROZOLE	1MG	ASTRAZENECA PHARMACEUTICALS LPNEWARK, DELAWARE	UNITED STATES	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2000
1463	NDA/MAL/HDP/1 782	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S 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

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1464	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
1465	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
1466	NDA/MAL/HDP/1785	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	ACTION TABLETS	ACETYL SALICYLATE + CAFFEINE + PARACETAMOL	600MG+50MG+300MG	BETA HEALTHCARE INTERNATIONAL LTD - PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X200.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER,1.0X110.0 TABLET STRIP,1.0X12.0 TABLET BLISTER	01/07/1997

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1467	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, 10.0X100.0 TABLET BLISTER	01/07/2001
1468	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
1469	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

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1470	NDA/MAL/HDP/1 795	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
1471	NDA/MAL/HDP/1 796	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ZAHA 250	AZITHROMYCIN	250 MG	AJANTA PHARMA LIMITEDPLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT- 392130 AJANTA PHARMA LIMITED PAITHANMANUFACT URING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X10.0X1 .0X6.0 TABLET BLISTER	01/07/2006
1472	NDA/MAL/HDP/1 797	KARNATAKA ANTIBIOTICS & PHARMACEUTICAL S LTD	TATA UGANDA LIMITED	AMPICILLIN+CLOX ACILLIN	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD #14, II PHASE PIA, BANGALORE 560058	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X500.0 MG VIAL	01/07/2010

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1473	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
1474	NDA/MAL/HDP/1800	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AMLONG-10	AMLODIPINE	10MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	01/07/2009
1475	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

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1476	NDA/MAL/HDP/1 803	ASTRA ZENECA AB	MACNAUGHTON LIMITED	NEXIUM 40MG	ESOMEPRAZOLE	40MG	ASTRAZENECA AB.GARTUNA & SNACKVIKEN STOCKHOLM	SWEDEN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X7.0 TABLET BLISTER,1.0X14.0 TABLET CARTON,1.0X28.0 TABLET CARTON	01/07/2001
1477	NDA/MAL/HDP/1 807	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/SYR UPS/DROPS	1.0X8.0 ML BOTTLE	01/07/1997
1478	NDA/MAL/HDP/1 809	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOVIT-6	PYRIDOXINE	25MG	AGOG PHARMA LTDPLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2004

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1479	NDA/MAL/HDP/1 810	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S 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
1480	NDA/MAL/HDP/1 811	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
1481	NDA/MAL/HDP/1 812	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REQUIN TABLETS	QUININE SULPHATE	300MG	RENE INDUSTRIES LIMITED PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2001

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1482	NDA/MAL/HDP/1 813	DAWA LIMITED	SUPER MEDIC LTD	MOXAFORTE	AMOXICILLIN + FLUCLOXACILLIN	125 MG + 125MG	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2014
1483	NDA/MAL/HDP/1 815	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	SUPIROCIN OINTMENT	MUPIROCIN	2%W/W	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL OTHER OINTMENTS	1.0X15.0 G TUBE,1.0X5.0 G TUBE	01/07/2003
1484	NDA/MAL/HDP/1 816	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	DRESS UP CREAM	NEOMYCIN SULPHATE	0.5%W/W	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	01/07/1998

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1485	NDA/MAL/HDP/1 820	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	AZICIN-250	AZITHROMYCIN	250MG	EAST AFRICAN (INDIA) OVERSEAS- PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	01/07/2009
1486	NDA/MAL/HDP/1 821	BLUE CROSS LABORATORIES LTD	STAR PHARMACEUTICAL S LTD	MEFTAL 500 TABLETS	MEFENAMIC ACID	500MG	BLUE CROSS LABORATORIES LTDL- 17, VERNA INDUSTRIAL ESTATE,VERNA GOA- 403722	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/1997
1487	NDA/MAL/HDP/1 822	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	EPHEDRINE	EPHEDRINE HYDROCHLORIDE	30MG	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2005

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1488	NDA/MAL/HDP/1825	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	COLDEASE SYRUP	PARACETAMOL+CHLORPHENIRAMINE MALEATE+PSEUDOEPHEDRINE HYDROCHLORIDE	120MG+2MG+15MG	RENE INDUSTRIES LIMITED PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2005
1489	NDA/MAL/HDP/1827	REGAL PHARMACEUTICALS LTD	REGAL PHARMACEUTICALS LTD	ALBASOL SUSPENSION	ALBENDAZOLE	200MG/5ML	REGAL PHARMACEUTICALS LTD BABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	01/07/2006
1490	NDA/MAL/HDP/1840	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	OVA-MIT	CLOMIPHENE	50MG	REMEDICA LIMITED AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2011

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1491	NDA/MAL/HDP/1 841	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	FUNGNIL CREAM	CLOTRIMAZOLE	1%W/W	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2000
1492	NDA/MAL/HDP/1 842	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	SUGAQUIN TABLETS	CHLOROQUINE PHOSPHATE	250MG	KAMPALA PHARMACEUTICALS INDUSTIESPLOT NO M44B STRETCHER ROAD INTINDA	UGANDA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2002
1493	NDA/MAL/HDP/1 843	USV PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ECORIN-75	ASPIRIN	75MG	REMEDEX PHARMAB- 249/250 PEENYA INDUSTRIAL ESTATE BANGALORE 560 058	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

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1494	NDA/MAL/HDP/1 844	GUILIN PHARMACEUTICAL S CO.LTD	TRIDEM PHARMA UGANDA LIMITED	SULFAMETHOXAZ OLE / TRIMETHOPRIM	SULFAMETHOXAZ OLE / TRIMETHOPRIM	800MG /160MG	GUILIN PHARMACEUTICAL CO.LTD.NO.43 QUILIDIAN ROAD GUILIN 541002, GUANGXI, CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2011
1495	NDA/MAL/HDP/1 846	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	ANTAGIT DS GEL ORANGE FLAVOUR	ALUMINIUM HYDROXIDE + MAGNESIUM + SIMETHICONE	400MG + 400MG + 50MG	LEBEN LABORATORIES PVT. LTD.PLOT NO. L-4, PHASE -III, M.I.D.C, AKOLA, 444104, MAHARASHTRA, INDIA.	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X170.0 ML BOTTLE	01/07/2013
1496	NDA/MAL/HDP/1 848	LABORATORY&ALLI ED LTD	HARLEYS UGANDA LIMITED	PARATAL	PARACETAMOL	500MG	LABORATORY & ALLIED LTD-PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/1997

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1497	NDA/MAL/HDP/1 849	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	CIFIN	CIPROFLOXACIN	0.2%W/V	ABACUS PARENTERAL DRUGS LTD PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2011
1498	NDA/MAL/HDP/1 850	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	ALZOL TABLETS	ALBENDAZOLE	400MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER, 1.0X10 00.0 TABLET CONTAINER	01/07/2010
1499	NDA/MAL/HDP/1 851	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	CAPSIFENAC GEL	CAPSAICIN + DICLOFENAC + LEVOMENTHOL + METHYL SALICYLATE	0.438 G + 0.335 G + 0.135 G + 0.918 G	STEDMAN PHARMACEUTICALS PVT LIMITED NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPURUR, 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

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1500	NDA/MAL/HDP/1 852	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICAL S LTD	VERCEF ORAL SUSPENSION	CEFACLOR	125MG/5ML	SUN PHARMACEUTICAL INDUSTRIES LIMITED INDUSTRIAL AREA 3, A.B. ROAD, DEWAS 455001, MADHYA PRADESH, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997
1501	NDA/MAL/HDP/1 854	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	FUROSEMIDE INJECTION	FUROSEMIDE	10MG/ML	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE,1.0X100. 0X2.0 ML AMPOULE	01/07/2004
1502	NDA/MAL/HDP/1 856	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PROPRANOLOL TABLETS B.P. 40MG	PROPRANOLOL HYDROCHLORIDE	40MG	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1998

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1503	NDA/MAL/HDP/1 861	GUILIN PHARMACEUTICAL S CO LTD	TRIDEM PHARMA UGANDA LIMITED	SULFAMETHOXAZ OLE / TRIMETHOPRIM	SULFAMETHOXAZ OLE / TRIMETHOPRIM	400MG /80MG	GUILIN PHARMACEUTICAL CO.LTD.NO.43 QUILIDIAN ROAD GUILIN 541002, GUANGXI, CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2011
1504	NDA/MAL/HDP/1 863	AMOUN PHARMACEUTICAL S COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ORACURE GEL	LIDOCAINE HCL+CETYL PYRIDINUM CHLORIDE	2 GM+0.1 GM	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	EGYPT	ORAL TOPICAL GELS AND SOLS	1.0X15.0 G TUBE	01/07/2004
1505	NDA/MAL/HDP/1 864	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	PATANOL	OLOPATADINE HYDROCHLORIDE	0.1%W/V	ALCON COUVREUR NVRIJKSWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML VIAL	01/07/2009

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1506	NDA/MAL/HDP/1 877	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	MINT-O-COOL	DRIED ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE	120MG + 250MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	01/07/2007
1507	NDA/MAL/HDP/1 879	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPENIV	PHENOXYMETHYL PENICILLIN	250MG	SPARSH BIO-TECH LTD PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2004
1508	NDA/MAL/HDP/1 880	SPARSH BIO-TECH PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMCLOX	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	SPARSH BIO-TECH LTD PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER,1.0X10 0.0X10.0 CAPSULE BLISTER	01/07/2004

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1509	NDA/MAL/HDP/1 881	SPARSH BIO-TECH PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMOX	AMOXYCILLIN	250MG	SPARSH BIO-TECH PVT. LIMITED PLOT NO. 1; SURVEY NO. 242/243/244, LAKHA BAVAD, JAMNAGAR- 361 006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0X10.0 CAPSULE BLISTER, 1.0X1.0X10 00.0 CAPSULE CONTAINER, 1.0X10. 0X10.0 CAPSULE BLISTER	01/07/2004
1510	NDA/MAL/HDP/1 882	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMCIL	AMPICILLIN	250MG	SPARSH BIO-TECH LTD PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0X10.0 CAPSULE BLISTER, 1.0X1000.0 CAPSULE CONTAINER, 1.0X10. 0X10.0 CAPSULE BLISTER	01/07/2004
1511	NDA/MAL/HDP/1 887	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMADOL	PARACETAMOL	500MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X10.0 TABLET BLISTER, 100.0 TABLET CONTAINER, 250.0 TABLET CONTAINER, 500.0 TABLET CONTAINER, 1.0X10 00.0 TABLET CONTAINER, 1.0X10. 0X10.0 TABLET BLISTER	01/07/1997

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1512	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,1.0X100.0 TABLET CARTON,1.0X10.0 TABLET CARTON	01/07/1997
1513	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
1514	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

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1515	NDA/MAL/HDP/1 894	KOPRAN LIMITED	TATA UGANDA LIMITED	TRIM-480	CO-TRIMOXAZOLE	480MG	KOPRAN LIMITEDVILLAGE- SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997
1516	NDA/MAL/HDP/1 895	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	TRIMAGO (PAEDIATRIC)	CO-TRIMOXAZOLE	100MG/20MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10 0.0X10.0 TABLET BLISTER	01/07/2007
1517	NDA/MAL/HDP/1 898	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	ZAPACID - 30	LANSOPRAZOLE	30MG	WIN MEDICARE PVT LIMITEDMEERUT, MUZAFFARNAGER ROAD, MODIPURAM - 250110, UTTAR PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	3.0X10.0 CAPSULE BLISTER	01/07/2001

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1518	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
1519	NDA/MAL/HDP/1901	AJANTA PHARMA LTD 31-0	ABACUS PHARMA (AFRICA) LIMITED	IBUMOL	IBUPROFEN + PARACETAMOL	100MG + 162.5 MG /5ML	AJANTA PHARMA LIMITED 31-0 MIDC INDUSTRIAL AREA CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA STATE	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2013
1520	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

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1521	NDA/MAL/HDP/1 911	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CODEINE PHOSPHATE TABLETS BP 30	CODEINE PHOSPHATE	30MG	COSMOS LIMITED RANGWA ROAD, OFF LUNGA LUNGA ROAD, INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1998
1522	NDA/MAL/HDP/1 912	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	D-WORM	ALBENDAZOLE	200MG	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	01/07/2008
1523	NDA/MAL/HDP/1 914	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	CHLORPHENIRAM INE	CHLORPHENIRAM INE	4MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2003

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1524	NDA/MAL/HDP/1 919	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	CANDIDERM CREAM	BECLOMETASONE /CLOTRIMAZOLE/ GENTAMYCIN	0.025%W/W+1%W /W+0.1%W/W	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE,1.0X15.0 G TUBE	01/07/1999
1525	NDA/MAL/HDP/1 922	IPCA LABORATORIES	MEDVIN PHARMA LIMITED	AZIFAST-500	AZITHROMYCIN	500MG	IPCA LABORATORIES LTD,PLOT NO. T-139 SEJAVTA, RATLAM- 457 002 (M.P.) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X3.0 TABLET BLISTER	01/07/2007
1526	NDA/MAL/HDP/1 924	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	AMPICILLIN SODIUM	AMPICILLIN SODIUM	500MG	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTD NO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSH OP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X500.0 MG VIAL	01/07/2013

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1527	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
1528	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 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, 1.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	01/07/2013
1529	NDA/MAL/HDP/1931	ASTRAZENECA	MACNAUGHTON LIMITED	ZOLADEX LA	GOSERELIN ACETATE	10.8MG	ASTRA ZENECA UK LIMITED ASTRAZENECA UK LIMITED SILK ROAD BUSINESS PARK, MACCLESFIELD, CHESHIRE SK 10 2NA,	UNITED KINGDOM	PARENTERAL RETARD PRE-FILLED SYRINGES	1.0X10.8 MG IMPLANT	01/07/2010

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1530	NDA/MAL/HDP/1 932	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	CANDISTAT CREAM	CLOTRIMAZOLE	1%W/W	ELYS CHEMICAL INDUSTRIES LIMITED- ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	KENYA	ORAL TOPICAL CREAMS	1.0X20.0 G TUBE	01/07/2001
1531	NDA/MAL/HDP/1 934	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENECHLOR SUSPENSION	CHLORAMPHENIC OL	125MG/5ML	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2001
1532	NDA/MAL/HDP/1 937	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICAL S 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

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1533	NDA/MAL/HDP/1938	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
1534	NDA/MAL/HDP/1941	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	RABELOC 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
1535	NDA/MAL/HDP/1942	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	AMCLOREN	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CONTAINER	01/07/2009

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1536	NDA/MAL/HDP/1 943	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	NITROCONTIN 2.6	NITROGLYCERIN (CONTROLLED RELEASE)	2.6MG	MODI MUNDIPHARMA (PVT) LTDMEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID RETARD TABLETS	1.0X25.0 TABLET CONTAINER	01/07/2009
1537	NDA/MAL/HDP/1 946	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	SOLUDOL TABLETS	DICLOFENAC SODIUM	50MG	WIN MEDICARE PVT LIMITEDMEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	10.0X10.0 TABLET STRIP	01/07/1998
1538	NDA/MAL/HDP/1 948	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	ZITHROMAX	AZITHROMYCIN DIHYDRATE	500MG	HAUPT PHARMA LATINA S.R.L LATINA- SS 156KM 47,600- 04100,BORGO SAN,MICHELE	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER,1.0X2.0 TABLET BLISTER	01/07/1998

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1539	NDA/MAL/HDP/1949	MACLEODS PHARMACEUTICALS LTDS LTD	VITACARE LIMITED	TRENAXA 500	TRANEXAMIC ACID	500MG	MACLEODS PHARMACEUTICALS PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X6.0 TABLET BLISTER	01/07/2011
1540	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	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER, 1.0X10.0 TABLET BLISTER	01/07/2006
1541	NDA/MAL/HDP/1954	: ALKEM LABORATORIES LIMITEDV	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

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1542	NDA/MAL/HDP/1 956	MILAN LABORATORIES LTD	GITTOES PHARMACEUTICAL S LIMITED	MILOXY	AMOXYCILLIN	250MG	MILAN LABORATORIES (INDIA) PVT LTD PLOT NOS 63, 67 & 87, JAWAHAR CO-OP. INDUSTRIAL ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/2006
1543	NDA/MAL/HDP/1 958	MILAN LABORATORIES LTD	GITTOES PHARMACEUTICAL S LIMITED	MILOXY	AMOXYCILLIN	125MG/5ML	MILAN LABORATORIES (INDIA) PVT LTD PLOT NOS 63, 67 & 87, JAWAHAR CO-OP. INDUSTRIAL ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2005
1544	NDA/MAL/HDP/1 959	MILAN LABORATORIES PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	BETRIM 480	CO-TRIMOXAZOLE	480MG	MILAN LABORATORIES (INDIA) PVT LTD PLOT NOS 63, 67 & 87, JAWAHAR CO-OP. INDUSTRIAL ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2005

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1545	NDA/MAL/HDP/1 960	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	DIFENAC	DICLOFENAC SODIUM	50MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD PLOT NO. M444B, STRETCHER ROAD, NTINDA, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2003
1546	NDA/MAL/HDP/1 966	MACK BROWN PHARMACEUTICAL S PVT LIMITED	SHURIK LTD	PARACIN	PARACETAMOL	500MG	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2005
1547	NDA/MAL/HDP/1 969	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN SR 75MG	DICLOFENAC SODIUM	75MG	NOVARTIS PHARMA SPA, TORRE ANNUNZIATA ITALY- NA	ITALY	ORAL SOLID RETARD TABLETS	1.0X30.0 TABLET CONTAINER	01/07/1997

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1548	NDA/MAL/HDP/1 970	MACK BROWN PHARMACEUTICAL S PVT LIMITED	SHURIK LTD	CETRAMAC	CETIRIZINE	10MG	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
1549	NDA/MAL/HDP/1 971	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOMPICLOX ORAL SUSPENSION	AMPICILLIN + CLOXACILLIN	125 MG/5ML + 125 MG/5ML	MILAN LABORATORIES (INDIA) PVT LTD PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTR A-410209,INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1998
1550	NDA/MAL/HDP/1 974	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	CEFROTIL	CEFUROXIME AXETIL	500MG	SAKAR HEALTH CARE PVT, LTDBLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ- BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2013

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1551	NDA/MAL/HDP/1 975	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	BET-CODERM N	BETAMETHASONE + NEOMYCIN	0.1 W/W + 0.5 W/W	LINCOLN PHARMACEUTICALS LTD10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI, KHATRAJ-382721, GHANDINAGAR GU ARAT, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2007
1552	NDA/MAL/HDP/1 977	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	LOSAR-H	LOSARTAN + HYDROCHLOROT HIAZIDE	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
1553	NDA/MAL/HDP/1 984	ELI-LILLY (SUISSE) SA	LABOREX UGANDA LIMITED	CIALIS	TADALAFIL	20MG	LILLY SA, AVDA DE LA INDUSTRIALILLY SA, AVDA DE LA INDUSTRIA, 30 28108 ALCOBENDAS - MADRID	SPAIN	ORAL SOLID ORDINARY TABLETS	2.0X2.0 TABLET BLISTER	01/07/2004

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1554	NDA/MAL/HDP/1 987	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	FOMYCETIN	CHLORAMPHENIC OL	250MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDA LUR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X10. 0X10.0 CAPSULE BLISTER	01/07/1997
1555	NDA/MAL/HDP/1 989	FERRER INTERNACIONAL S.A	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DERMOFIX	SERTACONAZOLE NITRATE	2%W/W	FERRER INTERNATIONAL, S.A.C/JOAN BUSCALLA, 1- 9.08173 SANT CUGAT DEL VALLES, BARCELONA	SPAIN	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2014
1556	NDA/MAL/HDP/1 990	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TAGERA FORTE	SECNIDAZOLE	1G	UNICHEM LABORATORIES LTDUNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205 UNICHEM LABORATORIES LTD-- C31 & 32 INDUSTRIAL AREA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X2.0 TABLET BLISTER	01/07/2005

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1557	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
1558	NDA/MAL/HDP/1999	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	CARBATOL 200	CARBAMAZEPINE	200MG	TORRENT PHARMACEUTICALS LTD INDRAD-382721, TAL KADI, AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,2.0X5.0X10.0 TABLET BLISTER	01/07/2000
1559	NDA/MAL/HDP/2000	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	CALCIGARD RETARD	NIFEDIPINE(SR)	20MG	TORRENT PHARMACEUTICALS LTD INDRAD-382721, TAL KADI, AHMEDABAD, INDIA	INDIA	ORAL SOLID RETARD TABLETS	1.0X2.0X5.0X10.0 TABLET BLISTER	01/07/2000

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1560	NDA/MAL/HDP/2004	MEDLEY PHARMACEUTICALS LTD	EUROPA HEALTHCARE (U) LTD	R.B.TONE	FERROUS GLUCONATE + VITAMIN C + VITAMIN B12 + VITAMIN B1 + VITAMIN B2 + VITAMIN B6 + CALCIUM PANTOTHENATE + VITAMIN B3 + FOLIC ACID + DIBASIC CA PO4 + ZINC SULPHATE	200MG + 38MG + 4MCG + 3MG + 2.5MG + 1MG + 2.5MG + 1MG + 2.5MG + 23MG + 0.5MG + 100MG + 33MG	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X15.0 CAPSULE BLISTER	01/07/2008
1561	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
1562	NDA/MAL/HDP/2008	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	CANDID -B- CREAM	CLOTRIMAZOLE + BECLOMETASONE DIPROPIONATE CREAM	1%W/W + 0.025%W/W	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2004

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1563	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
1564	NDA/MAL/HDP/2012	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS LTD	CANDID -B- LOTION	CLOTRIMAZOLE + BECLOMETHASONE DIPROPIONATE	1%W/V + 0.025%W/V	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL LOTIONS	1.0X15.0 ML BOTTLE	01/07/2004
1565	NDA/MAL/HDP/2014	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	CANI-MAKS	CLOTRIMAZOLE	1%W/W	S KANT HEALTHCARE LTD1802-1805 GIDC PHASE II VAPS-396195, GUJARAT, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	01/07/2009

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1566	NDA/MAL/HDP/2016	GLENMARK PHARMACEUTICALS 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
1567	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
1568	NDA/MAL/HDP/2019	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOHAL	HALOPERIDOL	10MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2011

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1569	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
1570	NDA/MAL/HDP/2022	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	TORACTIN	CYPROHEPTADINE	2MG/5ML	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1997
1571	NDA/MAL/HDP/2024	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	NEXPRO - 40	ESOMEPRAZOLE MAGNESIUM TABLET	40MG	TORRENT PHARMACEUTICALS LTDINDRAD-382 721, DIST.MEHSANA,INDIA.AT:VILL.MANAKPUR,TEH.NALAGARH,DIST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2004

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1572	NDA/MAL/HDP/2025	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	FERRO-B COMPLEX SYRUP	MULTI-INGREDIENT	MULTI-INGREDIENT	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE, 1.0X100.0 ML BOTTLE	01/07/1997
1573	NDA/MAL/HDP/2026	BROOKES PHARMACEUTICAL LABORATORIES L	HARLEYS UGANDA LIMITED	CORAM 10MG	AMLODIPINE BESYLATE	10MG	BROOKES PHARMACEUTICALS LABORATORIES (PAKISTAN) LTD PLOT 58 SECTOR 15 KORANGI INDUSTRIAL AREA, KARACHI-PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER, 1.0X10.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	01/07/2009
1574	NDA/MAL/HDP/2027	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CO-ANGINET 160/12.5MG	VALSARTAN + HYDROCHLOROT HIAZIDE	160MG + 12.5MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY 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

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1575	NDA/MAL/HDP/2029	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	CHLORAMPHENIC OL PALMITATE	CHLORAMPHENIC OL PALMITATE	125MG/5ML	MEDICAMEN BIOTECH LTDSP-1192, A &B, PHASE -IV, INDUSTRIAL AREA BHIWADI -301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2014
1576	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
1577	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

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1578	NDA/MAL/HDP/2 036	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
1579	NDA/MAL/HDP/2 040	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 MANUFACT URING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0X12.0 TABLET BLISTER, 1.0X3.0X8. 0 TABLET BLISTER, 1.0X30.0X2 4.0 TABLET BLISTER, 1.0X30.0X1 8.0 TABLET BLISTER, 1.0X30.0X6 .0 TABLET BLISTER, 1.0X1.0X6. 0 TABLET BLISTER, 1.0X1.0X12 .0 TABLET BLISTER, 1.0X1.0X24	01/07/2006
1580	NDA/MAL/HDP/2 042	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	BURN CURE	SILVER SULFADIAZINE	1%W/W	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997

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1581	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
1582	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
1583	NDA/MAL/HDP/2053	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ASOMEX-5	AMLODIPINE BESILATE	5MG	EMCURE PHARMACEUTICALS LTD LANE NO.3 PHASE II,SIDCO INDUSTRIAL COMPLEX,BARI-BRAHMANA JAMMU 181 133, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2005

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1584	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
1585	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
1586	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

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1587	NDA/MAL/HDP/2061	RENE PHARMACY(R) LTD..	RENE PHARMACY LTD	ADSOCARB TABLETS	ACTIVATED CHARCOAL	250MG	CYANO PHARMA(P)115-C IND ESTATE POLOGROUND, INDORE 452015	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER	01/07/1997
1588	NDA/MAL/HDP/2062	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED		DEXTROMETHORPHAN HYDROBROMIDE BP + CHLORPHENIRAMINE MALEATE BP + AMMONIUM CHLORIDE BP + PSEUDOEPHEDRINE HYDROCHLORIDE BP	(5MG + 2MG + 50MG + 10MG)/5ML	BETA HEALTHCARE INTERNATIONAL LTD -PLOT NO LR 209/6534 MOGADISHU ROAD	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	01/07/2006
1589	NDA/MAL/HDP/2063	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	MICROGYNON 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

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1590	NDA/MAL/HDP/2 066	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
1591	NDA/MAL/HDP/2 067	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	ZYNCET	CETIRIZINE DIHYDROCHLORID E	10MG	UNICHEM LABORATORIES LIMITED UNIT IIVILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X5.0X10.0 TABLET BLISTER	01/07/1999
1592	NDA/MAL/HDP/2 068	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	DOMADOL	TRAMADOL HYDROCHLORIDE	50MG	UNICHEM LABORATORIES LIMITED UNIT IIVILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1999

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1593	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
1594	NDA/MAL/HDP/2070	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	MIRENA	LEVONORGESTREL	52MG	BAYER OY PANSIONATE 47 20210 TURKU FINLAND	FINLAND	PARENTERAL RETARD IMPLANTS	1.0X1.0 IMPLANT CARTON	01/07/2009
1595	NDA/MAL/HDP/2071	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	CEFAMOR DRY SYRUP	CEFALEXIN	125MG/5ML	CADILA PHARMACEUTICALS LIMITED 1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2000

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1596	NDA/MAL/HDP/2073	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	SII MEASLES VACCINE LIVE ATTENUATED(FREZE-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
1597	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
1598	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

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1599	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, 1.0X10.0X10.0 TABLET BLISTER	01/07/2006
1600	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, MANDIDEEP PRADESH	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2007
1601	NDA/MAL/HDP/2083	BIOLOGICAL E. LTD	GITTOES PHARMACEUTICALS LIMITED	BEVAC	PURIFIED HEPATITIS B SURFACE ANTIGEN	20MCG	BIOLOGICAL E LTD PLOT NO. 1, S.P BIOTECHNOLOGY PARK, PHASE II KOLTHAR (V), SHAMEERPET (M), RANGA REDDY (DIST), ANDHRA PRADESH, INDIA 500078	INDIA	PARENTERAL ORDINARY VIALS	1.0X35.0X1.0 ML VIAL (1 DOSE VIAL), 1.0X24.0X10.0 ML VIAL (10 DOSE VIAL)	01/07/2015

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1602	NDA/MAL/HDP/2 087	ABBVIE (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	NORVIR	RITONAVIR	100MG	ABBVIE DEUTSCHLAND GMBH & CO. KG.KNOLLSTASSE 50, D-67061, LUDWIGSHAFEN, GERMANY.	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2013
1603	NDA/MAL/HDP/2 089	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DIABETMIN XR 500MG	METFORMIN HCL EXTENDED RELEASE	500MG	HOVID BHDLOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
1604	NDA/MAL/HDP/2 090	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

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1605	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
1606	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
1607	NDA/MAL/HDP/2094	MICRO LABS LTD	LABOREX UGANDA LIMITED	LEVOBACT-750	LEVOFLOXACIN HEMIHYDRATE	750MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2010

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1608	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
1609	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
1610	NDA/MAL/HDP/2099	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	HYDROCORTISON E 1% CREAM	HYDROCORTISON E	1%W/W	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1998

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1611	NDA/MAL/HDP/2 100	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ORALCON - F	LEVONORGESTRE L & ETHINYLESTRADI OL+ FERROUS FUMARATE	0.15MG + 0.03MG + 75MG	MYLAN LABORATORIES LIMITED..PLOT NO.20 & 21, PHARMEZ, SARKHEJ- BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL- SANAND, AHMEDABAD, GUJARAT, INDIA 382213 MYLAN LABORATORIES LIMITED.-PLOT NO.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X28.0 TABLET BLISTER	01/07/2007
1612	NDA/MAL/HDP/2 101	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,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2010
1613	NDA/MAL/HDP/2 104	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LAMIVUDINE/NEV IRAPINE /ZIDOVUDINE DISPERSIBLE TABLETS	LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE	30MG + 50MG + 60MG	MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2009

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1614	NDA/MAL/HDP/2 108	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYMOX CAPSULES 250MG	AMOXYCILLIN	250MG	ELYS CHEMICAL INDUSTRIES LTDROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/1997
1615	NDA/MAL/HDP/2 111	HETERO LABS LTD	AIVEEN (U) LIMITED	LOPINAVIR / RITONAVIR	LOPINAVIR / RITONAVIR	200MG /50MG	HETERO LABS LTD22- 110 IDA JEEDIMETLA HYDERABAD 500- 055 ANDHRA PRADESH HETERO LABS LTD. UNIT (V) .S.NO.439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET CONTAINER	01/07/2011
1616	NDA/MAL/HDP/2 112	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LOPINAVIR + RITONAVIR	LOPINAVIR + RITONAVIR	200MG + 50MG	MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET CONTAINER	01/07/2008

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1617	NDA/MAL/HDP/2 116	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	AMLOVAS-10	AMLODIPINE BESILATE	10MG	MACLEODS PHARMACEUTICALS LTD .PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET STRIP	01/07/2005
1618	NDA/MAL/HDP/2 120	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MEGAPIME	CEFEPIME	1G	SANCE LABORATORIES PVT LTDVI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA. 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
1619	NDA/MAL/HDP/2 124	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYMOX	AMOXYCILLIN	125MG/5ML	ELYS CHEMICAL INDUSTRIES LTDROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

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1620	NDA/MAL/HDP/2 125	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	BECLATE 100	BECLOMETASONE	100MCG/DOSE	CIPLA LTD.- PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	NASAL SYSTEMIC METERED-DOSE LIQUIDS	1.0X200.0 METERED DOSE CANNISTER	01/07/2009
1621	NDA/MAL/HDP/2 128	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	TRANSAMIN INJECTION 500MG	TRANEXAMIC ACID	500MG/5ML	HILTON PHARMA (PVT) LTD PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X10.0X5.0 ML AMPOULE	01/07/2005
1622	NDA/MAL/HDP/2 129	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	CLAVODAR	AMOXICILLIN/CLAVULANIC ACID	500MG/125MG	DAR AL DAWANA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2011

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1623	NDA/MAL/HDP/2 132	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	LOPINAVIR/ RITONAVIR	LOPINAVIR/ RITONAVIR	200MG/ 50MG	AUROBINDO PHARMA LTDUNIT III- SURVEY NO.313,BACHUPALL Y VILLAGE,QUTHUBUL LAPUR MANDAL R.R DISTRICT(A.P),INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET CONTAINER	01/07/2010
1624	NDA/MAL/HDP/2 133	NOVO NORDISK	PHILLIPS PHARMACEUTICAL S (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
1625	NDA/MAL/HDP/2 136	MEDICAL UNION PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	SEDIPROCT SUPOSITORY	HYDROCORTISON E+ CINCHOCAINE+ ESCULOSIDE+ FRAMYCETIN	5MG + 5MG +10MG +10MG	MEDICAL UNION PHARMA .COABU- SULTAN ISMAILIA EGYPT	EGYPT	TOPICAL EXTERNAL SUPPOSITORIES	1.0X6.0 SUPPOSITORY STRIP	01/07/2003

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1626	NDA/MAL/HDP/2 140	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	AVIRANZ	EFAVIRENZ	600MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2006
1627	NDA/MAL/HDP/2 141	CENTAUR PHARMACEUTICAL S PRIVATE LIMITED	GITTOES PHARMACEUTICAL S LIMITED	INFLAZONE	MULTIINGREDIEN T	N/A	CENTAUR PHARMACEUTICALS PVT LTD -PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE	01/07/2005
1628	NDA/MAL/HDP/2 143	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	GRISEOFIL	GRISEOFULVIN	500MG	FOURRTS INDIA LABORATORIES PVT. LIMITEDVANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1X10X10 TABLET BLISTER	01/07/2005

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1629	NDA/MAL/HDP/2 144	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
1630	NDA/MAL/HDP/2 145	FOURRTS (INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	METFIL 500	METFORMIN	500MG	FOURRTS INDIA LABORATORIES PVT. LIMITEDVANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER	01/07/2005
1631	NDA/MAL/HDP/2 147	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	DICLOFEN -50	DICLOFENAC	50MG	FOURRTS INDIA LABORATORIES PVT. LIMITEDVANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2006

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1632	NDA/MAL/HDP/2 149	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	PRIMOLUT DEPOT	HYDROXYPROGES TERONE HEXANOATE	250MG	BAYER PHARMA A.GMULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE	01/07/1997
1633	NDA/MAL/HDP/2 150	ELI-LILLY (SUISSE) SA	LABOREX UGANDA LIMITED	HUMULIN MIXTURE	HUMAN INSULIN	70/30 I.U	LILLY EGYPT S.A.E. & ELI LILLY AND COMPANY LILLY TECHNOLOGY CENTRE INDIANAPOLIS,INDIA NA 46285 USA	UNITED STATES	PARENTERAL ORDINARY S C VIALS	1.0X4.0 ML VIAL,1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE	01/07/1997
1634	NDA/MAL/HDP/2 155	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

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1635	NDA/MAL/HDP/2 160	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	ACEM-500	CLARITHROMYCIN	500MG	EMCURE PHARMACEUTICALS LTD LANE 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
1636	NDA/MAL/HDP/2 161	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
1637	NDA/MAL/HDP/2 170	ARISTO PHARMACEUTICAL S 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

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1638	NDA/MAL/HDP/2 173	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICAL S LTD	GLEVO-500	LEVOFLOXACIN	500MG	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X5.0 TABLET BLISTER	01/07/2003
1639	NDA/MAL/HDP/2 176	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	RISPITAS-2	RISPERIDONE	2MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2011
1640	NDA/MAL/HDP/2 178	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL CEFUROXIME-250	CEFUROXIME AXETIL	250MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/2008

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1641	NDA/MAL/HDP/2 181	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM PHEN	PHENOXYMETHYL PENICILLIN	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	100.0 TABLET CONTAINER,1000.0 TABLET CONTAINER,500.0 TABLET CONTAINER,250.0 TABLET CONTAINER	01/07/1997
1642	NDA/MAL/HDP/2 185	GLAXOSMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ROTARIX	LIVE ATTENUATED RIX4414 STRAIN OF HUMAN ROTAVIRUS OF THE G1P[8] TYPE	NOT LESS THAN 10 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
1643	NDA/MAL/HDP/2 186	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL DIPHENHYDRAMINE PAEDIATRIC SYRUP	DIPHENHYDRAMINE HYDROCHLORIDE + AMMONIUM CHLORIDE	7MG+67.5MG/5ML	KOTRA PHARMA- BHD 1, JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA, MALAYSIA	MALAYSIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2008

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1644	NDA/MAL/HDP/2 189	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL BETAMETHASONE	BETAMETHASONE	0.1%W/W	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X5.0 G TUBE	01/07/2008
1645	NDA/MAL/HDP/2 191	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	KLOXY	CLOXACILLIN	250MG	LABORATORY & ALLIED LTD.--PLOT 209/10349 OFF MOMBASA RD NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X10. 0X10.0 CAPSULE BLISTER	01/07/1997
1646	NDA/MAL/HDP/2 195	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	EUDERM CREAM	UREA	10%W/W	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X45.0 G TUBE	01/07/1997

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1647	NDA/MAL/HDP/2 197	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
1648	NDA/MAL/HDP/2 199	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	EUTHYROX 50MCG	LEVOTHYROXINE SODIUM	50MCG	MERCK KGAA - FRANKFRUTER STRASSE 250, D-64293,DARMSTADT-GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X4.0X25.0 TABLET BLISTER,1.0X1.0X30.0 TABLET BLISTER	01/07/2013
1649	NDA/MAL/HDP/2 201	SHAIGAN PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	CLYCIN	CLINDAMYCIN PHOSPHATE	10MG/ML	SHAIGAN PHARMACEUTICALS (PVT) LTD 14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN	PAKISTAN	TOPICAL EXTERNAL LOTIONS	1.0X30.0 ML BOTTLE	01/07/2008

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1650	NDA/MAL/HDP/2 208	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL CEPHALEXIN	CEPHALEXIN MONOHYDRATE	500MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2010
1651	NDA/MAL/HDP/2 211	GALENTIC PHARMA (PVT)LTD	VITACARE LIMITED	BENZYL BENZOATE	BENZYL BENZOATE	25%W/W	GALENTIC PHARMA PVT. LIMITEDR-673, TTC MIDC, RUBALE, THANE BELAPURNAVI MUMBAI 400 701 INDIA	INDIA	TOPICAL EXTERNAL EMULSIONS	1.0X200.0 ML BOTTLE,1.0X100.0 ML BOTTLE,1.0X1000.0 ML BOTTLE	01/07/2005
1652	NDA/MAL/HDP/2 212	DENK PHARMA	BENLE CONSULT LIMITED	CIPRO-DENK 500	CIPROFLOXACIN	500MG	ALLPHARMED PHARBIL ARZNEIMITTEL GMBH12 D377081	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2005

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1653	NDA/MAL/HDP/214	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	GENTAMICIN INJECTION	GENTAMICIN SULPHATE	40MG/ML	SCOTT-EDIL PHARMACIA LTD (UNIT I)56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X2.0 ML AMPOULE	01/07/2007
1654	NDA/MAL/HDP/216	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
1655	NDA/MAL/HDP/219	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

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1656	NDA/MAL/HDP/2 223	ROYAL PHARMA	ROYAL PHARMA 2011 LIMITED	BENZATHINE PENICILLIN INJECTION	BENZATHINE PENICILLIN	2400000 I.U	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTDNO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSH OP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1X2.4 MU VIAL	01/07/2002
1657	NDA/MAL/HDP/2 224	VOGEN LABORATORIES LTD	BUFFALO HEALTH CARE LTD	DURAMOX 500	AMOXICILLIN	500MG	VOGEN LABORATORIES LTD70, M.HERACLEOUS STR. AYIOS ATHANASIOS INDUSTRIAL AREA, LIMASSOL, CYPRUS	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER,1.0X10.0X1 0.0 CAPSULE BLISTER	01/07/2013
1658	NDA/MAL/HDP/2 226	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	HEPA-MERZ GRANULES	L-ORNITHINE-L- ASPARTATE	3G/5G	WIN-MEDICARE PRIVATE LIMITEDMEERUT- MUZAFFARNAGAR ROAD, MODIPURAM 250110 UTTAR PRADESH	INDIA	ORAL LIQUID ORDINARY OTHER POWDERS/GRANU LES	1.0X10.0X5.0 G SACHET	01/07/2004

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1659	NDA/MAL/HDP/2 231	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	PIRITEX WITH CODEINE	MULTI- INGREDIENT	MULTI- INGREDIENT	MEDIPHARM INDUSTRIES(EA) LTD PLOT 65 KAKAJJO ROAD BWEYOGERERE P.O.BOX 6218,KAMPALA,UGA NDA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997
1660	NDA/MAL/HDP/2 232	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNICAST	MONTELUKAST	10MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTDP.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL- RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
1661	NDA/MAL/HDP/2 233	ASTRAZENECA	MACNAUGHTON LIMITED	PULMICORT NEBULISER	BUDESONIDE	0.25MG/ML	ASTRA ZENECA SWEDEN OPERATIONS LIQUID PRODUCTION KVARNBERGAGATAN LZ SE-151- 85,SWEDEN	SWEDEN	LUNG ADMINISTRATION LIQUID FOR INHALATION	1.0X4.0X5.0X2.0 ML VIAL	01/07/2011

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1662	NDA/MAL/HDP/2 235	WOCKHARDT LTD	ABACUS PHARMA (AFRICA) LIMITED	WOSULIN-N	INSULIN HUMAN(RECOMB INANT DNA ORIGIN)	100IU/ML	WOCKHARDTWOCK HARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X3.0 ML VIAL,1.0X10.0 ML VIAL	01/07/2006
1663	NDA/MAL/HDP/2 236	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	TEGRETOL 200	CARBAMAZEPINE	200MG	NOVARTIS FARMA S.P.A.-VIA PROVINCIALE SCHITO 131, 80058 TORRE ANNUNZIATA, ITALY	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/1997
1664	NDA/MAL/HDP/2 237	WOCKHARDT LTD	ABACUS PHARMA (AFRICA) LIMITED	WOSULIN-30/70	INSULIN HUMAN(RECOMB INANT DNA ORIGIN)	100I.U/ML	WOCKHARDT LIMITED - WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL,1.0X3.0 ML VIAL	01/07/2006

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1665	NDA/MAL/HDP/2 239	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	TEGRETOL SYRUP	CARBAMAZEPINE	20MG/ML	DELPHARMA HUNINGUE S.A.S-26, RUE DE LA CHAPELLE, 68330 HUNINGUE, FRANCE	FRANCE	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X250.0 ML BOTTLE	01/07/2006
1666	NDA/MAL/HDP/2 242	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CYCLOVAX 200 TABLETS	ACYCLOVIR	200MG	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/1997
1667	NDA/MAL/HDP/2 243	AFRICURE PHARMACEUTICAL S (INDIA) PRIVATE LIMITED	AFRICURE PHARMACEUTICAL S U LIMITED	SIMDOL TABLETS	PARACETAMOL	500MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITEDPLOT 9- 12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997

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1668	NDA/MAL/HDP/2 245	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	X-PEL	MEBENDAZOLE	100MG	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2008
1669	NDA/MAL/HDP/2 248	GALENTIC PHARMA (PVT)LTD	VITACARE LIMITED	TETRACYCLINE OPHTHALMIC	TETRACYCLINE	1%W/W	GALENTIC PHARMA PVT. LIMITEDR-673, TTC MIDC, RUBALE, THANE, INDIA	INDIA	OPHTHALMIC OINTMENTS	1.0X3.5 G TUBE,1.0X5.0 G TUBE	01/07/2004
1670	NDA/MAL/HDP/2 249	WOCKHARDT LTD	ABACUS PHARMA (AFRICA) LIMITED	WOSULIN-R	INSULIN	100ML	WOCKHARDT LIMITED - WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X3.0 ML VIAL,1.0X10.0 ML VIAL	01/07/2006

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1671	NDA/MAL/HDP/2 252	JOHNSON&JOHNS ON PTY LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	VERMOX	MEBENDAZOLE	500MG	SPECPHARM HOLDINGS 15TH ROAD HALFWAY HOUSE JOHNSON & JOHNSON (PTY) LTD241 MAIN ROAD, RETREAT, 7945, CAPE TOWN	SOUTH AFRICA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0 TABLET BLISTER	01/07/2000
1672	NDA/MAL/HDP/2 254	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	BURN CUR CREAM	ACRIFLAVINE/THY MOL	N/A	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/1998
1673	NDA/MAL/HDP/2 256	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	AUGMENTIN 457MG/5ML	AMOXICILLIN + CLAVULANIC ACID	400 MG + 57 MG / 5 ML	GLAXO WELLCOME PRODUCTIONZI DE LA PEYENNIERE, 53100, MAYENNE	FRANCE	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X70.0 ML BOTTLE	01/07/2010

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1674	NDA/MAL/HDP/2 258	MYLAN LABORATORIES LIMITED (OTL)	KIMSY MEDS LTD	TENOFOVIR DISOPROXIL + LAMIVUDINE + EFAVIRENZ	TENOFOVIR DISOPROXIL + LAMIVUDINE + EFAVIRENZ	300MG/300MG/60 OMG	QUESTA CARE LIMITED PLOT NO 209/7184 HOMABAY RD TERMINUS GATE NO-19, INDUSTRIAL AREA NAIROBI, KENYA. MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD -	INDIA KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET BOTTLE,1.0X1.0X30 .0 TABLET BOTTLE	01/07/2009
1675	NDA/MAL/HDP/2 263	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	CELEMIN 10 PLUS	AMINO ACIDS/ELECTROLY TES	10%W/V+10%W/V	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X500.0 ML BOTTLE	01/07/2001
1676	NDA/MAL/HDP/2 265	HETERO DRUGS LTD	AIVEEN (U) LIMITED	TENOFOVIR/ LAMIVUDINE	TENOFOVIR DISOPROXIL FUMARATE + LAMIVUDINE	300MG + 300MG	HETERO LABS LTD 22- 110 IDA JEEDIMETLA HYDERABAD 500- 055 ANDHRA PRADESH HETERO LABS LTD (UNIT- V)SY.NO.438,439,44 0 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2010

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1677	NDA/MAL/HDP/2 267	MYLAN LABORATORIES LIMITED (OTL)	KIMSY MEDS LTD	TENOFOVIR DISOPROXIL FUMARATE + LAMIVUDINE	TENOFOVIR DISOPROXIL FUMARATE + LAMIVUDINE	300MG+300MG	QUESTA CARE LIMITEDPLOT NO 209/7184 HOMABAY RD TERMINUS GATE NO-19, INDUSTRIAL AREA NAIROBI, KENYA. MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD -	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2007
1678	NDA/MAL/HDP/2 269	DAWA LIMITED	SUPER MEDIC LTD	DAWAMOX	AMOXYCILLIN TRIHYDRATE	125MG/5ML	DAWA PHARMACEUTICALS LIMITEDPLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997
1679	NDA/MAL/HDP/2 271	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	ARTEMETHER 20MG/LUMEFANT RINE 120MG	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	IPCA LABORATORIES LTD PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X3.0X6.0 TABLET BLISTER,1.0X30.0X1 8.0 TABLET BLISTER,1.0X30.0X2 4.0 TABLET BLISTER,1.0X10.0X1 .0X6.0 TABLET BLISTER,1.0X10.0X2 .0X6.0 TABLET BLISTER,1.0X30.0X1 2.0 TABLET BLISTER,1.0X30.0X4 .0X6.0 TABLET BLISTER,1.0X30.0X3	01/07/2010

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1680	NDA/MAL/HDP/2 272	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	CLARANTA -500	CLARITHROMYCIN	500MG	AJANTA PHARMA LTD .B-4//5/6, MIDC INDUSTRIALAREA, PAITHAN-431 128, AURANGBAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X2.0X10.0 TABLET BLISTER	01/07/2005
1681	NDA/MAL/HDP/2 280	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	BETADROP-N	BETAMETHASONE + NEOMYCIN	0.1 %W/V + 0.5 %W/V	REMINGTON PHARMACEUTICAL INDUS. PVT LTD, 117 ALLAM	PAKISTAN	OPHTHALMIC DROPS	1.0X7.5 ML VIAL	01/07/1999
1682	NDA/MAL/HDP/2 281	PHARMACTIV FZCO	JEET PHARMACEUTICAL S LIMITED	LUMFORT	LORATADINE	10MG	NABIQASIM INDUSTRIES (PVT) LIMITED17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007

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1683	NDA/MAL/HDP/2 282	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	PROPAN	PROPRANOLOL	40MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2011
1684	NDA/MAL/HDP/2 283	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	SII DIPHTHERIA TETANUS PERTUSIS	DIPHTHERIA TOXOID+TETANU S TOXOID+B.PERTU SIS ADSORBED ON ALUMINIUM PHOSPATE	>25LF(>30IU)+>5LF (>40IU)+<16OU(>4 PU) ADSORBED ON ≥1.5MG	SERUM INSTITUTE OF INDIA LTD212/2 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
1685	NDA/MAL/HDP/2 287	GLAXO WELLCOME (KENYA) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZINNAT	CEFUROXIME AXETIL	250MG	GLAXOSMITHKLINE UK LTD HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X50.0 TABLET CARTON	01/07/1997

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1686	NDA/MAL/HDP/290	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LAMIVUDINE + ZIDOVUDINE	LAMIVUDINE + ZIDOVUDINE	150MG + 300MG	MYLAN LABORATORIES LTD-F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD - H-12 & H-13, MIDC, WALUJ,AURANGABAD- 431136 MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2008
1687	NDA/MAL/HDP/293	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TIOCON	TIOCONAZOLE	1%W/W	GLOBAL NAPI PHARMACEUTICALS - 2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	EGYPT	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2005
1688	NDA/MAL/HDP/295	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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1689	NDA/MAL/HDP/297	DAWA LIMITED	SUPER MEDIC LTD	SABULIN SYRUP	SALBUTAMOL SULPHATE	2MG/5ML	DAWA LIMITED BABA DOGO RWARAKA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	01/07/2008
1690	NDA/MAL/HDP/298	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, 1.0X1.0X10.0 TABLET BLISTER	01/07/2013
1691	NDA/MAL/HDP/299	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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1692	NDA/MAL/HDP/2 303	MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZIAK 5/6.25	BISOPROLOL + HYDROCHLOROT HIAZIDE	5 MG + 6.25 MG	MERCK KGAAFRANKFURTER STRASSE 250 64271 DARMSTADT GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014
1693	NDA/MAL/HDP/2 304	MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZIAK 10/6.25	BISOPROLOL + HYDROCHLOROT HIAZIDE	10 MG + 6.25 MG	MERCK KGAAFRANKFURTER STRASSE 250 64271 DARMSTADT GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014
1694	NDA/MAL/HDP/2 305	MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZIAK 2.5/6.25	BISOPROLOL + HYDROCHLOROT HIAZIDE	2.5 MG + 6.25 MG	MERCK KGAAFRANKFURTER STRASSE 250 64271 DARMSTADT GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014

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1695	NDA/MAL/HDP/2 306	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	MICROLUT	LEVONORGESTRE L	0.03MG	BAYER PHARMA A.GMULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X35.0 TABLET BLISTER	01/07/2010
1696	NDA/MAL/HDP/2 312	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CLAVOMID 625	AMOXICILLIN + CLAVULANIC ACID	500 MG + 125 MG	REMEDICA LIMITED AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	2.0X10.0 TABLET BLISTER	01/07/2006
1697	NDA/MAL/HDP/2 313	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CLAVOMID 375	AMOXICILLIN + CLAVULANIC ACID	250 MG + 125 MG	REMEDICA LIMITED AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	2.0X10.0 TABLET BLISTER	01/07/2006

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1698	NDA/MAL/HDP/2 314	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	RABEMAC-20	RABEPRAZOLE SODIUM	20MG	MACLEODS PHARMACEUTICALS LTD PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2005
1699	NDA/MAL/HDP/2 315	MICRO LABS LTD	LABOREX UGANDA LIMITED	GRAMOCEF-O-50	CEFIXIME	50MG/5ML	MICRO LABS LIMITED, BOMMASANDRA PLOT NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X30.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2006
1700	NDA/MAL/HDP/2 318	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DIAPRIDE-4	GLIMEPIRIDE	4MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2006

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1701	NDA/MAL/HDP/2 319	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSMOL	PARACETAMOL	120MG/5ML	COSMOS LIMITEDRANGWE ROAD, OFF LUNGA ROAD - INDUSTRIAL AREA NAROBI	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1998
1702	NDA/MAL/HDP/2 320	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	ERO-125 DRY SYRUP	ERYTHROMYCIN ESTOLATE	125MG/5ML	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2006
1703	NDA/MAL/HDP/2 322	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TREFLUCAN	FLUCONAZOLE	150MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X1.0 CAPSULE STRIP	01/07/2007

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1704	NDA/MAL/HDP/2 324	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	SWISSCLOXA	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X7.5 ML VIAL	01/07/2011
1705	NDA/MAL/HDP/2 330	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	COARTEM	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	NOVARTIS PHARMA AG- SCHAFFHAUSERSTRA SSE 4332 STEIN SWITZERLAND NORVATIS SAGLIK GIDA VE TARIM URENLERI SAN, VE TIC-AC-YENISEHIR MAHALLESİ IHLA VADISI SOKAK, NO.2, 34912 KURTKOY, INSTANBUL - TURKEY	SWITZERLAND TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X24.0 TABLET BLISTER,1.0X30.0X2 4.0 TABLET BLISTER,1.0X30.0X6 .0 TABLET BLISTER,1.0X36.0X6 .0 TABLET BLISTER,1.0X3.0X8. 0 TABLET BLISTER,1.0X30.0X1 2.0 TABLET BLISTER,1.0X30.0X1 8.0 TABLET BLISTER,1.0X4.0X6. 0 TABLET BLISTER	01/07/2005
1706	NDA/MAL/HDP/2 333	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	SII DIPHTHERIA & TETANUS VACCINE ADSORBED(PEDIA TRIC)	DIPHTHERIA TOXOID+TETANU S TOXOID ADSORBED ON ALUMINIUM PHOSPHATE	>25LF(>30IU)+>5LF (>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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1707	NDA/MAL/HDP/2 334	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
1708	NDA/MAL/HDP/2 335	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOBEN TABLETS(THANE)	MEBENDAZOLE	100MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	10.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X10 0.0 TABLET CONTAINER,1.0X25 0.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	01/07/2001
1709	NDA/MAL/HDP/2 338	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	CLAVULIN	AMOXICILLIN + CLAVULANIC ACID	200 MG + 28.5 MG	GLAXO WELLCOME PRODUCTIONZI DE LA PEYENNIERE, 53100, MAYENNE	FRANCE	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE,1.0X70.0 ML BOTTLE	01/07/2003

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1710	NDA/MAL/HDP/2 348	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	HEPATITIS B VACCINE(RDNA) 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
1711	NDA/MAL/HDP/2 350	ASTRA ZENECA AB	MACNAUGHTON LIMITED	PULMICORT TURBUHALER	BUDESONIDE	200MCG	ASTRAZENECA AB,GARTUNA & SNACKVIKEN STOCKHOLM	SWEDEN	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X100.0 DOSE CANNISTER	01/07/2001
1712	NDA/MAL/HDP/2 352	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	COLD CAP DAY TIME	PARACETAMOL/P SEUDOEPHEDRIN E HCL/CAFFEINE	500MG+30MG+30 MG	REGAL PHARMACEUTICALS LIMITED PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X12.0 CAPSULE BLISTER	01/07/2007

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1713	NDA/MAL/HDP/2 353	ASTRA ZENECA	MACNAUGHTON LIMITED	NEXIUM	ESOMEPRAZOLE (AS MAGNESIUM TRIHYDRATE)	10MG	ASTRA ZENECA ABSE- 151 85 SODERTALJE, SWEDEN (GARTUNAVAGEN & SNACKVIKEN)	SWEDEN	ORAL SOLID ORDINARY GRANULES	1.0X28.0 SACHET CARTON	01/07/2013
1714	NDA/MAL/HDP/2 356	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	QUININE	QUININE DIHYDROCHLORID E	600MG/2ML	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119, N-113 MIDC TARAPUR BOISAR DIST. THANE 401506 MAHARASHTRA	CHINA INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2005
1715	NDA/MAL/HDP/2 357	ACINO PHARMA AG	LABOREX UGANDA LIMITED	TRABILIN- 50 CAPSULES	TRAMADOL	50MG	MERCKLE GMBH,LUDWIG MERCKLE STRASSE3 D-89143 BLAUBEUREN	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2003

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1716	NDA/MAL/HDP/2 359	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	ASPIREM 75	ASPIRIN	75MG	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X2.0X28.0 TABLET BLISTER	01/07/2007
1717	NDA/MAL/HDP/2 360	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	FUNGISTIN PESSARIES	NYSTATIN	100000 IU	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	VAGINAL TABLETS	1.0X14.0 PESSARY PACK,5.0X3.0 PESSARY STRIP,1.0X100.0 PESSARY CONTAINER	01/07/2002
1718	NDA/MAL/HDP/2 361	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CLAREM 500	CLARITHROMYCIN	500MG	REMEDICA LTD AHARNON 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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1719	NDA/MAL/HDP/2 362	GALENTIC PHARMA LTD	VITACARE LIMITED	CANDISTATIN OINTMENT	NYSTATIN	100,000I.U	GALENTIC PHARMA PVT. LIMITED R-673, TTC MIDC, RUBALE, THANE BELAPUR NAVI MUMBAI 400 701 INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE	01/07/2009
1720	NDA/MAL/HDP/2 363	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	GENTAMICIN SULPHATE	GENTAMICIN SULPHATE	80MG/2ML	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE,1.0X10.0 X10.0X2.0 ML AMPOULE	01/07/2005
1721	NDA/MAL/HDP/2 364	AIVEEN (U) LIMITED	AIVEEN (U) LIMITED	VOXEL-500	LEVOFLOXACIN	500MG	MEDICO REMEDIES PVT LIMITED8 & 9 DEWAN & SONS, UDYOG NAGAR PALGAR, DISTRICT THANE MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2015

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1722	NDA/MAL/HDP/2 366	UNIQUE PHARMACEUTICAL S LTD	PLANET PHARMACEUTICAL S UGANDA LTD	IFICIPRO INJECTION	CIPROFLOXACIN	200MG/100ML	UNIQUE PHARMACEUTICALS LABS (A DIV OF J.B CHEMICALS & PHARMACEUTICAL LTD)-304-308 ,GIDC , PANOLI 394116	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2005
1723	NDA/MAL/HDP/2 368	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	DERMIDEX CREAM	MICONAZOLE NITRATE	2%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2007
1724	NDA/MAL/HDP/2 369	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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1725	NDA/MAL/HDP/2 371	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	TOPIZONE CREAM	FUSIDIC ACID + BETAMETHASONE VALERATE	20MG/G+1MG/G	PHARMA INTERNATIONAL COMPANY MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2007
1726	NDA/MAL/HDP/2 375	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	CLAVULIN 1G	AMOXICILLIN + CLAVULANIC ACID	875 MG + 125 MG	SMITHKLINE BEECHAM PHARMACEUTICALS, CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X1.0X7.0 TABLET BLISTER	01/07/2010
1727	NDA/MAL/HDP/2 379	PT SANBE FARMA	MEDVIN PHARMA LIMITED	PUMPITOR	OMEPRAZOLE	40MG	PT SANBE FARMA JI INDUSTRINO.8 KOMPLEKS INDUSTRI CIMAREME PADALARANG BANDUNG	INDONESIA	PARENTERAL ORDINARY VIALS	1.0X1.0 VIAL CARTON + 1 AMPOULE OF SOLVENT	01/07/2014

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1728	NDA/MAL/HDP/2 384	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CLARIX 500	CLARITHROMYCIN	500MG	PHARMA INTERNATIONAL COMPANY MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2007
1729	NDA/MAL/HDP/2 385	COSMOS LIMITED	ASTRA PHARMA (U) LIMITED	COZEPAM 5MG	DIAZEPAM	5MG	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2000
1730	NDA/MAL/HDP/2 387	DAWA LIMITED	SUPER MEDIC LTD	VERMOUT	MEBENDAZOLE	100MG/5ML	DAWA LIMITED BABA DOGO RWARAKA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2010

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1731	NDA/MAL/HDP/2 388	DAFRA PHARMA LTD	MULTIPHAR UGANDA LIMITED	DAFRACLAV	AMOXYCILLIN + POTASSIUM CLAVULANATE	400MG + 57MG	BILIM ILAC SAN. VE. TIC. A.S.CERKEZKOY ORGANIZE SANAYI BOLGESI, KARAAGAC, MH. 5. SK. NO. 6, KAPAKLI - TEKIRDAG 59510	TURKEY	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X70.0 ML BOTTLE	01/07/2011
1732	NDA/MAL/HDP/2 389	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELOCIN	ERYTHROMYCIN	250MG	ELYS CHEMICAL INDUSTRIES LIMITED- ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2007
1733	NDA/MAL/HDP/2 390	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	P-ALAXIN	DIHYDROARTEMI SININ/ PIPERAQUINE PHOSPHATE	80MG /640MG	BLISS GVS PHARMA LTD PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA- INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X80.0 ML BOTTLE,1.0X120.0 ML BOTTLE	01/07/2008

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1734	NDA/MAL/HDP/2 391	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	HEADAID TABLETS	ASPIRIN + CAFFEINE + PARACETAMOL	300MG + 30MG + 250MG	MILAN LABORATORIES (INDIA) PVT LTD PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X2.0 TABLET STRIP	01/07/1997
1735	NDA/MAL/HDP/2 394	MERCK SHARP & DOHME BV.	SURGIPHARM (U) LIMITED	STOCRIN	EFAVIRENZ	600MG	MERCK SHARP & DOHME B.V- WAARDENWEG 392031 BN, HAARLEM	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2004
1736	NDA/MAL/HDP/2 395	A.MENARINI INDUSTRIE FARMACEUTICHE S.R.I	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	FASTUM GEL	KETOPROFEN	2.5%W/W	A. MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.LVIA SETTE SANTI 3, 50131 FIRENZE- ITALY	ITALY	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE,1.0X30.0 G TUBE,1.0X50.0 G TUBE,1.0X100.0 G TUBE	01/07/2005

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1737	NDA/MAL/HDP/2 397	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	VITAMAKS	MULTI- INGREDIENT	MULTI- INGREDIENT	S KANT HEALTH CARE LTD PLOT 1802 - 1805	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2010
1738	NDA/MAL/HDP/2 399	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	VOLINI	MULTI INGREDIENT	MULTI INGREDIENT	SUN PHARMACEUTICAL INDUSTRIES LIMITED KH. 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,	INDIA	TOPICAL EXTERNAL OTHER GELS/SOLS	1.0X1.0X30.0 G TUBE	01/07/2005
1739	NDA/MAL/HDP/2 401	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	ENAT	NATURAL VITAMIN E	400IU	MEGA LIFE SCIENCES PUBLIC COMPANY LIMITED 384 SOIB PATTANA 3 RD BANGPOO INDUSTRIAL ESTATE SAMUTPRAKARN 10280	THAILAND	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2005

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1740	NDA/MAL/HDP/2 404	UNICHEM LABORATORIES LIMITEDV	EUROPA HEALTHCARE (U) LTD	LOSAR 50	LOSARTAN POTASSIUM	50MG	UNICHEM LABORATORIES LTD-- VILLAGE BHATAULI KALA, BADDI HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
1741	NDA/MAL/HDP/2 408	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	RENIRON TONIC	MULTI- INGREDIENT	MULTI- INGREDIENT	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2001
1742	NDA/MAL/HDP/2 410	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	DOXYREN	DOXYCYCLINE	100MG	RENE INDUSTRIES LIMITEDPLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2007

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1743	NDA/MAL/HDP/2 411	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	DREZ	POVIDONE IODINE + METRONIDAZOLE	5%W/W + 1%W/W	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE,1.0X10.0 G TUBE,1.0X100.0 G TUBE,1.0X250.0 G TUBE	01/07/2010
1744	NDA/MAL/HDP/2 414	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMCIL	AMPICILLIN	125MG/5ML	SPARSH BIO-TECH LTD PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1998
1745	NDA/MAL/HDP/2 415	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	SOLINA TABLETS	DIAZEPAM	5MG	CENTAUR PHARMACEUTICALS LTD PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER,1.0X100.0X 10.0 TABLET BLISTER	01/07/1997

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1746	NDA/MAL/HDP/2 426	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	PROBEX SYRUP	MULTI- INGREDIENT	MULTI- INGREDIENT	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X225.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2000
1747	NDA/MAL/HDP/2 427	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	CLONEM	CLOTRIMAZOLE	1%W/W	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/1997
1748	NDA/MAL/HDP/2 428	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	CLOTRI-DENK 1% CREAM	CLOTRIMAZOLE	1%W/W	C.P.M. CONTRACTPHARMA GMBH & COMPANY KGFRUHLINGSTR. 7, 83620 FELDKIRCHEN WESTERHAM	GERMANY	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/1998

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1749	NDA/MAL/HDP/2 429	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	CLOTRI-DENK 100 VAGINAL	CLOTRIMAZOLE	100MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING ARTESAN PHARMA GMBH & CO. KG WENDLANDSTRABE 1,29439 LUCHOW,GERMANY	GERMANY	VAGINAL TABLETS	1.0X6.0 PESSARY CARTON	01/07/1998
1750	NDA/MAL/HDP/2 434	STRIDES PHARMA SCIENCE LIMITED	DELMAW ENTERPRISES LIMITED	SOLCER	OMEPRAZOLE	40MG	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	01/07/2009
1751	NDA/MAL/HDP/2 438	INTAS, PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	HIFENAC	ACECLOFENAC	100MG	INTAS PHARMACEUTICALS LTDCAMP ROAD SELAQUI DEHRADUN	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2006

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1752	NDA/MAL/HDP/2 452	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
1753	NDA/MAL/HDP/2 458	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	PRISTINEX 2% CREAM	KETOCONAZOLE	2%W/W	XEPA-SOUL PATTINSON (MALAYSIA) SDA BHD1-5, CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	2.0X15.0 G TUBE	01/07/2006
1754	NDA/MAL/HDP/2 459	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	P2	LEVONORGESTRE L	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.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X2.0 TABLET BLISTER	01/07/2007

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1755	NDA/MAL/HDP/2 462	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	HISTALIN SYRUP	CHLORPHENIRAM INE MALEATE/PROME THAZINE/DIPHEN HYDRAMINE/EPH EDRINE/AMMONI UM CHLORIDE/SODIU M CITRATE	1.0MG+ 2.5MG+5.0MG+7.5 MG+90.0MG+48.0 MG/ 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
1756	NDA/MAL/HDP/2 471	GLAXOSMITHKLINE LIMITED-	UNITED HEALTHCARE DISTRIBUTORS LTD	OTRIVIN 0.1% NASAL DROPS	XYLOMETAZOLINE	0.1%W/V	GSK CONSUMER HEALTH SAGSK CONSUMER HEALTH SA, ROUTE DE L'ETRAZ, NYON, 1260, SWITZERLAND	SWITZERLAND	NASAL SYSTEMIC DROPS	1.0X10.0 ML BOTTLE	01/07/2003
1757	NDA/MAL/HDP/2 472	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	TRAN-GEL	DICLOFENAC DIETHYLAMMONI UM	1%W/W	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE,1.0X20.0 G TUBE	01/07/2011

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1758	NDA/MAL/HDP/2 473	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (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
1759	NDA/MAL/HDP/2 475	WIN-MEDICURE LTD	SURGIPHARM (U) LIMITED	URGENDOL INJECTION	TRAMADOL HYDROCHLORIDE	50MG/ML	WIN- MEDICARE LTDMODIPURAM - 250 110,UTTAR PRAADESH, INDIA.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE,1.0X2.0 ML AMPOULE	01/07/2001
1760	NDA/MAL/HDP/2 476	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	DERIVA AQUEOUS GEL	ADAPALENE	0.1%W/W	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X15.0 G TUBE	01/07/2003

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1761	NDA/MAL/HDP/2 478	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	DICLOMOL PLUS	PARACETAMOL+D ICLOFENAC	500MG+50MG	WIN MEDICARE PVT LIMITEDMEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH -INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
1762	NDA/MAL/HDP/2 479	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANCEPH-250 CAP	CEPHALEXIN	250MG	SANCE LABORATORIES PVT. LTD.VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT- 686573, KERALA, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2012
1763	NDA/MAL/HDP/2 481	GALENTIC PHARMA (PVT)LTD	VITACARE LIMITED	NETRACORT	HYDROCORTISON E	1%W/W	GALENTIC PHARMA PVT LIMITEDR- 673,MIDC TTC RABALE THANE- BELAPUR ROAD,NAVI MUMBAI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE,1.0X20.0 G TUBE	01/07/2005

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1764	NDA/MAL/HDP/2 492	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	PROFIL 25	PROMETHAZINE HYDROCHLORIDE	25MG	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED VANDALUR ROAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/1997
1765	NDA/MAL/HDP/2 502	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	PROBETA N EYE DROP	BETAMETHASONE + NEOMYCIN	0.1%W/V+0.5%W/ V	ATCO LABORATORIES PVT LTDB-18,S.I.T.E KARACHI 75700, PAKISTAN	PAKISTAN	OPHTHALMIC DROPS	1.0X7.5 ML VIAL	01/07/1997
1766	NDA/MAL/HDP/2 504	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	RESTOCIN	PARACETAMOL + CHLORPHENIRAM INE MALEATE + CAFFEINE + PHENYLEPHRINE HCL	500MG+ 2MG+ 2MG + 30MG	LINCOLN PHARMACEUTICALS LIMITEDTRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X1.0X4.0 TABLET STRIP	01/07/2008

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1767	NDA/MAL/HDP/2 507	CIPLA LTD	ABACUS PHARMA (AFRICA) LIMITED	EXERMET 1000	METFORMIN HCL	1000MG	CIPLA LTD ---D-7 MIDC INDUSTRIAL AREA, KURKUMBH, TAL	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2007
1768	NDA/MAL/HDP/2 509	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	OPELE LOTION	BENZYL BENZOATE	25%W/V	BETA HEALTHCARE INTERNATIONAL LTD - PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL LOTIONS	1.0X50.0 ML BOTTLE	01/07/1997
1769	NDA/MAL/HDP/2 510	PANACEA BIOTEC PHARMA LTD	VITACARE LIMITED	GIRO	ORDNIDAZOLE	500MG	PANACEA BIOTEC PHARMA LIMITEDMALPURI BADDI, DISTRICT SOLAN, HIMACHAL PRADESH-173205 - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0X2.0X10.0 TABLET BLISTER	01/07/2013

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1770	NDA/MAL/HDP/2 513	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	UNIPEN DRY SYRUP	PHENOXYMETHYL PENICILLIN	125MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997
1771	NDA/MAL/HDP/2 515	AFRICURE PHARMACEUTICAL S (INDIA) LTD	ROYAL PHARMA 2011 LIMITED	SIMFEN 200 TABLETS	IBUPROFEN	200MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITEDPLOT 9- 12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997
1772	NDA/MAL/HDP/2 521	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	MOTINORM	DOMPERIDONE	10MG	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

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1773	NDA/MAL/HDP/2 523	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	SULPHUR OINTMENT	SULPHUR	10%W/W	NEM LABORATORIES PVT LTD--133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X25.0 G TUBE	01/07/1997
1774	NDA/MAL/HDP/2 525	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DICLO-DENK 100 RETARD	DICLOFENAC SODIUM	100MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID RETARD TABLETS	10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	01/07/1998
1775	NDA/MAL/HDP/2 526	REGAL PHARMACEUCIALS LTD	REGAL PHARMA (U) LTD	UNISTEN COMBI PACK	CLOTRIMAZOLE	500MG & 1 %W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	VAGINAL COMBINATION PACK TABLETS	1.0X1.0 PESSARY BLISTER + 1*20G TUBE	01/07/2009

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1776	NDA/MAL/HDP/2 528	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LABESTEN	CLOTRIMAZOLE	1%W/W	LABORATORY & ALLIED LTD.--PLOT 209/10349 OFF MOMBASA RD NAIROBI	KENYA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE,1.0X1.0X20.0 G TUBE	01/07/1997
1777	NDA/MAL/HDP/2 529	B & O PHARM ZAC	TRIDEM PHARMA UGANDA LIMITED	G-CEFTRIA	CEFTRIAZONE	1G	CHINA NATIONAL MEDICINES, GUORUI PHARMACEUTICAL CO., LTD-CAOYANG EAST ROAD, HUAINAN ECONOMICAL AND TECHNOLOGICAL DEVELOPMENT ZONE, HUAINAN CITY ANHUI PROVINCE	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 10 ML AMPOULE WFI,1.0X1.0X50.0 G VIAL,1.0X1.0 VIAL CARTON	01/07/2012
1778	NDA/MAL/HDP/2 545	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	TOBREX	TOBRAMYCIN	0.3%W/V	ALCON COUVREUR NVRIJKSWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/1997

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1779	NDA/MAL/HDP/2 552	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	CAROFIT	VITAMIN C/ VITAMIN A/ ZINC SULPHATE	150MG/10MG/75 MG	AJANTA PHARMA LIMITEDB-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2005
1780	NDA/MAL/HDP/2 553	GLENMARK PHARMACEUTICAL LTD.	STAR PHARMACEUTICAL S LTD	ESOZ-20	ESOMEPRAZOLE	20MG	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP,1.0X10.0 TABLET STRIP	01/07/2003
1781	NDA/MAL/HDP/2 554	GLENMARK PHARMACEUTICAL LTD.	STAR PHARMACEUTICAL S LTD	ESOZ	ESOMEPRAZOLE	40MG	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET STRIP,1.0X10.0X10. 0 TABLET STRIP	01/07/2005

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1782	NDA/MAL/HDP/2 555	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PHENOBARBITON E TABLETS BP 30MG	PHENOBARBITON E	30MG	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10 0.0 TABLET CONTAINER	01/07/1998
1783	NDA/MAL/HDP/2 556	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	TRUVADA	EMTRICITABINE/T ENOFOVIR	200MG/300MG	PATHEON INC- ADDRESS: 2100 SYNTEX COURT, MISSISSAUGA, ONTARIO L5N 7K9 COUNTRY: CANADA TAKEDA GMBH- 16515 ORANIENBURG GERMANY	CANADA GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2005
1784	NDA/MAL/HDP/2 557	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	EPSITRON 25 TABLETS	CAPTOPRIL	25MG	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1999

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1785	NDA/MAL/HDP/2 558	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	MYCOREN SUSPENSION	NYSTATIN	100000 I.U/ML	RENE INDUSTRIES LTD680,KAMULI,KIR EKA KAMPALA,UGANDA	UGANDA	ORAL TOPICAL SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2007
1786	NDA/MAL/HDP/2 559	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	ERYTHROREN	ERYTHROMYCIN STEARATE	250MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2007
1787	NDA/MAL/HDP/2 562	ACINO PHARMA AG	LABOREX UGANDA LIMITED	TRABILIN-100	TRAMADOL	100MG/2ML	MERCKLE GMBH,LUDWIG MERCKLE STRASSE3 D-89143 BLAUBEUREN	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X2.0 ML AMPOULE	01/07/2005

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1788	NDA/MAL/HDP/2 565	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
1789	NDA/MAL/HDP/2 567	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CIPROBID-500	CIPROFLOXACIN	500MG	S.KANT HEALTHCARE LIMITED--PLOT NO. 1802-1805,GIDC PHASE II- 396195,DIST.VALSAD ,GUJARAT,INDIA PINNACLE LIFE SCIENCE PVT LTD- KHASRA NO. 1328 - 1330, VILLAGE MANPURA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH - 174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	10.0X10.0 TABLET BLISTER	01/07/1997
1790	NDA/MAL/HDP/2 568	GLAXO WELLCOME (KENYA) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZINNAT	CEFUROXIME AXETIL	500MG	GLAXOSMITHKLINE UK LTDHARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X50.0 TABLET CARTON	01/07/1997

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1791	NDA/MAL/HDP/2 571	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	CO-METHER	ARTEMETHER + LUMEFANTRINE	180 MG + 1080 MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE,1.0X30.0 ML BOTTLE	01/07/2010
1792	NDA/MAL/HDP/2 575	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	MYTEKA	MONTELUKAST SODIUM	10MG	HILTON PHARMA (PVT) LTD PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2005
1793	NDA/MAL/HDP/2 576	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEQUINE TABLETS	CHLOROQUINE PHOSPHATE	250MG	RENE INDUSTRIES LTD 680,KAMULI,KIR EKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X250.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	01/07/2000

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1794	NDA/MAL/HDP/2 578	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	MAGNOMINT TABLETS	ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE	125MG + 250MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X 10.0 TABLET BLISTER,1.0X50.0X2 .0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	01/07/1997
1795	NDA/MAL/HDP/2 580	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	HEDON TABLETS	PARACETAMOL + ASPIRIN + CAFFEINE	250 MG+ 300 MG + 30 MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA MILAN LABORATORIES (INDIA) PVT LTD - 63,67,87,35,36, 64, 65 JAWAHAR CO-OP INDUSTRIAL ESTATE KAMOTHE, PANVEL NAVI MUMBAI LINCOLN PHARMACEUTICALS	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X2.0 TABLET STRIP	01/07/1998
1796	NDA/MAL/HDP/2 591	HEALTHCARE LTD.	HEALTHCARE LTD.	VITAGLOBIN SYRUP	MULTI- INGREDIENT	MULTI- INGREDIENT	AL FAZAL PHARMA INDUSTRIES (PVT) LTD-PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X90.0 ML BOTTLE,1.0X250.0 ML BOTTLE	01/07/2001

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1797	NDA/MAL/HDP/2 593	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	ATENOLOL DENK 50	ATENOLOL	50MG	ARTESAN PHARMA GMBH & CO. KG WENDLANDSTRABE 1,29439 LUCHOW,GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
1798	NDA/MAL/HDP/2 594	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	FEF	FERROUS SULPHATE + FOLIC ACID	200MG + 0.4MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2009
1799	NDA/MAL/HDP/2 595	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	ZEPILEN	CEFAZOLIN	1000MG	MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X1.0 G VIAL	01/07/2009

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1800	NDA/MAL/HDP/2 597	E DENK OHG	BENLE CONSULT LIMITED	PARA DENK 250	PARACETAMOL	250MG	RUBIEPHARM ARZNEIMITTEL GMHH BRUDER- GRIMM-STRABE 62, 36396, STEINAU AN DER STRABE	GERMANY	RECTAL SYSTEMIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP,1.0X2.0X5.0 SUPPOSITORY STRIP	01/07/2005
1801	NDA/MAL/HDP/2 600	IND SWIFT LTD	PLANET PHARMACEUTICAL S UGANDA LTD	CLARIE-OD	CLARITHROMYCIN (EXTENDED RELEASE)	500MG	IND-SWIFT- LTD,GLOBAL BUSINESS UNIT, JAWAHARPUR, OFF NH-21 DERABASSI	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X1.0X7.0 TABLET BLISTER	01/07/2008
1802	NDA/MAL/HDP/2 601	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	AXETINE 750MG	CEFUROXIME	750MG	MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X750.0 MG VIAL	01/07/2009

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1803	NDA/MAL/HDP/2 602	: ALKEM LABORATORIES LIMITEDV	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM BID	AMOXICILLIN + CLAVULANIC ACID	200 MG + 28.5 MG/ 5 ML	INDCHEMIE HEALTH SPECIALTIES PVT. LTD-(UNIT 3 BETA LACTAM BLOCK) VILLAGE: THANA, TEHSIL: BADDI, DISTRICT: SOLAN HIMACHAL PRADESH -173205 INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE,1.0X70.0 ML BOTTLE	01/07/2010
1804	NDA/MAL/HDP/2 604	USV PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GROVIT SYRUP	MULTI- INGREDIENT	MULTI- INGREDIENT	SAKAR HEALTHCARE PVT LTDSAKAR HEALTHCARE PVT LTD, BLOCK NO 10- 13, M.N. DESA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2000
1805	NDA/MAL/HDP/2 612	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	RENIRON	MULTI- INGREDIENT	MULTI- INGREDIENT	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	3.0X10.0 CAPSULE BLISTER	01/07/2005

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1806	NDA/MAL/HDP/2 614	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	DIALIN	LOPERAMIDE HCL	2MG	REGAL PHARMACEUTICALS LIMITED PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/2007
1807	NDA/MAL/HDP/2 615	ASTRA ZENECA AB	MACNAUGHTON LIMITED	SYMBICORT TURBUHALER	BUDESONIDE+FO RMOTEROL	160MCG+4.5MCG/ DOSE	ASTRAZENECA AB,GARTUNA & SNACKVIKEN STOCKHOLM	SWEDEN	LUNG ADMINISTRATION METERED-DOSE POWDER INHALER	1.0X60.0 DOSE CANNISTER,1.0X12 0.0 DOSE CANNISTER	01/07/2001
1808	NDA/MAL/HDP/2 628	MICRO LABS LTD 92 SIPCOT	LABOREX UGANDA LIMITED	AZILIDE-500	AZITHROMYCIN	500MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	01/07/2004

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1809	NDA/MAL/HDP/2 641	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 ATHANASSIOUS LIMASSOL CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET STRIP	01/07/2014
1810	NDA/MAL/HDP/2 642	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MEDOXANUM	CEFTRIAZONE	1G	MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 10 ML AMPOULE WFI	01/07/2016
1811	NDA/MAL/HDP/2 645	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANZIDIME 1000	CEFTAZIDIME	1000MG	SANCE LABORATORIES PVT LTDVI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL	01/07/2010

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1812	NDA/MAL/HDP/2 647	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	IBUPROFEN DENK 400MG	IBUPROFEN	400MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X1.0X10 .0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2005
1813	NDA/MAL/HDP/2 648	E DENK OHG	BENLE CONSULT LIMITED	PARA DENK 125	PARACETAMOL	125MG	RUBIEPHARM ARZNEIMITTEL GMHH BRUDER- GRIMM-STRABE 62, 36396, STEINAU AN DER STRABE	GERMANY	RECTAL SYSTEMIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP,1.0X2.0X5.0 SUPPOSITORY STRIP	01/07/2005
1814	NDA/MAL/HDP/2 650	DENK PHARMA	BENLE CONSULT LIMITED	VIT-B-DENK	THIAMINE HCL + PYRIDOXINE HCL	100MG + 200MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET CARTON,1.0X10.0X 10.0 TABLET BLISTER	01/07/2005

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1815	NDA/MAL/HDP/2 651	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	RINAVIT SYRUP	MULTIVITAMIN	MULTI- INGREDIENT	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/1997
1816	NDA/MAL/HDP/2 653	BLUE CROSS LABORATORIES LTD	STAR PHARMACEUTICAL S LTD	SONADERM-GM	CLOBETASOL + MICONAZOLE + GENTAMICIN	0.05%W/W + 2% W/W+ 0.1%W/W	BLUE CROSS LABORATORIES LTD- 17, VERNA INDUSTRIAL ESTATE,VERNA GOA- 403722	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE	01/07/2007
1817	NDA/MAL/HDP/2 654	MEDICAL UNION PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	BEBE VIT	VITAMIN A+ VITAMIN D3+VITAMIN E+ VITAMIN C +VITAMIN B1 + VITAMIN B2	1500IU+ 400IU+ 5MG+ 40MG+0.5MG+0.6 MG	MEDICAL UNION PHARMACEUTICAL CO.PLANT: ABU- SULTAN, ISMAILIA, EGYPT	EGYPT	ORAL LIQUID ORDINARY LIQUIDS	1.0X30.0 ML BOTTLE	01/07/2006

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1818	NDA/MAL/HDP/2 656	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AMINOPHYLLINE	AMINOPHYLLINE	100MG	SCOTT-EDIL PHARMACIA LTD (UNIT I)56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2008
1819	NDA/MAL/HDP/2 661	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	FUNGIFEN	CLOTRIMAZOLE	1%W/W	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED VANDALUR ROAD	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997
1820	NDA/MAL/HDP/2 671	CIPLA LTD..	ABACUS PHARMA (AFRICA) LIMITED	DUOLIN RESPULES	IPRATROPIUM BROMIDE & SALBUTAMOL	500MG + 2.5 MG /2.5ML	CIPLA LTD.- PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	LUNG ADMINISTRATION LIQUID FOR INHALATION	4.0X5.0X2.5 ML VIAL	01/07/2005

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1821	NDA/MAL/HDP/2 675	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	LIBITUS PLUS SYRUP	TERBUTALINE/ BROMHEXINE/ GUAIPHENESIN	1.25MG/ 4MG/ 50 MG	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2011
1822	NDA/MAL/HDP/2 678	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	FORCAN-150	FLUCONAZOLE	150MG	CIPLA LTD PLOT NO. L-139, VERNA, GOA 403 722 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X5.0 CAPSULE BLISTER	01/07/2006
1823	NDA/MAL/HDP/2 680	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMPIREN CAPSULES	AMPICILLIN TRIHYDRATE	250MG	RENE INDUSTRIES LTD680,KAMULI,KIR EKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER	01/07/2007

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1824	NDA/MAL/HDP/2 681	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMOXIREN	AMOXICILLIN TRIHYDRATE	250MG	RENE INDUSTRIES LTD680,KAMULI,KIR EKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER	01/07/2007
1825	NDA/MAL/HDP/2 683	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	VITAMIN C	ASCORBIC ACID	100MG	RENE INDUSTRIES LTD680,KAMULI,KIR EKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2005
1826	NDA/MAL/HDP/2 685	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEDOL(SUSPEN SION)	PARACETAMOL	120MG/5ML	RENE INDUSTRIES LTD680,KAMULI,KIR EKA KAMPALA,UGANDA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60 .0 ML BOTTLE	01/07/2007

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1827	NDA/MAL/HDP/2 690	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AMPIMAX-250	AMPICILLIN	250MG	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/2011
1828	NDA/MAL/HDP/2 691	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AMPIMAX-500	AMPICILLIN	500MG	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA INJECT CARE PARENTERALS PVT LTD PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195	CHINA INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X500.0 MG VIAL,1.0X100.0 VIAL CARTON	01/07/2011
1829	NDA/MAL/HDP/2 695	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	IDUMSTRA	PARACETAMOL + IBUPROFEN + CAFFEINE	325MG + 200MG + 40MG	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED VANDALUR ROAD	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X20.0X10.0 CAPSULE BLISTER	01/07/2009

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1830	NDA/MAL/HDP/2 696	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	AMPHOTRET	AMPHOTERICIN B	50MG	BHARAT SERUMS AND VACCINES LTD PLOT NO. K-27 ADDITIONAL MIDC AMBERNATH (E) 412 501	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 VIAL CARTON	01/07/2012
1831	NDA/MAL/HDP/2 697	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	LUCIN OINTMENT	HYDROCORTISON E	1%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997
1832	NDA/MAL/HDP/2 698	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	AZICIN-500	AZITHROMYCIN	500MG	PINNACLE LIFE SCIENCE PVT LTD- KHASRA NO. 1328 - 1330, VILLAGE MANPURA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH - 174101 EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	01/07/2009

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1833	NDA/MAL/HDP/2 703	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	KOACT 312.50	CO-AMOXICLAV (AMOXYCILLIN TRIHYDRATE+POT ASSIUM CLAVUNATE)	250+62.50MG/ 5ML	AUROBINDO PHARMA LTD, UNIT XII,,SURVEY NO 314, BACHUPALLY VILLAGE, QUTHUBULLAPAR, R.R DISTRICT .A. PRADESH	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2007
1834	NDA/MAL/HDP/2 705	ASTRAZENECA	MACNAUGHTON LIMITED	PULMICORT NEBULISER	BUDESONIDE	0.5MG/ML	ASTRA ZENECA SWEDEN OPERATIONS LIQUID PRODUCTION KVARNBERGAGATAN LZ SE-151- 85,SWEDEN	SWEDEN	LUNG ADMINISTRATION LIQUID FOR INHALATION	1.0X4.0X5.0X2.0 ML VIAL	01/07/2011
1835	NDA/MAL/HDP/2 707	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMCLOXA	CLOXACILLIN	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD PLOT M 444B STRETCHER ROAD NTINDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	100.0 CAPSULE CONTAINER,250.0 CAPSULE CONTAINER,500.0 CAPSULE CONTAINER,1000.0 CAPSULE CONTAINER,10.0 CAPSULE CONTAINER	01/07/1997

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1836	NDA/MAL/HDP/2 708	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	HYPER TABLETS	PROPRANOLOL HYDROCHLORIDE	40MG	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X2.0 X50.0 TABLET BLISTER	01/07/2000
1837	NDA/MAL/HDP/2 710	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	AUGMENTIN BD	AMOXICILLIN + CLAVULANIC ACID	500 MG + 125 MG	SMITHKLINE BEECHAM PHARMACEUTICALS, CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X14.0 TABLET BLISTER	01/07/1997
1838	NDA/MAL/HDP/2 712	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	ANAWIN	BUPIVACAINE	0.025%W/V	NEON LABORATORIES LTD PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL	01/07/2014

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1839	NDA/MAL/HDP/2 715	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LAMIVUDINE	LAMIVUDINE	150MG	MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X60.0 TABLET CONTAINER	01/07/2008
1840	NDA/MAL/HDP/2 717	CENTAUR PHARMACEUTICAL S PRIVATE LIMITED	GITTOES PHARMACEUTICAL S LIMITED	OCUMYCIN EYE OINTMENT	CHLORAMPHENIC OL	1%W/W	CENTAUR PHARMA PVT. LTD PLOT 39-41, TIVIM INDUSTRIAL ESTATE, KARASWADA, MAPUSA GOA INDIA	INDIA	OPHTHALMIC OINTMENTS	1.0X3.5 G TUBE	01/07/2000
1841	NDA/MAL/HDP/2 719	SEDICO PHARMACEUTICAL CO.	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LORASED	LORATADINE	10MG	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET STRIP	01/07/2016

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1842	NDA/MAL/HDP/2 720	SEDICO PHARMACEUTICAL CO.	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FLUCAMOX 250MG POWDER FOR ORAL SUSPENSION	AMOXICILLIN +FLUCLOXACILLIN	125MG/5ML+125 MG/5ML	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X80.0 ML BOTTLE	01/07/2007
1843	NDA/MAL/HDP/2 721	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	PRIMAFEN TABLET	IBUPROFEN + PARACETAMOL	400MG + 325MG	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007
1844	NDA/MAL/HDP/2 722	MACK BROWN PHARMACEUTICAL S PVT LIMITED	SHURIK LTD	NO SORES	CHOLINE SALICYLATE/LIDO CAINE	8.7%W/W+2%W/ W	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X10.0 G TUBE	01/07/2007

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1845	NDA/MAL/HDP/2 723	TABROS PHARMA	HEALTHCARE LTD.	DURAGESIC TABLET	PARACETAMOL + ORPHENADRINE	450MG+35MG	TABROS PHARMAL- 20/B SECTOR 22 FB INDUSTRIAL AREA KARACHI PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997
1846	NDA/MAL/HDP/2 728	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	DEXAMETHASONE INJECTION	DEXAMETHASONE	4MG/ML	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	INDIA	PARENTERAL ORDINARY I V AMPOULES	1.0X100.0X1.0 ML AMPOULE,1.0X100. 0X1.0 ML AMPOULE (IN A 2ML AMPOULE)	01/07/2006
1847	NDA/MAL/HDP/2 734	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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1848	NDA/MAL/HDP/2 737	SHAIGAN PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	SENEX FORTE	SECNIDAZOLE	1G	SHAIGAN PHARMACEUTICALS (PVT) LTD14TH KM, ADYALA ROAD, RAWALPINDI- PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X2.0 TABLET BLISTER	07/01/2004
1849	NDA/MAL/HDP/2 738	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	HEPA-MERZ INFUSION	L-ORNITHINE- L- ASPARTATE	5G/10ML	WIN-MEDICARE PRIVATE LIMITEDMEERUT- MUZAFFARNAGAR ROAD, MODIPURAM 250110 UTTAR PRADESH	INDIA	PARENTERAL ORDINARY I V VIALS	1.0X5.0X10.0 ML VIAL	01/07/2001
1850	NDA/MAL/HDP/2 739	REGAL PHARMACEUCIALS LTD	REGAL PHARMA (U) LTD	BISPANOL TABLET	HYOSCINE BUTYLBROMIDE	10MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER,1.0X100.0X 10.0 TABLET BLISTER	01/07/2001

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1851	NDA/MAL/HDP/2 743	BEIJING HOLLEY COTEC PHARMA CHINA	SUPER PHARMACEUTICAL S LIMITED	DUO-COTECXIN	DIHYDROARTEMI SININ + 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,1.0X1.0X4. 0 TABLET BLISTER,1.0X30.0X9 .0 TABLET BLISTER	01/07/2005
1852	NDA/MAL/HDP/2 745	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENFORMIN	METFORMIN HYDROCHLORIDE	500MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2015
1853	NDA/MAL/HDP/2 746	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	ACYCLOVIR DENK 200	ACYCLOVIR	200MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X25.0 TABLET BLISTER	01/07/2000

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1854	NDA/MAL/HDP/2 753	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	PRASIL	METOCLOPRAMI DE HYDROCHLORIDE	10MG	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
1855	NDA/MAL/HDP/2 756	PFIZER LABORATORIES LTD	LABOREX UGANDA LIMITED	CYTOTEC	MISOPROSTOL	200MCG	PIRAMAL HEALTHCARE LIMITEDWALTON ROAD MORPETH NORTHUMBERLAND NE 613YA	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2010
1856	NDA/MAL/HDP/2 760	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	DELAED DRY COUGH SYRUP	DIPHENHYDRAMINE HYDROCHLORIDE +DEXTROMETHO RPHAN+SODIUM CITRATE+MENTH OL	14MG+6.5MG+57 MG+2MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997

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1857	NDA/MAL/HDP/2 763	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	CANDISTAT	CLOTRIMAZOLE	100MG	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	VAGINAL SUPPOSITORIES	1.0X2.0X3.0 PESSARY STRIP	01/07/1997
1858	NDA/MAL/HDP/2 773	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	BISPANOL ELIXIR	HYOSCINE-N- BUTYLBROMIDE	5MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE,1.0X1.0X10 0.0 ML BOTTLE	01/07/2004
1859	NDA/MAL/HDP/2 774	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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1860	NDA/MAL/HDP/2 776	UNIQUE PHARMACEUTICAL S LABORATORIES	PLANET PHARMACEUTICAL S UGANDA LTD	TENSIMIN-100	ATENOLOL	100MG	UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)216-219 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,14.0X1 0.0 TABLET BLISTER	01/07/1997
1861	NDA/MAL/HDP/2 777	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	CO-DIOVAN 160/12.5MG TABLETS	VALSARTAN + HYDROCHLOROT HIAZIDE	160MG + 12.5MG	NOVARTIS PHARMA AGSCHAFFHAUSERS TRASSE 4332 STEIN SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER,1.0X2.0X14 .0 TABLET BLISTER	01/07/2006
1862	NDA/MAL/HDP/2 779	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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1863	NDA/MAL/HDP/2 781	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	CARVETAS 6.25	CARVEDILOL	6.25MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
1864	NDA/MAL/HDP/2 783	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
1865	NDA/MAL/HDP/2 787	MEDOPHARM PRIVATE LIMITED	PLANET PHARMACEUTICAL S 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,1.0X10.0X1 0.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2013

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1866	NDA/MAL/HDP/2 788	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	MULTIREN	MULTIINGREDIEN T	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
1867	NDA/MAL/HDP/2 793	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	VIREAD	TENOFOVIR DISOPROXIL FUMARATE	300MG	TAKEDA GMBH, PLANT ORANIENBURG- LEHNITZSTRASSE 70- 98, 16515, ORANIENB URG-GERMANY PATHEON YM INC. TORONTO- TORONTO, CANADA	GERMANY CANADA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X30.0 TABLET BOTTLE	01/07/2004
1868	NDA/MAL/HDP/2 796	ASTRA PHARMA (UK) LTD	ASTRA PHARMA (U) LIMITED	BENZYL PENICILLIN INJECTION	BENZYL PENICILLI N SODIUM	1,000,000 I.U	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO. LTD NO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE (WORKSH OP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 VIAL CARTON, 1.0X50.0 VIAL CARTON	01/07/2001

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1869	NDA/MAL/HDP/2 797	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
1870	NDA/MAL/HDP/2 800	NOVO NORDISK	PHILLIPS PHARMACEUTICAL S (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	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
1871	NDA/MAL/HDP/2 802	CENTAUR PHARMACEUTICAL S PRIVATE LIMITED	GITTOES PHARMACEUTICAL S LIMITED	TASOL	CLOBETASOL	0.05%W/W	CENTAUR PHARMACEUTICALS PVT LTD -PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2005

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1872	NDA/MAL/HDP/2 805	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	NIFELAT 20R TABLETS	NIFEDIPINE	20MG	REMEDICA LIMITED AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/1997
1873	NDA/MAL/HDP/2 807	GUILIN PHARMACEUTICAL S CO.LTD	TRIDEM PHARMA UGANDA LIMITED	ASAQ GPSC	ARTESUNATE + AMODIAQUINE	100 MG + 270 MG	GUILIN PHARMACEUTICALS CO. LTDNO 43 QULIDIAN ROAD GUILIN GUANGXI CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X20.0X3.0 TABLET BLISTER,1.0X20.0X6 .0 TABLET BLISTER,1.0X25.0X3 .0 TABLET BLISTER,1.0X25.0X6 .0 TABLET BLISTER	01/07/2011
1874	NDA/MAL/HDP/2 811	REGAL PHARMACEUCIALS LTD	REGAL PHARMA (U) LTD	SULPHUR OINTMENT	SULPHUR PRECIPITATED	10%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X25.0 G TUBE	01/07/2001

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1875	NDA/MAL/HDP/2 812	DAFRA PHARMA LTD	MULTIPHAR UGANDA LIMITED	CO-ARTESIANE	BETA ARTEMETHER + LUMEFANTRINE	180 MG/60ML + 1080 MG/60ML	S KANT HEALTHCARE LIMITED1802 – 1805, G.I.D.C., PHASE III, VAPI - 396195 GUJARAT, INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE	01/07/2005
1876	NDA/MAL/HDP/2 813	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	INTACYCLINE SKIN OINTMENT	TETRACYCLINE HYDROCHLORIDE	3%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997
1877	NDA/MAL/HDP/2 816	ZYDUS LIFESCIENCES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CATENOL-100 TABLETS	ATENOLOL	100MG	ZYDUS LIFESCIENCES LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER	01/07/1997

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1878	NDA/MAL/HDP/2 821	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	DIOLIN-M	GLIBENCLAMIDE+ METFORMIN HYDROCHLORIDE TABLETS	5MG+500MG	LINCOLN PHARMACEUTICAL LIMITED..LINCOLN PHARMACEUTICALS LIMITED, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2011
1879	NDA/MAL/HDP/2 826	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PIRITON SYRUP	CHLORPHENIRAM INE MALEATE	4MG/10ML	GLAXOSMITHKLINELI KONI ROAD IND. AREA, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X2.0 L BOTTLE	01/07/1997
1880	NDA/MAL/HDP/2 835	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	SOLUDINE-M	POVIDONE IODINE / METRONIDAZOLE	5%W/W / 1%W/W	LINCOLN PHARMACEUTICALS 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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1881	NDA/MAL/HDP/2 837	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	GRAMOFIL TABLETS	NALIDIXIC ACID	500MG	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED VANDALUR ROAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1997
1882	NDA/MAL/HDP/2 838	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	DILCONTIN XL 120	CONTROLLED RELEASE TABLETS OF DILTIAZEM HYDROCHLORIDE	120MG	MODI MUNDIPHARMA (PVT) LTDMEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2010
1883	NDA/MAL/HDP/2 850	MEDICAL UNION PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	DISPERCAM	PIROXICAM	20MG	MEDICAL UNION PHARMACEUTICAL CO.PLANT: ABU- SULTAN, ISMAILIA, EGYPT	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X2.0X3.0X1.0 ML AMPOULE	01/07/2007

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1884	NDA/MAL/HDP/2 869	GLAXO SMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PRIORIX VACCINE	MEASLES + MUMPS + RUBELLA	103.0CCID50 + 103.7CCID50 + 103.0CCID50	GLAXO SMITHKLINE BIOLOGICALS S.ARUÉ DE L'INSTITUT, 89 B- 1330 RIXENSART	BELGIUM	PARENTERAL ORDINARY DRY VIALS	1.0X0.5 ML VIAL (1 DOSE)	01/07/2010
1885	NDA/MAL/HDP/2 873	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	HELIGO KIT	TINIDAZOLE/CLAR ITHROMYCIN/LAN SOPRAZOLE	500MG+ 250MG+30MG	INTAS PHARMACEUTICALS LTD .PLOT NOS. 457, 458 & 191/218P SARKHEJ-BAVLA HIGHWAY MATODA SANAND AHMEDABAD GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X7.0X6.0 TABLET BLISTER	01/07/2001
1886	NDA/MAL/HDP/2 875	GLAXOSMITHKLINE LIMITED-	UNITED HEALTHCARE DISTRIBUTORS LTD	OTRIVIN 0.05% NASAL DROPS	XYLOMETAZOLINE	0.05%W/V	GSK CONSUMER HEALTH SAGSK CONSUMER HEALTH SA, ROUTE DE L'ÉTRAZ, NYON, 1260, SWITZERLAND	SWITZERLAND	NASAL TOPICAL DROPS	1.0X10.0 ML BOTTLE	01/07/2003

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1887	NDA/MAL/HDP/2 880	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CARBIMAZOLE 5	CARBIMAZOLE	5MG	REMEDICA LIMITED,LIMASSOL INDUSTRIAL ESTATE, AHARNON ST, P.O. BOX 51706,3508 LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010
1888	NDA/MAL/HDP/2 885	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	FORECOX-TRAC	RIFAMPICIN + ISONIAZID + PYRAZINAMIDE + ETHAMBUTOL	150MG + 75MG+ 400MG + 275MG	OXALIS LABS LIMITEDVILLAGE THEDA, P.O LODHIMAJRA, TEHSIL,BADDI, DIST.SOLAN, INDIA MACLEODS PHARMACEUTICALS LTD .PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X6.0 TABLET BLISTER,1.0X24.0X2 8.0 TABLET BLISTER	01/07/2005
1889	NDA/MAL/HDP/2 888	VHB MEDI SCIENCES LTD	NORVIK ENTERPRISES LIMITED	SUCCICORT	HYDROCORTISON E SODIUM SUCCINATE	100MG/VIAL	VHB MEDI SCIENCES LTD PLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	, 1X100 MG VIAL	07/01/2013

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1890	NDA/MAL/HDP/2 891	MACLEODS PHARMACEUTICAL S 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
1891	NDA/MAL/HDP/2 892	UNIQUE PHARMACEUTICAL S LABORATORIES	PLANET PHARMACEUTICAL S UGANDA LTD	NICARDIA-20 TABLETS	NIFEDIPINE	20MG	UNIQUE PHARMACEUTICAL LABORATORIESPLOT 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,1.0X10.0X1 0.0 TABLET BLISTER	01/07/1997
1892	NDA/MAL/HDP/2 893	DAWA LIMITED	SUPER MEDIC LTD	STOPACID SUSPENSION	MAGNESIUM TRISILICATE + ALUMINIUM HYDROXIDE	250MG/5ML + 120MG/5ML	DAWAPLOT 7879, BABA DOGO ROAD RUARAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2009

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1893	NDA/MAL/HDP/2 894	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MUCOGEL SUSPENSION	DRIED ALUMINIUM HYDROXIDE + MAGNESSIUM HYDROXIDE + OXETHAZAINE	8G/100ML + 2G/100ML + 0.2 G/100ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO EIPICO10TH OF RAMADAN CITY- FIRST INDUSTRIAL AREA -EGYPT	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X125.0 ML BOTTLE	01/07/2005
1894	NDA/MAL/HDP/2 896	KPI INDUSTRIES(1996) LTED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	MCG CREAM	MICONAZOLE NITRATE BP + CLOBETASOL PROPIONATE BP + GENTAMYCIN SULPHATE	2.0%W/W + 0.05%W/W + 0.1 %W/W	KPI INDUSTRIES (1996) LTD PLOT NO.M444B STRETCHER RD, NTINDA, KAMPALA	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE,1.0X15.0 G TUBE,1.0X25.0 G TUBE	01/07/2005
1895	NDA/MAL/HDP/2 898	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	TORVAST 10	ATORVASTATIN	10MG	MACLEODS PHARMACEUTICALS LTD .PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2006

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1896	NDA/MAL/HDP/2 900	MICRO LABS LTD	LABOREX UGANDA LIMITED	GRAMOCEF-O- 200	CEFIXIME	200MG	MICRO LABS LIMITED, BOMMASANDRA PLOT NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/2005
1897	NDA/MAL/HDP/2 902	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	MEGALIS-20	TADALAFIL	20MG	MACLEODS PHARMACEUTICALS LIMITED (BLOCK -N1)VILLAGE THEDA, P.O. LODHI MAJRA,TEHSIL BADDI, HIMACHAL PRADESH - 174101,INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X15.0X1.0X4.0 TABLET STRIP	01/07/2005
1898	NDA/MAL/HDP/2 905	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BRONCHOPHANE SYRUP	GUAIPHENESIN+E PHEDRINE HYDROCHLORIDE +DIPHENHYDRAM INE HYDROCHLORIDE +DEXTROMETHO RPHAN	50MG+7.5MG+5M G+4.58MG	ORCHIDIA10TH STREET RAMADAN CITY, FIST INDUSTRIES ARE	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X125.0 ML BOTTLE	01/07/2007

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1899	NDA/MAL/HDP/2 906	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	RIFAMPICIN/ISON IAZID/ETHAMBUT OL	RIFAMPICIN+ISON IAZID+ETHAMBUT OL	150MG+75MG+27 5MG	MACLEODS PHARMACEUTICALS LTD .PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X24.0X28.0 TABLET BLISTER	01/07/2012
1900	NDA/MAL/HDP/2 907	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	LONART DS	ARTEMETHER + LUMEFANTRINE	80 MG + 480 MG	BLISS GVS PHARMA LIMITEDNO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER	01/07/2008
1901	NDA/MAL/HDP/2 908	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	PAINGO MEDICATED CREAM	METHYLSALICYLA TE+CAPSICUM OLEORESIN+TURP ENTINE OIL	15%W/W + 1%W/W + 1.47%W/W	NEM LABORATORIES PVT LTDPLOT NO. 133 KRISHNA IND. ESTATE, VASAI E,DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL CREAMS	1.0X2.0X15.0 G TUBE	01/07/2010

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1902	NDA/MAL/HDP/2 910	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	TENVIR EM	TENOFOVIR DISOPROXIL FUMARATE + EMTRICITABINE	300MG+200MG	CIPLA LTD.- PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2009
1903	NDA/MAL/HDP/2 911	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL LORATADINE	LORATADINE	10MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010
1904	NDA/MAL/HDP/2 914	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	CHLOROCIDE SUSPENSION	CHLORAMPHENIC OL PALMITATE	125MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/1997

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1905	NDA/MAL/HDP/2 917	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	CETAMOL TABLETS	PARACETAMOL	500MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	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
1906	NDA/MAL/HDP/2 920	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	TRANSLIPO -C CREAM	CLOTRIMAZOLE	1%W/W	CENTAUR PHARMACEUTICALS PVT LTD -PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X20.0 G TUBE,1.0X10.0 G TUBE	01/07/2001
1907	NDA/MAL/HDP/2 940	CENTAUR PHARMACEUTICAL S PVT. LTD	GITTOES PHARMACEUTICAL S LIMITED	BENZOX 5 GEL	BENZOYL PEROXIDE	5%W/W	CENTAUR PHARMACEUTICALS LTD PLOT NO. 39 TIVIN IN	INDIA	TOPICAL EXTERNAL OTHER GELS/SOLS	1.0X20.0 G TUBE	01/07/2005

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1908	NDA/MAL/HDP/2 942	CENTAUR PHARMACEUTICAL S PRIVATE LIMITED	GITTOES PHARMACEUTICAL S LIMITED	ARGISSEPT CREAM	CHOLRHEXIDINE GLUCONATE/SILV ER SULPHADIAZINE	0.2%W/W / 1%W/W	CENTAUR PHARMACEUTICALS PVT LTD -PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE,1.0X10.0 G TUBE	01/07/2005
1909	NDA/MAL/HDP/2 946	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	TRIMAGO ORAL SUSPENSION	CO-TRIMOXAZOLE	240MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1998
1910	NDA/MAL/HDP/2 947	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	TRIMAGO TABLETS	CO-TRIMOXAZOLE	480MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. 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,1.0X25 0.0 BLISTER CARTON	01/07/1998

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1911	NDA/MAL/HDP/2 948	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	METFORMIN DENK 850	METFORMIN HYDROCHLORIDE	850MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X15.0 TABLET BLISTER,1.0X8.0X15 .0 TABLET BLISTER	01/07/2007
1912	NDA/MAL/HDP/2 951	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	LONART FORTE TABLETS	ARTEMETHER + LUMEFANTRINE	40 MG + 240 MG	BLISS GVS PHARMA LIMITEDNO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X2.0X6.0 TABLET BLISTER	01/07/2007
1913	NDA/MAL/HDP/2 956	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	TRANLOK 500MG TABLETS	TRANEXAMIC ACID	500MG	ARISTO PHARMACEUTICALS PVT LIMITEDPLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP- 462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2010

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1914	NDA/MAL/HDP/2 957	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
1915	NDA/MAL/HDP/2 959	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	CETAMOL SYRUP	PARACETAMOL	120MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/1997
1916	NDA/MAL/HDP/2 960	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

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1917	NDA/MAL/HDP/2 969	UNIQUE PHARMACEUTICAL S LTD	PLANET PHARMACEUTICAL S UGANDA LTD	TENSIMIN-50	ATENOLOL	50MG	UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)216-219 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,14.0X10.0 TABLET BLISTER	01/07/1997
1918	NDA/MAL/HDP/2 971	TORRENT PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S LTD.	LEFRA-20 TABLETS	LEFLUNOMIDE	20MG	TORRENT PHARMACEUTICALS LTDINDRAD-382 721, DIST.MEHSANA,INDI A.AT:VILL.MANAKPU R,TEH.NALAGARH,DI ST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2004
1919	NDA/MAL/HDP/2 974	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	TRAVATAN	TRAVOPROST	4µG/ML	ALCON COUVREUR NVRIJKSWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X2.5 ML VIAL	01/07/2009

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1920	NDA/MAL/HDP/2 979	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	BETADERM N CREAM	BETAMETHASONE VALERATE + NEOMYCIN	0.1%W/W + 0.5%W/W	ATCO LABORATORIES PVT LTDB-18,S.I.T.E KARACHI 75700, PAKISTAN	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE,1.0X15.0 G TUBE	01/07/1997
1921	NDA/MAL/HDP/2 980	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	LONART TABLETS	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	BLISS GVS PHARMA LIMITEDNO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X3.0X8.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X2.0X6. 0 TABLET BLISTER,1.0X3.0X6. 0 TABLET BLISTER,1.0X24.0 TABLET BLISTER,1.0X12.0 TABLET BLISTER,1.0X18.0 TABLET BLISTER,1.0X24.0	01/07/2007
1922	NDA/MAL/HDP/2 982	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	NEURO-FORTE TABLETS	VITAMIN B1 + VITAMIN B6 + VITAMIN B12	200MG + 50MG + 1MG	CENTAUR PHARMACEUTICALS LTD PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2004

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1923	NDA/MAL/HDP/2 983	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	FUCOL 200	FLUCONAZOLE	200MG	CIPLA LTD PLOT NO. L-139, VERNA, GOA 403 722 INDIA CIPLA LTD KURKUMBHD-7 MIDC INDUSTRIAL AREA, KURKUMBH, TALUKA-DAUND, PUNE, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X1.0X4.0 CAPSULE BLISTER	01/07/2004
1924	NDA/MAL/HDP/2 985	SANOFI 410 THALES	LABOREX UGANDA LIMITED	EPILIM CHRONO	SODIUM VALPROATE PH. EUR	500MG	SANOFI WINTHROP INDUSTRIE1,RUE DE LA VIERGE ,AMBARES ET LAGRAVE 33565,CARBON BLANC CEDEX FRANCE	FRANCE	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2004
1925	NDA/MAL/HDP/2 990	MICRO LABS LTD	LABOREX UGANDA LIMITED	PULMOCEF-500	CEFUROXIME AXETIL USP	500MG	MICRO LABS LTD- NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X3.0X4. 0 TABLET BLISTER	01/07/2004

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1926	NDA/MAL/HDP/2 995	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S 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
1927	NDA/MAL/HDP/2 997	MEDLEY PHARMACEUTICAL S	EUROPA HEALTHCARE (U) LTD	ACENAC TABLETS	ACECLOFENAC	100 MG	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007
1928	NDA/MAL/HDP/2 998	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	FITIN-5	LEVOCETIRIZINE DIHYDROCHLORID E	5MG	MEDLEY PHARMACEUTICALS LTD PLOT NO 18 & 19, SURVEY NO. 378/7& 8,379/2&3 ZARI AUSEWAY ROAD,, KACHIGAM, DAMAN-396 210	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009

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1929	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
1930	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
1931	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

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1932	NDA/MAL/HDP/3009	VENUS REMEDIES LIMITED	HARLEYS UGANDA LIMITED	SULBACTOMAX 1.5G	CEFTRIAXONE+SULBACTAM	1000MG+500MG	VENUS REMEDIES LTD, UNIT II, HILL TOP INDUSTRIAL ESTATE, JHARMAJTI, EPIP, PHASE-1 (EXTENSION), BHATOLI KALAN, BADDI -HP	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL	01/07/2009
1933	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
1934	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, 1.0X500.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER, 1.0X50.0X1.0 TABLET BLISTER	01/07/2007

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1935	NDA/MAL/HDP/3 017	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	LIDOCAINE INJECTION	LIDOCAINE HYDROCHLORIDE	20MG/ML	SANJAR PHARMA LLP HIMATNAGAR- VIJOPUR HIGHWAY, DEDHROTA HIMATNAGAR 383 220, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X25.0X20.0 ML VIAL,1.0X30.0 ML VIAL	01/07/2008
1936	NDA/MAL/HDP/3 019	MJ BIOPHARM PVT LTD	VITACARE LIMITED	BIOSULIN 30/70	INSULIN SOLUBLE + INSULIN ISOPHANE	30 I.U + 70 I.U	MJ BIOPHARM PRT LTDL-7 MIDC INDUSTRIAL AREA, TALOJA, NARI MUMBAI MAHARASHTRA	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	01/07/2008
1937	NDA/MAL/HDP/3 020	M.J BIOPHARM PVT LTD	VITACARE LIMITED	BIOSULIN N	INSULIN ISOPHANE	100 I.U/ML	M.J .BIOPHARML7, M.I.D.C INDUSTRIAL AREA TALOJA, NAVI MUMBAI MAHARAHTRA	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL	01/07/2008

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1938	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
1939	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,1.0X10.0X1.0 X3.0 TABLET STRIP,1.0X500.0 TABLET CONTAINER	01/07/2007
1940	NDA/MAL/HDP/3024	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE	LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE	150MG + 200MG + 300MG	QUESTA CARE LIMITED PLOT NO 209/7184 HOMABAY RD TERMINUS GATE NO-19, INDUSTRIAL AREA NAIROBI, KENYA. MYLAN LABORATORIES LTD-F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD -	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2008

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1941	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
1942	NDA/MAL/HDP/3030	MJ BIOPHARM PVT LTD	VITACARE LIMITED	BIOSULIN R	INSULIN SOLUBLE	100 IU/ML	M.J BIOPHARM PVT LTD -L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL	01/07/2008
1943	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

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1944	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
1945	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 LIMITEDPLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE,1.0X60.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE	01/07/2007
1946	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 LIMITEDPLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE	01/07/2007

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1947	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
1948	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
1949	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

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1950	NDA/MAL/HDP/3048	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	TRIMAGO-DS TABLETS	SULFAMETHOXAZOLE/TRIMETHOPRIM	800MG/160MG	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	1.0X6.0X10.0 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
1951	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
1952	NDA/MAL/HDP/3057	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	COLD-A-GO CAPSULES	PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + DIPHENHYDRAMINE + CAFFEINE	400MG + 5MG + 12.5MG + 30MG	AGOG PHARMA LIMITED PLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER,1.0X10.0X10.0 CAPSULE BLISTER	01/07/2007

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1953	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
1954	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
1955	NDA/MAL/HDP/3067	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	PROMAGO SYRUP	PROMETHAZINE	5MG/5ML	AGOG PHARMA LIMITEDPLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60.0 ML BOTTLE	01/07/2007

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1956	NDA/MAL/HDP/3068	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	OPTACHLOR EYE DROPS	CHLORAMPHENIC OL	0.5%W/V	REMINGTON PHARMACEUTICAL INDUS. PVT LTD, 117 ALLAM	PAKISTAN	OPHTHALMIC DROPS	1.0X10.0 ML VIAL	01/07/1999
1957	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
1958	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

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1959	NDA/MAL/HDP/3076	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO TELVAS 40	TELMISARTAN	40MG	ARISTO PHAMACUTLAB PVT LTD PLOT NO.208 NEW INDUSTRIAL AREA NO.2 MANIDIDEEP 462.046	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP,3.0X10.0 TABLET BLISTER	01/07/2007
1960	NDA/MAL/HDP/3077	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNISTEN HC CREAM	CLOTRIMAZOLE + HYDROCORTISONE	1%W/W + 1%W/W	REGAL PHERMACUTICALS PLOT 7879/18 OFF BABA RWARAKA NAIROBI KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2008
1961	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

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1962	NDA/MAL/HDP/3083	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO TELVAS 80	TELMISARTAN	80MG	ARISTO PHARMACEUTICALS PVT. LIMITED PLOT 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
1963	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
1964	NDA/MAL/HDP/3090	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFODOX	CEFPODOXIME PROXETIL	100MG/5ML	PHARMA INTERNATIONAL CO.AMMAN JORDAN PLANT AL-QARTAL MARKETING DEPARTMENT ALBUJAH COMPLEX, ALJUBAIHA	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X50.0 ML BOTTLE	01/07/2004

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1965	NDA/MAL/HDP/3 091	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	ONDI	ONDANSETRON	2MG/ML	SAKAR HEALTH CARE PVT, LTDBLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ- BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X2.0 ML AMPOULE	01/07/2013
1966	NDA/MAL/HDP/3 092	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	EXFORGE HCT 10MG/160MG/12 .5MG	AMLODIPINE + VALSARTAN + HYDROCHLOROT HIAZIDE	10MG + 160MG +12.5MG	NOVARTIS PHARMA STEIN AGSCHAFFHARVSER TRASSE CH-4332 STEIN SWITZERLAND.	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER	01/07/2015
1967	NDA/MAL/HDP/3 095	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	AMPHEN SUSPENSION	CHLORAMPHENIC OL PALMITATE	125MG/5ML	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2007

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1968	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-OBOUR CITY, EGYPT.	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2004
1969	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
1970	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

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1971	NDA/MAL/HDP/3 104	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	NYSTALEB ORAL SUSPENSION	NYSTATIN	100000IU/ML	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2007
1972	NDA/MAL/HDP/3 108	IPCA LABORATOIES LTD	MEDVIN PHARMA LIMITED	ZERODOL	ACECLOFENAC	100MG	IPCA LABORATORIES LTD,PLOT NO. T-139 SEJAVTA, RATLAM- 457 002 (M.P.) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2005
1973	NDA/MAL/HDP/3 111	GLAXOSMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CALPOL	PARACETAMOL	120MG/5ML	GLAXOSMITHKLINE LIMITED - 78392- 00507, VIWANDANI LIKONI ROAD NAIROBI KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1997

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1974	NDA/MAL/HDP/3 116	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	KLOXY	CLOXACILLIN	125MG/5ML	LABORATORY & ALLIED LTD.--PLOT 209/10349 OFF MOMBASA RD NAIROBI	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X100.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/1997
1975	NDA/MAL/HDP/3 117	KARNATAKA ANTIBIOTICS & PHARMACEUTICAL S LTD	TATA UGANDA LIMITED	HYDROCORTISON E SODIUM SUCCINATE	HYDROCORTISON E 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
1976	NDA/MAL/HDP/3 118	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,1.0X30.0X1 8.0 TABLET BLISTER,1.0X30.0X2 4.0 TABLET BLISTER,1.0X30.0X1 2.0 TABLET BLISTER,1.0X30.0X6 .0 TABLET BLISTER,1.0X1.0X18 .0 TABLET BLISTER,1.0X1.0X12 .0 TABLET BLISTER,1.0X1.0X6.	01/07/2011

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1977	NDA/MAL/HDP/3 122	USV PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GROVIT CHEWABLE TABLETS	MULTI- INGREDIENT	MULTI- INGREDIENT	REMIDEX PHARMA PVT LTD B-249+ 250 II STAGE PEENYA INDUSTRIAL ESTATE BANGLORE 560058.	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2002
1978	NDA/MAL/HDP/3 123	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	RECTOL 250 SUPPOSITORY	PARACETAMOL BP	250 MG	BLISS GVS PHARMA LIMITED PLOT NO. 10/11 SURVEY NO.39/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	RECTAL SYSTEMIC PAEDIATRIC SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY BLISTER	01/07/2007
1979	NDA/MAL/HDP/3 125	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	AMLODAR 5	AMLODIPINE BESILATE	5MG	DAR AL DAWANA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER	01/07/2009

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1980	NDA/MAL/HDP/3 134	PANACEA BIOTEC PHARMA LTD	VITACARE LIMITED	TOFF PLUS	PARACETAMOL+C HLORPHENIRAMI NE MALEATE+ DEXTROMETHOR PHAN + PHENYLEPHRINE	500 MG + 2 MG + 15 MG + 10 MG	PANACEA BIOTEC PHARMA LIMITEDMALPURI BADDI, DISTRICT SOLAN, HIMACHAL PRADESH-173205 - INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2004
1981	NDA/MAL/HDP/3 136	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	TENOFOVIR DISOPROXIL FUMARATE	TENOFOVIR DISOPROXIL FUMARATE	300MG	MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2007
1982	NDA/MAL/HDP/3 139	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	OMEDAR	OMEPRAZOLE	20MG	DAR AI DAWANA UR PLANT,AMMAN,JOR DAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER,1.0X2.0X14 .0 TABLET BLISTER	01/07/2009

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1983	NDA/MAL/HDP/3 141	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	AMLOPRESS-5	AMLODIPINE BESYLATE	5MG	CIPLA LTDCIPLA LTD PLOT NO L- 139,VERNA IND ESTATE, VERNA GOA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER	01/07/2007
1984	NDA/MAL/HDP/3 144	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	ULSEC	OMEPRAZOLE	20MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE STRIP	01/07/2007
1985	NDA/MAL/HDP/3 145	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AMOXICAP	AMOXYCILLIN	500MG	HOVID BHD 121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2010

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1986	NDA/MAL/HDP/3 146	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	ZOKAST	MONTELUKAST SODIUM	10MG	UNICHEM LABORATORIES LTDUNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205 UNICHEM LABORATORIES LTD ,,PLOT 17 & 18, PILERNE IND. ESTATE, PILERNE, BARDEZ GOA- 403511	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2016
1987	NDA/MAL/HDP/3 147	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO TELVAS-H 40/12.5	TELMISARTAN/HY DROCHLOROTHIA ZIDE	40MG/12.5MG	ARISTO PHARMACEUTICALS PVT LIMITEDPLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP- 462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP,3.0X10.0 TABLET BLISTER	01/07/2009
1988	NDA/MAL/HDP/3 156	PFIZER LABORATORIES (PTY)	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	BENYLIN DAYTIME FLU	PSEUDOEPHEDRI NE HCL + IBUPROFEN	30MG + 200MG	JOHNSON&JOHNSO N PTY LTD.EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET STRIP	01/07/2008

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1989	NDA/MAL/HDP/3 158	MJ BIOPHARM PVT LTD	VITACARE LIMITED	GLIBEX-5	GLIBENCLAMIDE	5MG	M.J BIOPHARM PVT LTD -L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2012
1990	NDA/MAL/HDP/3 159	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	LARTEM FORTE	ARTEMETHER + LUMEFANTRINE	80MG + 480MG	SKANT HEALTH CARE LTD 1802-1805 GIDC PHASE III VAPI GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER	01/07/2015
1991	NDA/MAL/HDP/3 163	NORVATIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN SUPPOSITORIES 50MG	DICLOFENAC SODIUM	50MG	DELPHARM HUNINGUE S.A.S- SITE INDUSTRIAL HUNINGUE26, RUE DE LA CHAPELLE, F- 68330, HUNINGUE	FRANCE	RECTAL SYSTEMIC ADULT SUPPOSITORIES	1.0X1.0X10.0 SUPPOSITORY STRIP	01/07/2006

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1992	NDA/MAL/HDP/3 167	MJ BIOPHARM PVT LTD	KIMSY MEDS LTD	MONAN-0.5G	MEROPENEM	0.5G	M.J BIOPHARM PVT LTD -L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X0.5 G VIAL	01/07/2010
1993	NDA/MAL/HDP/3 169	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	RANOPHAGE OD	METFORMIN HCL	1000MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED INDUSTRIAL AREA 3, A.B. ROAD, DEWAS 455001, MADHYA PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008
1994	NDA/MAL/HDP/3 175	M.J.BIOPHARM PVT LTD	VITACARE LIMITED	SPACOVIN	DROTAVERINE	40MG	M.J. BIOPHARM PVT. LTDL-7, M.I.D.C. , TALOJA, DISTRICT RAIGAD - 410 208 NAVI MUMBAI, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2012

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1995	NDA/MAL/HDP/3 176	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
1996	NDA/MAL/HDP/3 177	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	BETADERM CREAM	BETAMETHASONE VALERATE	0.1%W/W	ATCO LABORATORIES PVT LTDB-18, S.I.T.E KARACHI 75700, PAKISTAN	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE, 1.0X5.0 G TUBE	01/07/1997
1997	NDA/MAL/HDP/3 178	COSMOS LTD	ASTRA PHARMA (U) LIMITED	BENDURIC TABLETS	BENDROFLUMET HIAZIDE	5MG	COSMOS LTD. RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X1000.0 TABLET CONTAINER	01/07/2005

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1998	NDA/MAL/HDP/3 179	GOOD DAY PHARMACY LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	SULFUR OINTMENT	SULPHUR	10%W/W	KREMOINT PHARMA PVT LTD--B-8 ADDITIONAL AMBERNATH MIDC OPP. ANAND NAGAR POLICE CHECK POST AMBERNATH (E) DIST THANE 421 506	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X25.0 G TUBE	01/07/2013
1999	NDA/MAL/HDP/3 181	THEMIS MEDICARE LTD	STAR PHARMACEUTICAL S LTD	EMAL	ALPHA & BETA ARTEETHER	150MG/2ML	THEMIS MEDICARE LIMITEDSECTOR 6A, PLOT NO. 16 TO18, IIE, BHEL HARIDWA, UTTARAKHAND	INDIA	PARENTERAL ORDINARY AMPOULES	3.0X2.0 ML VIAL	01/07/2009
2000	NDA/MAL/HDP/3 184	M.J BOPHARM PUT LTD	KIMSY MEDS LTD	MONAN	MEROPENEM	1G	M.J BIOPHARM PUT LTD L-7 MIDC INDUSTRIOL DIST GAIDED TOLOJA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2008

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2001	NDA/MAL/HDP/3 191	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	ERECTO -100	SILDENAFIL CITRATE	100 MG	CIPLA LIMITED PUNEMIDC, KURKUMBH DISTRICT PUNE 413802	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0 TABLET BLISTER	01/07/2007
2002	NDA/MAL/HDP/3 192	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ANZAVIR-R	ATAZANAVIR + RITONAVIR	300 MG + 100 MG	MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2013
2003	NDA/MAL/HDP/3 193	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	ERECTO- 50	SILDENAFIL CITRATE	50MG	CIPLA LIMITED PUNEMIDC, KURKUMBH DISTRICT PUNE 413802	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0 TABLET BLISTER	01/07/2005

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2004	NDA/MAL/HDP/3 196	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	MOTINORM	DOMPERIDONE	10MG	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X30.0 ML BOTTLE	01/07/2000
2005	NDA/MAL/HDP/3 197	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	TRIAM-DENK 40 INJECTION	TRIAMCINOLON E ACETONIDE	40 MG/ML	FISIOPHARMA S.R.L.- NUCLEOO INDUSTRIALE, 84020, PALOMONTE (SA) - ITALY	ITALY	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2004
2006	NDA/MAL/HDP/3 200	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LETRAX	LEVAMISOLE HYDROCHLORIDE	40MG	LABORATORY & ALLIED LTD-PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X20 0.0 TABLET CONTAINER,1.0X25. 0X3.0 TABLET BLISTER,1.0X3.0 TABLET BLISTER	01/07/1997

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2007	NDA/MAL/HDP/3 202	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	PRESARTAN-50	LOSARTAN	50MG	IPCA LABORATORIES LTD PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2008
2008	NDA/MAL/HDP/3 204	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S 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
2009	NDA/MAL/HDP/3 206	HEALTHCARE LTD.	HEALTHCARE LTD.	POSTINOR 2	LEVONORGESTRE L	0.75MG	GEDEON RICHTER PLC1103 BUDAPEST GYOMROI UT 19-21	HUNGARY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X2.0 TABLET BLISTER	01/07/2010

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2010	NDA/MAL/HDP/3 207	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	DILCONTIN XL 90	CONTROLLED RELEASE TABLETS OF DILTIAZEM HYDROCHLORIDE	90MG	MODI MUNDIPHARMA (PVT) LTDMEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2010
2011	NDA/MAL/HDP/3 212	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	CLOPRESS 75MG	CLOPIDOGREL BISULPHATE	75MG	CIPLA LTD-PLOT NO L-139,VERNA IND ESTATE, VERNA GOA- 403 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2005
2012	NDA/MAL/HDP/3 214	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	INDICONTIN	INDAPAMIDE	1.5MG	MODI MUNDIPHARMA PVT. LTDMEERUT- MUZAFFARNAGAR ROAD, MODIPURAM – 250110 UTTAR PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010

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2013	NDA/MAL/HDP/3 215	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	SEROCORT 125	SALMETEROL XINAFOATE + FLUTICASONE PROPIONATE	25MCG + 125MCG	CIPLA LTDCIPLA LTD PLOT NO L- 139,VERNA IND ESTATE, VERNA GOA INDIA	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER	01/07/2009
2014	NDA/MAL/HDP/3 219	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOPHENOL ORAL SUSPENSION	CHLORAMPHENIC OL	125MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/1998
2015	NDA/MAL/HDP/3 220	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	PYLO KIT	LANSOPRAZOLE+T INIDAZOLE+CLARI THROMYCIN	30MG+500MG+25 0 MG	CIPLA LIMITED PUNEMIDC, KURKUMBH DISTRICT PUNE 413802	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X7.0X1.0X6.0 TABLET BLISTER (BLISTER CONTAINS 2 CAPSULES AND 4 TABLETS)	01/07/2005

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2016	NDA/MAL/HDP/3 221	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	OPTADEX-N EYE DROPS	DEXAMETHASON E/NEOMYCIN	1MG/3MG	REMINGTON PHARMACEUTICAL INDUS. PVT LTD, 117 ALLAM	PAKISTAN	OPHTHALMIC DROPS	1.0X5.0 ML VIAL	01/07/1999
2017	NDA/MAL/HDP/3 224	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM FLUFED ELIXIR	MULTI- INGREDIENT	MULTI- INGREDIENT	TIL HEALTHCARE PVT LIMITEDPLOT 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
2018	NDA/MAL/HDP/3 225	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	DIFLAME	DICLOFENAC DIETHYLAMINE + LINSEED OIL + METHYL SALICYLATE MENTHOL	N/A	LINCOLN PHARMACEUTICAL LIMITEDTRIMAL 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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2019	NDA/MAL/HDP/3 226	SEARLE PAKISTAN LIMITED	SURGIPHARM (U) LIMITED	PEDITRAL	ORAL REHYDRATION SALT	N/A	SEARLE PAKISTAN LTD..F-319, S.I.T.E., OPP. KESC POWER STATION, KARACHI	PAKISTAN	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X29.5 G SACHET	01/07/1997
2020	NDA/MAL/HDP/3 231	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	FLUCOMOL	PARACETAMOL/P HENYLEPHRINE HCL/DEXTROMET HORPHAN HBR/CHLORPHENI RAMINE MALEATE	500MG/10MG/15 MG/2MG	LINCOLN PHARMACEUTICAL LIMITEDTRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER,1.0X10.0X1 .0X10.0 CAPSULE BLISTER	01/07/2008
2021	NDA/MAL/HDP/3 236	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM COTRI	CO-TRIMOXAZOLE	480MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER,1.0X25 0.0 TABLET CONTAINER,1.0X50 0.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER,1.0X10 0.0X10.0 TABLET BLISTER	01/07/1997

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2022	NDA/MAL/HDP/3 237	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S 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
2023	NDA/MAL/HDP/3 241	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	CLOTRILIN	CLOTRIMAZOLE	1%W/W	LINCOLN PHARMACEUTICALS LTD-TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE, 1.0X15.0 G TUBE	01/07/2008
2024	NDA/MAL/HDP/3 243	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	RAPITUS	LEVODROPROPIZI NE	30MG/5ML	MACLEODS PHARMACEUTICALS LTD BLOCK N2, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2016

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2025	NDA/MAL/HDP/3 244	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	UMICILLIN	AMPICILLIN	250MG	UNI MEDICOLABS. 21-22 PHARMACITY SELAQUI DEHRADUN 248197	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2015
2026	NDA/MAL/HDP/3 245	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NYSTATIN ORAL DROPS	NYSTATIN	100,000 I.U/ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL TOPICAL DROPS	1.0X30.0 ML BOTTLE	01/07/2013
2027	NDA/MAL/HDP/3 246	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	COMPOUND MAGNESIUM TRISILICATE	MAGNESIUM TRISILICATE	370MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. 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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2028	NDA/MAL/HDP/3 252	GALENTIC PHARMA LTD	VITACARE LIMITED	PYLOOCAIN	BETAMETHASONE + PHENYLEPHRINE + LIDOCAINE	0.5 MG/G + 1 MG/G + 25 MG/G	GALENTIC PHARMA(INDIA) PVT LTDR- 673,MIDC TTC RABALE THANE- BELAPUR ROAD,NAVI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X30.0 G TUBE	01/07/2005
2029	NDA/MAL/HDP/3 255	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	SATISFIL-50	SILDENAFIL CITRATE	50MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2011
2030	NDA/MAL/HDP/3 259	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	TIGBODERM	BETAMETHASONE + CHLOROCRESOL + GENTAMICIN + CLIOQUINOL + TOLNAFTATE	0.05% W/W + 0.1% W/W + 0.1% W/W + 1% W/W + 1% W/W	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E,DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997

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2031	NDA/MAL/HDP/3 261	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	TENOFOVIR DF + EMTRICITABINE + EFAVIRENZ	TENOFOVIR DF + EMTRICITABINE + EFAVIRENZ	300MG+200MG+6 00MG	MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD - PLOT NO. H-12 & H- 13 MIDCWALUJ INDUSTRIAL AREA AURANGABAD 431136 MAHARASTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2008
2032	NDA/MAL/HDP/3 262	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEGEL	MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE	250MG + 250MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007
2033	NDA/MAL/HDP/3 263	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	TRIMEX MUCOLYTIC SYRUP	SALBUTAMOL SULPHATE + BROMHEXINE HYDROCHLORIDE + GUAIFENESIN	2MG/5ML + 4MG/5ML + 100MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA, NAIROBI, K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2009

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2034	NDA/MAL/HDP/3 265	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AMOXICILLIN	AMOXICILLIN TRIHYDRATE	250MG	CSPC ZHONGNUO PHARMACEUTICALS (SHIJIAZHUANG) CO. LTD-SHIJIAZHUANG CITY	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,10.0X1 0.0 CAPSULE BLISTER	01/07/2010
2035	NDA/MAL/HDP/3 266	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	SALIMIA LINIMENT	METHYL SALICYLATE+TURP ENTINE OIL	5ML+25ML	BETA HEALTHCARE INTERNATIONAL LTD - PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL LIQUIDS	1.0X60.0 ML BOTTLE,1.0X50.0 ML BOTTLE	01/07/1997
2036	NDA/MAL/HDP/3 270	ASTRA PHARMA (UK) LTD	ASTRA PHARMA (U) LIMITED	FORTIFIED PROCAINE PENICILLIN	FORTIFIED PROCAINE PENICILLIN	4000000 IU	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTDNO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSH OP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 VIAL CARTON,1.0X50.0 VIAL CARTON	01/07/2001

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2037	NDA/MAL/HDP/3 273	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	BETASOL CREAM	BETAMETHASONE VALERATE	0.1%W/W	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X30.0 G TUBE	01/07/1997
2038	NDA/MAL/HDP/3 275	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	MEFLIN-500	MEFENAMIC ACID	500MG	LINCOLN PHARMACEUTICALS LIMITED 10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010
2039	NDA/MAL/HDP/3 276	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICAL S LTD	ROSUVAS 10	ROSUVASTATIN	10MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER	01/07/2014

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2040	NDA/MAL/HDP/3 277	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	TRANSAMIN CAPSULES 500MG	TRANEXAMIC ACID	500MG	HILTON PHARMA (PVT) LTD PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2001
2041	NDA/MAL/HDP/3 279	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	HAEMOFORTE SYRUP	MULTI- INGREDIENT	MULTI- INGREDIENT	MILAN LABORATORIES (INDIA) PVT LTD PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA BAROQUE PHARMACEUTICALS PVT LTD -S.NO.192/2 & S.NO.192/2 &3 SOKHADA-388 620 KHAMBHAT. DIST. ANAND GUJARAT INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X90.0 ML BOTTLE,1.0X250.0 ML BOTTLE,1.0X200.0 ML BOTTLE	01/07/1997
2042	NDA/MAL/HDP/3 282	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	KOFF-GO	PHENYLEPHRINE HCL + CHLORPHENIRAM INE MALEATE + DEXTROMETHOR PHAN	5MG/5ML + 2MG/5ML + 10MG/5ML	TORQUE PHARMACEUTICALS (P) LTDP.O.DAPPAR VILLISS	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	01/07/2009

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2043	NDA/MAL/HDP/3 284	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	CHALEATE	CHLORPHENIRAMINE MALEATE	4MG	LABORATORY & ALLIED LTD-PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997
2044	NDA/MAL/HDP/3 285	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	AMOXIL FORTE 250MG/5ML	AMOXYCILLIN	250MG/5ML	GLAXO WELLCOME PRODUCTION.ZONE INDUSTRIELLE DE LA PEYENNIERE 53100 MAYENNE, FRANCE	FRANCE	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997
2045	NDA/MAL/HDP/3 288	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	DELAISED 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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2046	NDA/MAL/HDP/3 289	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	CANDID DUSTING POWDER	CLOTRIMAZOLE	1%W/W	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL DUSTING POWDERS	1.0X30.0 G BOTTLE,1.0X100.0 G BOTTLE	01/07/1999
2047	NDA/MAL/HDP/3 291	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICAL S LTD	FINTOP	BUTENAFINE HCL	1%W/W	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2003
2048	NDA/MAL/HDP/3 292	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	DELAED PAEDIATRIC SYRUP	DIPHENHYDRAMINE HYDROCHLORIDE +SODIUM CITRATE+MENTH OL	7MG+28.5MG+0.5 5MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1997

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2049	NDA/MAL/HDP/3 294	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	URGENDOL CAPSULES	TRAMADOL HYDROCHLORIDE	50 MG	WIN- MEDICARE LTDMODIPURAM - 250 110,UTTAR PRAADESH, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2004
2050	NDA/MAL/HDP/3 295	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICAL S LTD	GLEVATE	CLOBETASOL	0.05%W/W	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2008
2051	NDA/MAL/HDP/3 297	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	NEPIN-SR-20	NIFEDIPINE	20MG	LINCOLN PHARMACEUTICALS LIMITED TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT - INDIA	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER, 1.0X10.0X1 0.0 TABLET BLISTER	01/07/2011

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2052	NDA/MAL/HDP/300	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
2053	NDA/MAL/HDP/312	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	TIDOMET FORTE	CO-CARELDOPA	25MG/250MG	TORRENT PHARMACEUTICALS LTD VILLAGE: BHUD & MAKHNU MAJRA, TEHSIL: BADDI " 173205, DIST: SOLAN, HIMACHAL PRADESH, TORRENT PHARMACEUTICAL LTD AHMEDABAD-MEHSANA HIGHWAY, TALUKA-KADI, DIST. MEHSANA ,INDRAD-382721	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2004
2054	NDA/MAL/HDP/314	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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2055	NDA/MAL/HDP/3 315	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	ERO-250 TABLETS	ERYTHROMYCIN STEARATE	250MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2003
2056	NDA/MAL/HDP/3 316	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMOX	AMOXYCILLIN TRIHYDRATE	125MG/5ML	SPARSH BIO-TECH LTD PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1998
2057	NDA/MAL/HDP/3 318	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENETRIM TABLETS	CO-TRIMOXAZOLE	480MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2000

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2058	NDA/MAL/HDP/3 319	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	FERROTONE CAPSULES	FERROUS FUMERATE+FOLIC ACID+VITAMIN B12	162MG +0.75MG +7.5MCG	MEGA LIFESCIENCES LTD.384 PATTANA 3 ROAD BANGPOO INDUSTRIAL ESTATE SUMUTPRAKAN	THAILAND	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X10.0 CAPSULE BLISTER	01/07/2005
2059	NDA/MAL/HDP/3 321	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	DERMOLIN-GM	CLOBETASOL+GE NTAMICIN+MICO NAZOLE	0.05%W/W+0.1% W/W+2%W/W	LINCOLN PHARMACEUTICALS LIMITEDTRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT - INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2008
2060	NDA/MAL/HDP/3 328	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	BENZYL PENICILLIN INJECTION	BENZYL PENICILLI N	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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2061	NDA/MAL/HDP/333	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
2062	NDA/MAL/HDP/334	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MYCLAV 375	AMOXICILLIN + CLAVULANIC ACID	250 MG + 125 MG	UNICHEM LABORATORIES LIMITED UNIT IIVILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET STRIP, 1.0X10.0X6.0 TABLET STRIP	01/07/2005
2063	NDA/MAL/HDP/341	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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2064	NDA/MAL/HDP/3 342	SEARLE PAKISTAN LTD	HEALTHCARE LTD.	METODINE DF TABLETS	METRONIDAZOLE +DILOXANIDE	400MG+500MG	SEARLE PAKISTAN LTD..F-319, S.I.T.E., OPP. KESC POWER STATION, KARACHI	PAKISTAN	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X3.0X5.0 TABLET BLISTER	01/07/2004
2065	NDA/MAL/HDP/3 343	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	MEDIVEN-CREAM	BETAMETHASONE VALERATE	0.1%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997
2066	NDA/MAL/HDP/3 346	WOCKHARDT LTD	STAR PHARMACEUTICAL S LTD	ZEDEX	BROMHEXINE +AMMONIUM CHLORIDE+ MENTHOL + DEXTROMETHOR PHAN	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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2067	NDA/MAL/HDP/3 347	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	UNIPEN TABLETS	PHENOXYMETHYL PENICILLIN	250MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1997
2068	NDA/MAL/HDP/3 348	VENUS REMEDIES LTD	HARLEYS UGANDA LIMITED	PIMCEF	CEFEPIME USP	1G	VENUS REMEDIES LTD.UNIT 11 HOLL TOP INDUSTRIAL ESTATE JHARMAJRI	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL	01/07/2007
2069	NDA/MAL/HDP/3 354	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	MEDIVEN OINTMENT	BETAMETHASONE VALERATE	0.1%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997

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2070	NDA/MAL/HDP/3 357	CENTAUR PHAMACUITICALS	GITTOES PHARMACEUTICAL S LIMITED	ESOREST 20	ESOMEPRAZOLE	20MG	CENTAUR PHARMACEUTICALS PVT L.T.D.CENTAUR HOUSE NEAR	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008
2071	NDA/MAL/HDP/3 359	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	ARTI	ARTEMETHER	80MG/ML	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE	01/07/2011
2072	NDA/MAL/HDP/3 364	CENTAUR PHAMACUITICALS	GITTOES PHARMACEUTICAL S LIMITED	ESOREST 40	ESOMEPRAZOLE	40MG	CENTAUR PHARMACEUTICALS PVT L.T.D.CENTAUR HOUSE NEAR	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008

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2073	NDA/MAL/HDP/3 367	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOMOL SUSPENSION	PARACETAMOL	125 MG/5ML	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE, 1.0X100.0 ML BOTTLE	01/07/2000
2074	NDA/MAL/HDP/3 369	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	AZILIN-500	AZITHROMYCIN	500MG	LINCOLN PHARMACEUTICALS LIMITED TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X3.0 TABLET BLISTER	01/07/2008
2075	NDA/MAL/HDP/3 370	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	DERMOREN 500	GRISEOFULVIN	500MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009

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2076	NDA/MAL/HDP/372	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	MUCOLEX	AMBROXOL HYDROCHLORIDE + SALBUTAMOL SULPHATE + GUAIFENESIN + MENTHOL	30 MG/5ML + 1 MG/5ML + 50 MG/5ML + 0.5 MG/5ML	S KANT HEALTHCARE LTD1802-1805 GIDC PHASE III VAPI 396 195	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2014
2077	NDA/MAL/HDP/373	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MYCLAV 625	AMOXILLICIN/CLAVULANATE	500MG/125MG	UNICHEM LABORATORIES LIMITED UNIT IIVILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X7.0 TABLET STRIP, 1.0X10.0X6.0 TABLET STRIP	01/07/2005
2078	NDA/MAL/HDP/374	COSMOS LIMITED	ASTRA PHARMA (U) LIMITED	ZITHROX 250MG	AZITHROMYCIN	250MG	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	01/07/2008

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2079	NDA/MAL/HDP/3 377	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AMILINE	AMITRIPTYLINE	25 MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER,1.0X100.0X 10.0 TABLET BLISTER	01/07/2011
2080	NDA/MAL/HDP/3 378	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	CHLOZINE TABLETS	CHLORPROMAZIN E	100MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2011
2081	NDA/MAL/HDP/3 379	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIFASI	HUMAN CHORIONIC GONADOTROPIN	5000I.U	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X2.0 AMPOULE CARTON	01/07/2011

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2082	NDA/MAL/HDP/3 382	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOFEN SUSPENSION	IBUPROFEN	100MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X60.0 ML BOTTLE,1.0X1.0X10 0.0 ML BOTTLE	01/07/2010
2083	NDA/MAL/HDP/3 383	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	ZEPIN-200	CARBAMAZEPINE	200 MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2010
2084	NDA/MAL/HDP/3 384	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PROXIMEXA 250MG	CEFUROXIME AXETIL	250MG	GLAXOSMITHKLINE UK LTD HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2007

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2085	NDA/MAL/HDP/3 385	BLUE CROSS LABORATORIES LTD	STAR PHARMACEUTICAL S 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
2086	NDA/MAL/HDP/3 387	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
2087	NDA/MAL/HDP/3 390	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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2088	NDA/MAL/HDP/3 391	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	CEZIN TABLET	CETIRIZINE	10MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. 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
2089	NDA/MAL/HDP/3 393	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	AUGMENTIN 375MG	AMOXICILLIN + CLAVULANIC ACID	250 MG + 125 MG	SMITHKLINE BEECHAM PHARMACEUTICALS, CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	2.0X10.0 TABLET BLISTER	01/07/1997
2090	NDA/MAL/HDP/3 399	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LDNIL 10	ROSUVASTATIN	10MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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2091	NDA/MAL/HDP/3 400	ACINO PHARMA AG	LABOREX UGANDA LIMITED	OLFEN GEL	DICLOFENAC SODIUM	1%W/W	SOFARIMEX INDUSTRIA QUIMIRA E FARMACEUTICA SAAV. DAS INDUSTRIAS - ALTO DO COLARIDE, 2735- 213 AGUALVA CACEM	PORTUGAL	TOPICAL EXTERNAL GELS AND SOLS	1.0X50.0 G TUBE,1.0X20.0 G TUBE	01/07/1997
2092	NDA/MAL/HDP/3 405	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PANADOL BABY AND INFANT 120MG/5ML	PARACETAMOL	120MG/5ML	GLAXOSMITHKLINE LIMITEDLIKONI ROAD, INDUSTRIAL AREA, P.O. BOX 78392-00507, VIWANDANI, NAIROBI	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2008
2093	NDA/MAL/HDP/3 406	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	MICRONEMA	SODIUM CITRATE + SODIUM LAURYL SULPHATE + GLYCERIN	450MG/10ML+75 MG/10ML+ 90%V/V	ATCO LABORATORIES PVT LTDB-18,S.I.T.E KARACHI, PAKISTAN	PAKISTAN	RECTAL SYSTEMIC ENEMA LIQUIDS	1.0X10.0 ML BOTTLE,1.0X20.0 ML BOTTLE	01/07/2005

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2094	NDA/MAL/HDP/3 409	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	CLARITYNE	LORATADINE	10MG	BAYER BITTERFELD GMBHORTSTEIL GREPPIN SALEGASTER CHAUSSEE 1, 06803 BITTERFELD, WOLFEN - GERMANY	NULL	ORAL SOLID ORDINARY TABLETS	3.0X10.0 TABLET BLISTER,1.0X1.0X10 .0 TABLET BLISTER	01/07/2000
2095	NDA/MAL/HDP/3 411	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABNAL NASAL DROPS	SODIUM CHLORIDE	0.9%W/V	ABACUS PARENTERAL DRUGS LTD.PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	NASAL SYSTEMIC DROPS	1.0X10.0 ML VIAL	01/07/2011
2096	NDA/MAL/HDP/3 414	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	EXFORGE 10MG/160MG	AMLODIPINE + VALSARTAN	10 MG + 160 MG	NOVARTIS PHARMA STEIN AGH-4332 STEIN SCHAFFHAUSERTRASS E	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2007

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2097	NDA/MAL/HDP/3 415	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	CANDID V-1	CLOTRIMAZOLE	500MG	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	VAGINAL TABLETS	1.0X1.0 PESSARY STRIP	01/07/2004
2098	NDA/MAL/HDP/3 423	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	AMOXICLAV- DENK 1000/125	AMOXICILLIN TRIHYDTATE + POTASSIUM CLAVULANATE	1000 MG + 125 MG	PENCEF PHARMA GMBHBREITENBACHS TRASSE 13 D-13509 BERLIN	GERMANY	ORAL LIQUID ORDINARY UNIT DOSE POWDERS	1.0X12.0X3.0 G SACHET, 1.0X8.0X3. 0 G SACHET	01/07/2011
2099	NDA/MAL/HDP/3 426	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	RUBEM CREAM	METHYL NICOTINATE + CAPSICUM OLEORESIN+ METHYLSALICYLA TE	1%W/W+0.1%W/ W+5%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA, NAIROBI, K ENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE	01/07/1997

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2100	NDA/MAL/HDP/3 429	XEPA-SOUL PATTINSON	DELMAW ENTERPRISES LIMITED	EZEDE	LORATADINE	10MG	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2006
2101	NDA/MAL/HDP/3 433	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	CO-DIOVAN 80/12.5	VALSARTAN + HYDROCHLOROT HIAZIDE	80 MG +12.5 MG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND NOVARTIS PHARMA SPA,-TORRE ANNUNZIATA ITALY	ITALY SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2006
2102	NDA/MAL/HDP/3 434	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	SEPTRIN	CO-TRIMOXAZOLE	480MG	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO. LR 209/6554, MOGADISHU ROAD INDUSTRIAL AREA, NAIROBI KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0 TABLET CARTON,1.0X50.0 TABLET CARTON,1.0X10.0X 10.0 TABLET BLISTER,1.0X2.0X10 .0 TABLET BLISTER	01/07/1997

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2103	NDA/MAL/HDP/3 437	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	REMYCIN 100 CAPSULES	DOXYCYCLINE HYDROCHLORIDE	100MG	REMEDICA LIMITED AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1997
2104	NDA/MAL/HDP/3 439	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENECHLOR CAPSULE	CHLORAMPHENIC OL	250MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER, 10.0X1 0.0 CAPSULE BLISTER	01/07/2000
2105	NDA/MAL/HDP/3 440	ELI-LILLY EXPORT SA	LABOREX UGANDA LIMITED	HUMALOG	INSULIN LISPRO	100IU	LILLY FRANCE SAFRANCE	FRANCE	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL	01/07/2000

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2106	NDA/MAL/HDP/3 444	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	CORVADIL 10	AMLODIPINE BESILATE	10MG	UNICHEM LABORATORIES LIMITEDUNICHEM LABORATORIES LIMITED. UNIT II, VILLAGE BHATAULI KALAN, BADDI, DIST. SOLAN PIN CODE 173 205, HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2010
2107	NDA/MAL/HDP/3 449	VENUS REMEDIES LTD	HARLEYS UGANDA LIMITED	IMMUNOX	CEFTRIAZONE SODIUM	1000MG	VENUS REMEDIES LIMITED ,,HILL TOP,INDUSTRIAL ESTATE,JHARMAJRI, EPIP,PHASE 1,(EXTN.) ,BHATOLI KALAN,BADDI - H.P.INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL,1.0X10.0X1.0X 10.0 ML VIAL	01/07/2008
2108	NDA/MAL/HDP/3 451	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOPHENOL CAPSULES (THANEO	CHLORAMPHENIC OL	250MG	AGOG PHARMA LTDPLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER,1.0X100.0 CAPSULE CONTAINER,1.0X10 00.0 CAPSULE CONTAINER,1.0X50 0.0 CAPSULE CONTAINER	01/07/1998

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2109	NDA/MAL/HDP/3 458	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNIXIL 250MG	AMOXYCILLIN TRIHYDRATE	250MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/1997
2110	NDA/MAL/HDP/3 459	AMOUN PHARMACEUTICAL S COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ENEMAX	HYPERTONIC SOLUTION OF SODIUM PHOSPHATES	6GM AND 16GM/100ML	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY CAIRO EGYPT	EGYPT	RECTAL SYSTEMIC ENEMA LIQUIDS	1.0X120.0 ML BOTTLE	01/07/1997
2111	NDA/MAL/HDP/3 460	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	MALANIL ADULT TABLETS	ATOVAQUONE + PROGUANIL HCL	250MG + 100MG	GLAXO WELLCOME S.A ARANDAARANDA AVDA EXTREMADURA 3, 09400 ARANDA DE DUERO BURGOS	SPAIN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X12.0 TABLET BLISTER	01/07/2007

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2112	NDA/MAL/HDP/3 464	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TARTAR CONTROL LISTERINE ANTISEPTIC	ZINC CHLORIDE + DENATURED ALCOHOL MENTHOL 95% + THYMOL	18MG/ 20ML + 0.9ML/20ML + 12.7MG/20ML	JOHNSON&JOHNSO N PTY LTD..241 MAIN ROAD RETREAT 794	SOUTH AFRICA	ORAL LIQUID ORDINARY OTHER LIQUIDS	1.0X500.0 ML BOTTLE,1.0X250.0 ML BOTTLE	01/07/2007
2113	NDA/MAL/HDP/3 465	MONDI-MUNDI PHARMA PVT LIMITED	SURGIPHARM (U) LIMITED	FECONTIN-Z	FERROUS GLYCINE SULPHATE+ZINC SULPHATE+FOLIC ACID	100MG+61.8MG+0 .5MG	MODI MUNDIPHARMA (PVT) LTDMEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008
2114	NDA/MAL/HDP/3 466	DAWA LIMITED	SUPER MEDIC LTD	DAWASEC	SECNIDAZOLE	1G	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	01/07/2015

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2115	NDA/MAL/HDP/3 467	VENUS REMEDIES LTD	HARLEYS UGANDA LIMITED	RONEM	MEROPENEM TRIHYDRATE	1000MG	VENUS REMEDIES LTD -UNIT II HILL TOP INDUSTRIAL ESTATE JHARMAJRI EPIP PHASE I BHATOLI KALAN BADDI (H.P)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL	01/07/2008
2116	NDA/MAL/HDP/3 473	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TRIXONE	CEFTRIAZONE	1G	P.R & INJECT CARE PARENTERALS PVT LTD-PLOT 130, SILVASSA ROAD,G.I.D.C,VAPI- 396195,GUJARAT,IN DIA ZEISS PHARMA LIMITED-IGC,SIDCO, PHASE II, SAMBA, JAMMU - 184121,(J&K)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL,1.0X10.0X1.0 G VIAL	01/07/2016
2117	NDA/MAL/HDP/3 474	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMCLOREN DRY SYRUP	AMPICILLIN + CLOXACILLIN	125MG+125MG/5 ML	RENE INDUSTRIES LTD680,KAMULI,KIR EKA KAMPALA,UGANDA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2008

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2118	NDA/MAL/HDP/3 475	VENUS REMIDIES LTD	HARLEYS UGANDA LIMITED	RONEM	MEROPENEM	500MG	VENUS REMEDIES LTD, UNIT II,HILL TOP INDUSTRIAL ESTATE, JHARMAJTI, EPIP, PHASE-1 (EXTENSION), BHATOLI KALAN, BADDI -HP	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL	01/07/2010
2119	NDA/MAL/HDP/3 476	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	PARAFIL	PARACETAMOL	500MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDA LUR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1997
2120	NDA/MAL/HDP/3 478	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	DICLOREN	DICLOFENAC SODIUM BP	50MG	RENE INDUSTRIES LTD680,KAMULI,KIR EKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009

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2121	NDA/MAL/HDP/3 483	JOHNSON&JOHNSON ON PTY LTD. 241	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SINUTAB 3-WAY	IBUPROFEN + PSEUDOEPHEDRI NE HCL	200MG + 30MG	JOHNSON&JOHNSON N PTY LTD.EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2007
2122	NDA/MAL/HDP/3 485	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
2123	NDA/MAL/HDP/3 490	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	LAXOLAC SYRUP	LACTULOSE	67G/100ML	MEDICAL UNION PHARMACEUTICALS LTDABU SULTAN, ISMAILLIA, EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2003

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2124	NDA/MAL/HDP/3 492	ACINO PHARMA AG -	LABOREX UGANDA LIMITED	OLFEN-50 GASTRO- RESISTANT TABLETS	DICLOFENAC SODIUM	50MG	ACINO PHARMA AGBIRSWEG 2, 4253, LIESBERG - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/1997
2125	NDA/MAL/HDP/3 494	FERRER INTERNATIONAL, S.A.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	GAMALATE B6 SOLUTION	MAGNESIUM GLUTAMATE HYDROBROMIDE + AMINOBUTYRIC ACID + AMINO HYDROXYBUTYRIC ACID + VITAMIN B6	2G + 2G + 1G +1G	FERRER INTERNATIONAL, S.A.C/JOAN BUSCALLA, 1- 9.08173 SANT CUGAT DEL VALLES, BARCELONA	SPAIN	ORAL LIQUID ORDINARY LIQUIDS	1.0X80.0 ML BOTTLE	01/07/2015
2126	NDA/MAL/HDP/3 497	MEGA LIFSCIENCES (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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2127	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
2128	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
2129	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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2130	NDA/MAL/HDP/3 506	ABBVIE (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ULTANE	SEVOFLURANE	100%W/W	AESICA QUEENSBOROUGH LTD NORTH RD. QUEENSBOROUGH KENT ABBVIE SRLS.R. 148 PONTINA KM 52 - 04011 CAMPOVERDE DI APRILIA (LT) - ITALY	ITALY UNITED KINGDOM	NASAL SYSTEMIC UNIT DOSE LIQUIDS	1.0X250.0 ML BOTTLE	01/07/2011
2131	NDA/MAL/HDP/3 507	MEDOPHARM PRIVATE LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	MEDOMOX 250	AMOXICILLIN	250MG	MEDOPHARM PVT LTD.NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/2011
2132	NDA/MAL/HDP/3 512	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	LAMISIL 250MG	TERBINAFINE	250MG	NORVATIS PHARMA PRODUKTIONS GMBH 79644 WEHR/BADEN- GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X14.0 TABLET CARTON	01/07/1997

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2133	NDA/MAL/HDP/3 515	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN 40/240	ARTEMETHER + LUMEFANTRINE	40 MG + 40 MG	AJANTA PHARMA LTD .B-4//5/6, MIDC INDUSTRIALAREA, PAITHAN-431 128, AURANGBAD AJANTA PHARMA LIMITEDPLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT- 392130	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X6.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER (WITH AMFM LOGO),1.0X30.0X1. 0X6.0 TABLET BLISTER (WITH AMFM LOGO),1.0X30.0X1. 0X6.0 TABLET BLISTER (WITHOUT AMFM LOGO)	01/07/2007
2134	NDA/MAL/HDP/3 516	COSMOS LTD	ASTRA PHARMA (U) LIMITED	BENZHEXOL TABLETS BP 5MG	TRIHXYPHENIDY L HYDROCHLORIDE	5MG	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10 0.0 TABLET BLISTER	01/07/1998
2135	NDA/MAL/HDP/3 517	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TOTO ZINC	ZINC SULPHATE	20MG	MEDICAMEN BIOTECH LTDSP- 1192, A &B, PHASE Â€"IV, INDUSTRIAL AREA BHIWADI -301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013

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2136	NDA/MAL/HDP/3 520	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	DREZ POWDER	POVIDONE IODINE + METRONIDAZOLE	1%W/W + 5%W/W	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	TOPICAL EXTERNAL POWDERS	1.0X100.0 G BOTTLE,1.0X10.0 G BOTTLE,1.0X40.0 G CONTAINER	01/07/2010
2137	NDA/MAL/HDP/3 522	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	CLOXACILLIN SODIUM FOR INJECTION	CLOXACILLIN SODIUM	500MG	CSPC ZHONGNUO PHARMACEUTICAL (SCJIJAZHUANG) 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
2138	NDA/MAL/HDP/3 525	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOCLLIN	AMPICILLIN TRIHYDRATE	250MG	MILAN LABORATORIES (INDIA) PVT LTD PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTR A-410209,INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER,1.0X10 0.0X10.0 CAPSULE BLISTER	01/07/1998

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2139	NDA/MAL/HDP/3 526	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,1.0X10. 0X10.0 TABLET BLISTER	01/07/2001
2140	NDA/MAL/HDP/3 527	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	LEVOTOP-500	LEVOFLOXACIN	500MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2009
2141	NDA/MAL/HDP/3 533	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	LEVOZIN	LEVOCETIRIZINE	5MG	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008

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2142	NDA/MAL/HDP/3 535	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	ADIFLAM-50	DICLOFENAC SODIUM GASTRO- RESISTANT TABLETS BP	50MG	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007
2143	NDA/MAL/HDP/3 540	EAGLEVET UGANDA LIMITED	MEDVIN PHARMA LIMITED	CLOPACT-75	CLOPIDOGREL	75 MG	IPCA LABORATORIESLIMIT ED-IPCA LABORATORIES LTD P.O SEJANTA DISTRICT RATLAM 457002 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008
2144	NDA/MAL/HDP/3 542	BETA HEALTH CARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	MARA MOJA	ASPIRIN + PARACETAMOL + CAFFEINE	400MG + 200MG + 50MG	BETA HEALTHCARE INTERNATIONAL LTD - PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X2.0 TABLET STRIP,1.0X110.0X2. 0 TABLET STRIP	01/07/2005

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2145	NDA/MAL/HDP/3 545	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	CANDID MOUTH PAINT	CLOTRIMAZOLE	1%W/W	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	ORAL TOPICAL LIQUIDS	1.0X15.0 ML BOTTLE	01/07/2000
2146	NDA/MAL/HDP/3 546	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENETRIM D.S	SULPHAMETHOX AZOLE + 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,1.0X10 00.0 TABLET CONTAINER	01/07/2013
2147	NDA/MAL/HDP/3 547	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	CORBIS-10	BISOPROLOL	10 MG	UNICHEM LABORATORIES LIMITED UNIT IIVILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2008

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2148	NDA/MAL/HDP/3 548	CIPLA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BECORT 200	BECLOMETASONE	200MCG/DOSE	CIPLA LTD.- PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER	01/07/2009
2149	NDA/MAL/HDP/3 549	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	TRIMEX PAEDIATRIC COUGH EXPECTORANT	CHLORPHENIRAM INE MALEATE+PSEUD O EPHEDRINE HCL+GUAIPHENISI N+MENTHOL	1.0MG+15.0MG+5 0.0MG+0.5MG / 5ML	REGAL PHARMACEUTICALS LIMITED PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2007
2150	NDA/MAL/HDP/3 551	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ZAHA-500MG	AZITHROMYCIN	500MG	AJANTA PHARMA LIMITEDPLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT- 392130 AJANTA PHARMA LIMITED PAITHANMANUFACT URING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER,1.0X10.0X1 .0X3.0 TABLET BLISTER	01/07/2009

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2151	NDA/MAL/HDP/3 553	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	FALCIMON 25/67.5 B/L	ARTESUNATE+AM ODIAQUINE	25MG+67.5MG	CIPLA LTD UNIT IIA- 42 MIDC PATALGANGA DISTRICT RAIGAD MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0 TABLET BLISTER,1.0X25.0X3 .0 TABLET BLISTER,1.0X25.0X6 .0 TABLET BLISTER	01/07/2014
2152	NDA/MAL/HDP/3 556	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	GRISACTIN-500 TABLETS	GRISEOFULVIN TABLETS	500MG	REGAL PHARMACEUTICALS LIMITED PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007
2153	NDA/MAL/HDP/3 558	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	SEROCORT 250	SALMETEROL+ FLUTICASONE PROPIONATE	25MCG + 250MCG	CIPLA LTD.- PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER	01/07/2009

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2154	NDA/MAL/HDP/3 561	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOCILLIN ORAL SUSPENSION	AMPICILLIN TRIHYDRATE	125MG/5ML	MILAN LABORATORIES (INDIA) PVT LTD PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1998
2155	NDA/MAL/HDP/3 566	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	ARTESUN	ARTESUNATE	60 MG	GUILIN PHARMACEUTICAL CO LTD-NO. 43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 1*5% NAHCO3 + 5 ML NACL INJECTION	01/07/2008
2156	NDA/MAL/HDP/3 571	CADILA PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	CADIPHEN EXPECTORANT	CHLORPHENIRAM INE/GUAIFENESIN /AMMONIUM CHLORIDE	2MG//80MG/100 MG	CADILA PHARMACEUTICALS LIMITED 1389, 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

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2157	NDA/MAL/HDP/3 573	VENUS REMEDIES LTD	REDDYS PHARMA LIMITED	PARIN-E	ENOXAPARIN SODIUM	40MG/0.4ML	VENUS REMEDIES LTD -UNIT II HILL TOP INDUSTRIAL ESTATE JHARMAJRI EPIP PHASE I BHATOLI KALAN BADDI (H.P)	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X2.0X0.4 ML PRE FILLED SYRINGE	01/07/2008
2158	NDA/MAL/HDP/3 574	CENTAUR PHARMACEUTICAL S PRIVATE LIMITED	GITTOES PHARMACEUTICAL S LIMITED	METOZ 2.5 TABLET	METOLAZONE TABLETS USP	2.5MG	CENTAUR PHARMA PVT.LIMITED-PLANT IPL0T3,TIVIM INDUSTRIAL ESTATE,KARASWAD A,MAPUSA GOA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2007
2159	NDA/MAL/HDP/3 575	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFIX 400 CAPSULES	CEFIXIME	400MG	PHARMA INTERNATIONAL CO.,AL-QASTAL AREA, AIRPORT ROAD, 11941, AMMAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X5.0 CAPSULE BLISTER	01/07/2007

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2160	NDA/MAL/HDP/3 577	ASTRA PHARMA (U) LTD	ASTRA PHARMA (U) LIMITED	METOCLOPRAMID E	METOCLOPRAMI DE	5MG/ML	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE,1.0X10.0 X10.0X2.0 ML AMPOULE	01/07/2009
2161	NDA/MAL/HDP/3 578	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CINNARON 25	CINNARIZINE	25MG	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2005
2162	NDA/MAL/HDP/3 580	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	FEXOFEN-120	FEXOFENADINE HYDROCHLORIDE	120MG	ARISTO PHARMACEUTICALS PVT LTD PLOT NO 208 NEW INDUSTRIAL AREA NO 11 MANDIDEEP	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X6.0 TABLET BLISTER	01/07/2008

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2163	NDA/MAL/HDP/3 581	CENTAUR PHARMACEUTICAL S PRIVATE LIMITED	GITTOES PHARMACEUTICAL S LIMITED	METZO 5	METOLAZONE	5MG	CENTAUR PHARMA PVT.LTD-PLANT IPLLOT 3,TIVIM INDUSTRIAL ESTATE,KARASWAD A,MAPUSA GOA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2007
2164	NDA/MAL/HDP/3 588	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	FEXOFEN-180	FEXOFENADINE	180MG	ARISTO PHARMACEUTICALS PVT LTD PLOT NO 208 NEW INDUSTRIAL AREA NO 11 MANDIDEEP	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X6.0 TABLET BLISTER	01/07/2008
2165	NDA/MAL/HDP/3 590	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	ALFOXAN 500 FC TABLETS	MEFENAMIC ACID	500MG	REMEDICA LIMITED LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2004

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2166	NDA/MAL/HDP/3 591	DAFRA PHARMA LTD	MULTIPHAR UGANDA LIMITED	ARTESIANE 80MG/ML	ARTEMETHER	80MG/ML	ANFARM HELLAS S.A.61ST KM. NATIONAL ROAD, ATHENS-LAMIA, 320 09 SCHIMATARI VIOTIAS - GREECE	GREECE	PARENTERAL ORDINARY I M AMPOULES	1.0X5.0X1.0 ML AMPOULE	01/07/1998
2167	NDA/MAL/HDP/3 592	FOURRTS (INDIA) LABORATORIES PUT LTD	DELMAW ENTERPRISES LIMITED	MEGATRIM DS	CO-TRIMOXAZOLE BP	960 MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDA LUR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2008
2168	NDA/MAL/HDP/3 593	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DROX 500	CEFADROXIL	500MG	AUROBINDO PHARMA LIMITED, FORMULATIONS UNIT-VI- R7AUROBINDO PHARMA LIMITED, FORMULATIONS UNIT-VI SY.NO.329/39 & 329/47 CHITKUL(V) PATANCHERU MANDAL, SANGA REDDY DISTTELANGANA502 307	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER,1.0X10.0X1 0.0 CAPSULE BLISTER	01/07/2007

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2169	NDA/MAL/HDP/3 594	CIRON DRUGS & PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	STERILE QUININE DIHYDROCHLORID E	QUININE DIHYDROCHLORID E	300MG/ML	CIRON DRUGS AND PHARMACEUTICALS PVT LIMITEDN-118, N119, N113, MIDC TARAPUR BOISAR DIST THANE 401506, INIDA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X2.0 ML AMPOULE	01/07/2007
2170	NDA/MAL/HDP/3 598	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
2171	NDA/MAL/HDP/3 600	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	P-ALAXIN TABLETS	DIHYDROARTEMI SININ + PIPERAQUINE PHOSPHATE	40MG + 320MG	BLISS GVS PHARMA LTD PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA- INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X9.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X12.0 TABLET BLISTER,1.0X15.0 TABLET BLISTER	01/07/2008

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2172	NDA/MAL/HDP/3 601	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	HYDROKANT	HYDROCORTISON E ACETATE	1%W/W	SKANT HEALTH CARE LTD 1802-1805 GIDC PHASE III VAPI GUJARAT	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2009
2173	NDA/MAL/HDP/3 603	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	VUMTREX SYRUP	LEVAMISOLE	40MG/5ML	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X30.0 ML BOTTLE	01/07/2003
2174	NDA/MAL/HDP/3 604	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	AC-FENAC	ACECLOFENAC	100MG	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILSHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008

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2175	NDA/MAL/HDP/3 607	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
2176	NDA/MAL/HDP/3 609	AMOUN PHARMACEUTICAL S COMPANY	BOOTS PHARMACEUTICAL S LIMITED	ANTINAL	NIFUROXAZIDE	200MG	AMOUN PHARMACEUTICALS COMPANY 1ST INDUSTRIAL ZONE EL BOUR CITY CAIRO EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X12.0 CAPSULE BLISTER,1.0X12.0 CAPSULE BLISTER	01/07/1997
2177	NDA/MAL/HDP/3 610	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PROMETHAZINE TABLETS BP 25MG	PROMETHAZINE HYDROCHLORIDE	25MG	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10 0.0 TABLET CONTAINER	01/07/1998

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2178	NDA/MAL/HDP/3 611	SHELYS PHARMACEUTICAL S LTD	BETA HEALTHCARE UGANDA LIMITED	COLDRIL SYRUP	PARACETAMOL + CHLORPHENIRAM INE + PSEUDOEPHEDRI NE	120MG+1MG+10M G	BETA HEALTHCARE INTERNATIONAL LIMITED-PLOT NUMBER LR 209/6554,MOGADIS HU ROAD,OFF LUNGA LUNGA ROAD INDUSTRIAL AREA, P.O.BOX 42569-00100 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2000
2179	NDA/MAL/HDP/3 612	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	LOSARTAS-H 12.5	LOSARTAN POTASSIUM + HYDROCHLOROT HIAZIDE	50MG + 12.5MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
2180	NDA/MAL/HDP/3 613	HETERO LABS LTD	AIVEEN (U) LIMITED	ZIDOVUDINE ORAL SOLUTION	ZIDOVUDINE	50MG/5ML	HETERO LABS LTD UNIT III22-110 IDA JEEDIMETIA HYDERABAD ANDHRA PRADESH ,	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X240.0 ML BOTTLE	01/07/2013

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2181	NDA/MAL/HDP/3 614	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	ERYTHROREN SUSPENSION	ERYTHROMYCIN STEARATE	125MG/5ML	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2008
2182	NDA/MAL/HDP/3 618	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	CLOXACILLIN SODIUM	CLOXACILLIN SODIUM	500MG	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTD NO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSH OP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0 VIAL CARTON, 1.0X10.0 VIAL CARTON	01/07/2011
2183	NDA/MAL/HDP/3 619	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	CAPTOPRIL DENK - 25	CAPTOPRIL	25MG	DENK PHARMA, GOLLSTR.,1-D-845 529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER, 2.0X10.0 TABLET BLISTER, 1.0X10.0 TABLET BLISTER	01/07/2000

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2184	NDA/MAL/HDP/3 620	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
2185	NDA/MAL/HDP/3 622	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PROXIMEXA	CEFUROXIME AXETIL	125MG/5ML	GLAXOSMITHKLINE UK LTDHARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X50.0 ML BOTTLE	01/07/2008
2186	NDA/MAL/HDP/3 626	ZYDUS LIFESCIENCES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ORIPHEX CAPSULES	CEPHALEXIN	250MG	SPARSH BIO-TECH LTD PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006 SAKAR HEALTHCARE LIMITED BLOCK NO. 10-13, SARKHEJ- BAVLA HIGHWAY, VILL: CHANGODAR, DIST: AHMEDABAD- 382213, GUJARAT – INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1997

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2187	NDA/MAL/HDP/3 628	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	CELEMIN 5S	AMINO ACIDS/SORBITOL	5%W/V+5%W/V	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTDVILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X500.0 ML BOTTLE	01/07/2001
2188	NDA/MAL/HDP/3 630	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	UNICONTIN 600	THEOPHYLLINE	600MG	MODI MUNDIPHARMA (PVT) LTDMEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
2189	NDA/MAL/HDP/3 631	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	ENA-DENK 10	ENALAPRIL MALEATE	10MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008

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2190	NDA/MAL/HDP/3 634	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOPLUS	PARACETAMOL+D EXTROMETHORP HAN HCL+ CHLORPHENIRAM INE+PHENYLEPHR INE HCL	500MG+15MG+2M G+10MG	AGOG PHARMA LTD PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2008
2191	NDA/MAL/HDP/3 635	CIRON DRUGS & PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	CIROGAN	PROMETHAZINE HYDROCHLORIDE	25MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE	01/07/2011
2192	NDA/MAL/HDP/3 637	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	TINODERM	MULTI- INGREDIENT	MULTI- INGREDIENT	NEM LABORATORIES PVT LTD 133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X18.0 G TUBE	01/07/1997

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2193	NDA/MAL/HDP/3 639	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PANADOL ADVANCE	PARACETAMOL	500MG	GLAXOSMITHKLINE DUNGARAVAN LTDKNOCKBRACK DUNGARVAN CO. WATERFORD	IRELAND	ORAL SOLID ORDINARY TABLETS	1.0X11.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER,1.0X2.0X10 .0 TABLET BLISTER	01/07/2010
2194	NDA/MAL/HDP/3 641	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	TRD-CONTIN 100	TRAMADOL HYDROCHLORIDE	100MG	MODI MUNDIPHARMA (PVT) LTDMEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2009
2195	NDA/MAL/HDP/3 642	IND-SWIFT	PLANET PHARMACEUTICAL S UGANDA LTD	CLARIE 250	CLARITHROMYCIN	250MG	IND-SWIFT- LTD,GLOBAL BUSINESS UNIT, JAWAHARPUR, OFF NH-21 DERABASSI	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X2.0X7.0 TABLET BLISTER	01/07/2007

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2196	NDA/MAL/HDP/3 647	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	NYSTAGO ORAL SUSPENSION	NYSTATIN	100000 IU	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL TOPICAL SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2008
2197	NDA/MAL/HDP/3 648	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	UNICONTIN 400	THEOPHYLLINE	400MG	MODI MUNDIPHARMA (PVT) LTD MEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
2198	NDA/MAL/HDP/3 649	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	LAMISIL	TERBINAFINE	125MG	NOVARTIS BARBERA SPAIN	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/1997

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2199	NDA/MAL/HDP/3 650	AMOUN PHARMACEUTICAL S COMPANY	BOOTS PHARMACEUTICAL S LIMITED	ANTINAL	NIFUROXAZIDE	220MG/5ML	AMOUN PHARMACEUTICALS COMPANY1ST INDUSTRIAL ZONE EL OBOUR CITY, CAIRO EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2011
2200	NDA/MAL/HDP/3 651	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ORIPHEX SYRUP	CEPHALEXIN	125MG/5ML	SPARSH BIO-TECH LTD PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006 SAKAR HEALTHCARE LIMITED BLOCK NO. 10-13, SARKHEJ- BAVLA HIGHWAY, VILL: CHANGODAR, DIST: AHMEDABAD- 382213, GUJARAT – INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997
2201	NDA/MAL/HDP/3 653	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN	ARTEMETHER + LUMEFANTRINE	80 MG + 480 MG	AJANTA PHARMA LIMITED PLOT NO.Z/103/A, DAHEJ SEZ PART 11, DISTRICT: BHARUCH, GUJARAT- 392130 AJANTA PHARMA LIMITED PAITHAN MANUFACT URING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER (WITH AMFM LOGO), 1.0X6.0 TABLET BLISTER (WITHOUT AMFM LOGO), 30.0X1.0X6. 0 TABLET BLISTER (WITH AMFM LOGO), 30.0X1.0X6. 0 TABLET BLISTER (WITHOUT AMFM LOGO)	01/07/2008

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2202	NDA/MAL/HDP/3 655	FOURRTS (INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	QUADRAJEL GEL	CHLORHEXIDINE+ METRONIDAZOLE +LIDOCAINE	5%W/W+1.61%W/ W+2.13%W/W	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDA LUR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X15.0 G TUBE	01/07/2008
2203	NDA/MAL/HDP/3 656	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	LUMERAX	ARTEMETHER / LUMEFANTRINE	80MG/480MG	IPCA LABORATORIES LTD,- SEJAVTA,RATLAM 457-002 REG.OFF.48 KANDIVLI IND.ESTATE MUMBAI 400067	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X6.0 TABLET BLISTER	01/07/2011
2204	NDA/MAL/HDP/3 657	DAWA LIMITED	SUPER MEDIC LTD	DAWASTIN	NYSTATIN	100000IU/ML	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2009

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2205	NDA/MAL/HDP/3 664	MACK BROWN PHARMACEUTICAL S PVT LIMITED	SHURIK LTD	AZZY	AZITHROMYCIN	500MG	TORQUE PHARMACEUTICALS PVT LTDISAAPUR P.O DAPPAR 140056 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER	01/07/2011
2206	NDA/MAL/HDP/3 666	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICAL S LIMITED	STROM 50	TRAMADOL HYDROCHLORIDE	50MG	LINCOLN PHARMACEUTICAL LIMITEDTRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2008
2207	NDA/MAL/HDP/3 668	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	AUGMENTIN BD	AMOXICILLIN + CLAVULANIC ACID	200 MG/ 5 ML + 28.5 MG/ 5 ML	GLAXO WELLCOME PRODUCTIONZI DE LA PEYENNIERE, 53100, MAYENNE	FRANCE	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X70.0 ML BOTTLE,1.0X140.0 ML BOTTLE	01/07/1998

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2208	NDA/MAL/HDP/3 669	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	CO-TRIMOXAZOLE	SULFAMETHOXAZ OLE/TRIMETHOPR IM	200MG/40MG	MEDICAMEN BIOTECH LTD - SP- 1192 A&B PHASE IV INDUSTRIAL AREA BHIWADI 301019 DIST. ALWAR (RAJASTHAN) - INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2014
2209	NDA/MAL/HDP/3 670	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	TETRAREN CAPSULES	TETRACYCLINE HYDROCHLORIDE	250MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X10. 0X10.0 CAPSULE BLISTER	01/07/2000
2210	NDA/MAL/HDP/3 671	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	CLAVULIN TABLETS	AMOXICILLIN + CLAVULANIC ACID	500 MG + 125 MG	SMITHKLINE BEECHAM PHARMACEUTICALS, CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X14.0 TABLET STRIP,10.0X10.0 TABLET STRIP,1.0X20.0 TABLET STRIP	01/07/2003

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2211	NDA/MAL/HDP/3 672	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	NITROCONTIN 6.4	NITROGLYCERIN	6.4MG	MODI MUNDIPHARMA (PVT) LTDMEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID ORDINARY SUBLINGUAL TABLETS	1.0X25.0 TABLET CONTAINER	01/07/2008
2212	NDA/MAL/HDP/3 674	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	INTAMINE SYRUP	PROMETHAZINE HYDROCHLORIDE	5MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X5.0 L JERRYCAN	01/07/1997
2213	NDA/MAL/HDP/3 677	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	IBUREN	IBUPROFEN	200MG	RENE INDUSTRIES LTD680,KAMULI,KIR EKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008

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2214	NDA/MAL/HDP/3 678	FOURRTS LABORATORIES LTD	DELMAW ENTERPRISES LIMITED	REDINPLUS	IRON PENTACARBONYL + ZINC SULPHATE MONOHYDRATE + FOLIC ACID + SODIUM SELENITE + LYSINE HYDROCHLORIDE + HISTIDINE HYDROCHLORIDE + CHOLINE BITARTRATE	100MG + 30MG + 7.5MG + 0.11MG + 26MG + 4.4MG + 52MG	FOURRTS (INDIA) LABS PVT LTD .VANDALUR ROAD. KELAMBAKK AM- 603103 TAMIL, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X30.0 CAPSULE BLISTER	01/07/2008
2215	NDA/MAL/HDP/3 681	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEDOL	PARACETAMOL	500MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER, 1.0X1000.0 TABLET CONTAINER	01/07/2000
2216	NDA/MAL/HDP/3 683	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	COLD TABS FORTINSA	PARACETAMOL + PHENYLEPHRINE +CHLORPHENIR AMINE + 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

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2217	NDA/MAL/HDP/3 685	GALPHAR LABORATORIES LTD	DAWASANA PHARMACEUTICAL S LTD	ODICEF	CEFTRIAZONE	1G	ALKEM LABORATORIES LIMITED.VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205INJECT CARE PARENTERALS PVT LTDPLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2013
2218	NDA/MAL/HDP/3 686	ACINO PHARMA AG -	LABOREX UGANDA LIMITED	NEURORUBINE™- FORTE 20 FILM- COATED TABLETS	MULTIVITAMIN	MULTINGREDIENT	ACINO PHARMA AGBIRSWEG 2, 4253, LIESBERG - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X100.0X 10.0 TABLET BLISTER	01/07/1997
2219	NDA/MAL/HDP/3 687	DAWA LIMITED	SUPER MEDIC LTD	DAWA-PROM	PROMETHAZINE HCL	5MG/5ML	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE	01/07/2010

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2220	NDA/MAL/HDP/3 688	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	NEUTRAFLUX MINT FLAVOUR	ALGNIC ACID + MAGNESIUM HYDROXIDE +ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE + SIMETHICONE	200MG +250MG + 250MG + 250MG + 125MG	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE,1.0X30.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2013
2221	NDA/MAL/HDP/3 698	CADILA HEALTHCARE PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	HIPEN SYRUP	AMOXICILLIN	125MG/5ML	SPARSH BIO-TECH LTD PLOT NO. 1, SURVEY NO. 42/243/244, VILLAGE LAKHABAVAD POST KHODIYAR COLONY DISTRICT, JAMNAGAR – 361006 GUJARAT INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997
2222	NDA/MAL/HDP/3 699	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SINOPRIL 5MG TABLETS	LISINOPRIL	5MG	GLOBAL NAPI PHARMACEUTICALS - 2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2005

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2223	NDA/MAL/HDP/3 702	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORFIT-20	ATORVASTATIN	20MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2005
2224	NDA/MAL/HDP/3 703	REGAL PHARMACEUCALS LTD	REGAL PHARMA (U) LTD	SONATEC	CETYLPYRIDINIU M CHLORIDE	0.05%W/V	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL TOPICAL LIQUIDS	1.0X250.0 ML BOTTLE	01/07/2014
2225	NDA/MAL/HDP/3 705	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

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2226	NDA/MAL/HDP/3 707	INTAS PHARMACEUTICAL S LIMITED	NORVIK ENTERPRISES LIMITED	OBETAS-120	ORLISTAT	120MG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI- 248197,DEHRADUN UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2010
2227	NDA/MAL/HDP/3 709	MEDICAL UNION PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	NIGHT & DAY -N	PARACETAMOL/ DIPHENHYDRAMINE CHLORIDE + PARACETAMOL/ PSEUDOEPHEDRI NE	500MG/ 25MG +600MG/ 90MG	MEDICAL UNION PHARMA .COABU- SULTAN ISMAILIA EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2010
2228	NDA/MAL/HDP/3 710	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LACILLIN	AMPICILLIN	250MG	LABORATORY & ALLIED LTD-PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/1997

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2229	NDA/MAL/HDP/3 711	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	POLY-MXB	POLYMYXIN B	500,000 UNITS	BHARAT SERUMS AND VACCINES LIMITED,PLOT NO. K- 27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X5.0 ML VIAL	01/07/2013
2230	NDA/MAL/HDP/3 712	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	AMLOZAAR	LOSARTAN POTASSIUM / AMLODIPINE	50MG + 5MG	MICRO LABS LTD92,SIPCOT INDUSTRIAL COMPLEX,HOSUR- 635-126(T.N)INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2010
2231	NDA/MAL/HDP/3 714	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	ADALAT LA	NIFEDIPINE	30MG	BAYER PHARMA AGD-51368 LEVERKUSEN, GERMANY	GERMANY	ORAL SOLID RETARD FILM- COATED TABLETS	2.0X14.0 TABLET BLISTER,3.0X10.0 TABLET BLISTER	01/07/2001

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2232	NDA/MAL/HDP/3 717	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	CEFTRIAZONE SODIUM	CEFTRIAZONE SODIUM	1G	CSPC ZHONGNUO PHARMACEUTICALS LTDNO. 88, YANGZI ROAD, SHIJIAZHUANG CITY CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL,1.0X10.0X1.0 G VIAL	01/07/2011
2233	NDA/MAL/HDP/3 723	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	LACILLIN	AMPICILLIN	125MG/5ML	LABORATORY & ALLIED LTD-PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X100.0 ML BOTTLE	07/07/1997
2234	NDA/MAL/HDP/3 724	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	EPIGAB	PREGABALIN	150MG	DAR AL DAWANA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X14.0 CAPSULE BLISTER	01/07/2015

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2235	NDA/MAL/HDP/3 725	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	NEW TUXIRIL	DEXTROMETHOR PHAN HBR + PHENYLEPHRINE HCL + MENTHOL	10MG/ML + 5MG/10ML + 5MG/10ML	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2007
2236	NDA/MAL/HDP/3 728	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DICLO-DENK 50	DICLOFENAC SODIUM	50MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	10.0X10.0 TABLET BLISTER + 1 * 10 SAMPLE	01/07/1998
2237	NDA/MAL/HDP/3 729	MEDLEY PHARMACEUTICAL S	EUROPA HEALTHCARE (U) LTD	DECIFEN-SR	DICLOFENAC SODIUM	100MG	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID RETARD ENTERIC- COATED TABLETS	1.0X10.0X20.0 TABLET STRIP,1.0X3.0X10.0 TABLET STRIP	01/07/2008

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2238	NDA/MAL/HDP/3 730	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	AVELOX	MOXIFLOXACIN HYDROCHLORIDE	400MG	BAYER PHARMA AG 51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	2.0X5.0 TABLET BLISTER,1.0X5.0 TABLET BLISTER	01/07/2001
2239	NDA/MAL/HDP/3 732	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	ALBASOL TABLETS 200MG	ALBENDAZOLE	200MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET STRIP	01/07/2003
2240	NDA/MAL/HDP/3 734	XEPA-SOUL PATTINSON	DELMAW ENTERPRISES LIMITED	ZARICORT CREAM	MICONAZOLE + HYDROCORTISON E	2%W/W + 1%W/W	XEPA SAUL PATTINSON MALAYSIA1-5 INDUSTRIAL ESTATE 75250 MELAKA MALYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1998

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2241	NDA/MAL/HDP/3 736	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
2242	NDA/MAL/HDP/3 737	MEDLEY PHARMACEUTICAL S 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	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
2243	NDA/MAL/HDP/3 738	KARNATAKA ANTIBIOTICS & PHARMACEUTICAL S LTD	TATA UGANDA LIMITED	AMPICILLIN SODIUM	AMPICILLIN SODIUM	500MG	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD #14, II PHASE PIA, BANGALORE 560058	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X500.0 MG VIAL,1.0X50.0X500. 0 MG VIAL	01/07/2010

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2244	NDA/MAL/HDP/3 741	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	ACTIZINE	CETIRIZINE HYDROCHLORIDE	10MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD PLOT M 444B STRETCHER ROAD NTINDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X15.0X10.0 TABLET BLISTER	01/07/2006
2245	NDA/MAL/HDP/3 744	ABBOTT HEALTHCARE PRODUCTS B.V.	HARLEYS UGANDA LIMITED	DUPHALAC SOLUTION	LACTULOSE	67G/100ML	ABBOTT BIOLOGICALS B.V ABBOTT BIOLOGICALS B.V VEERWEG 12 8121 AA OLST	NETHERLANDS	ORAL LIQUID ORDINARY LIQUIDS	1.0X200.0 ML BOTTLE, 1.0X10.0X1 5.0 ML BOTTLE	01/07/2001
2246	NDA/MAL/HDP/3 745	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	WINDERM CREAM	BECLOMETHASON E+MICONAZOLE+ NEOMYCIN	0.025%W/W + 2%W/W + 0.5%W/W	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	01/07/2008

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2247	NDA/MAL/HDP/3 746	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	BENDRO	BENDROFLUMET HIAZIDE	5MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2011
2248	NDA/MAL/HDP/3 747	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	ALZOL TABLETS	ALBENDAZOLE	200MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	30.0X2.0 TABLET BLISTER	01/07/2002
2249	NDA/MAL/HDP/3 753	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	MYFORTIC 180	MYCOPHENOLAT E SODIUM	180MG	NORVATIS PHARMA STEIN AGSCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND NORVATIS PHARMA PRODUCTIONS GMBH, WEHROEFLINGER STR. 4479664 WEHR GERMANY	SWITZERLAND GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X12.0X10.0 TABLET BLISTER	01/07/2006

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2250	NDA/MAL/HDP/3 754	CENTAUR PHARMACEUTICAL S PRIVATE LIMITED	GITTOES PHARMACEUTICAL S LIMITED	SINAREST PD NASAL DROPS	OXYMETAZOLINE HYDROCHLORIDE	0.025%W/V	CENTAUR PHARMACEUTICALS LTD PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	NASAL TOPICAL DROPS	1.0X10.0 ML BOTTLE	01/07/2006
2251	NDA/MAL/HDP/3 757	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNITRIM SUSPENSION	CO-TRIMOXAZOLE	240MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA, NAIROBI, K ENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE, 1.0X60.0 ML BOTTLE	01/07/1997
2252	NDA/MAL/HDP/3 760	AFRICURE PHARMACEUTICAL S (INDIA) PRIVATE LIMITED	AFRICURE PHARMACEUTICAL S U LIMITED	COMPOUND MAGNESIUM TRISILICATE	MAGNESIUM TRISILICATE	370MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED PLOT 9- 12, DEWAN & SONS INDL. AREA, VEOOR, PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X1000.0 TABLET CONTAINER	01/07/1997

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2253	NDA/MAL/HDP/3 761	COSMOS LTD	ASTRA PHARMA (U) LIMITED	RIFACOS-300	RIFAMPICIN	300 MG	COSMOS LIMITEDRANGWE ROAD, OFF LUNGA ROAD - INDUSTRIAL AREA NAROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/1997
2254	NDA/MAL/HDP/3 765	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ALPRIM	CO-TRIMOXAZOLE	480MG	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1997
2255	NDA/MAL/HDP/3 766	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	BUKOL TABLETS	HYOSCINE N- BUTYLBROMIDE	10MG	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997

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2256	NDA/MAL/HDP/3 767	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	AMPOXIN 500	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	UNICHEM LABORATORIES LIMITED UNIT IIVILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER	01/07/1999
2257	NDA/MAL/HDP/3 768	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	NIMOTOP 30MG	NIMODIPINE	30MG	BAYER PHARMA AG 51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
2258	NDA/MAL/HDP/3 770	AMOUN PHARMACEUTICAL S COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	XITHRONE	AZITHROMYCIN	500 MG	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY, CAIRO EGYPT	EGYPT	ORAL SOLID ORDINARY COATED TABLETS	1.0X1.0X5.0 TABLET BLISTER	01/07/2005

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2259	NDA/MAL/HDP/3 771	FAES FARMA S.A	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	BRONQUIDIAZINA C.R	TRIMETHOPRIM/S ULFAMETHOXAZO LE/BROMHEXINE/ SODIUM BENZOATE/TOLU BALSAM	80MG/400MG/4M G/250MG/325MG	FAES FARMA, S.A MAXIMO AGUIRRE, 14, LEJONA 48940 VIZCAYA	SPAIN	ORAL LIQUID ORDINARY LIQUIDS	1.0X150.0 ML BOTTLE	01/07/2014
2260	NDA/MAL/HDP/3 772	ELI-LILLY (SUISSE) SA	LABOREX UGANDA LIMITED	HUMULIN N NPH	HUMAN INSULIN ISOPHANE	100IU	LILLY EGYPT S.A.E. & ELI LILLY AND COMPANY LILLY TECHNOLOGY CENTRE INDIANAPOLIS,INDIA NA 46285 USA	UNITED STATES	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE	01/07/2005
2261	NDA/MAL/HDP/3 773	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOBUTOL-4	SALBUTAMOL SULPHATE	4 MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10 0.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2005

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2262	NDA/MAL/HDP/3 778	AMOUN PHARMACEUTICAL S COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	XITHRONE	AZITHROMYCIN	200MG/5ML	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL BOUR CITY, CAIRO EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X15.0 ML BOTTLE	01/07/2004
2263	NDA/MAL/HDP/3 781	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ALZENTAL	ALBENDAZOLE	20MG/ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X20.0 ML BOTTLE	01/07/2014
2264	NDA/MAL/HDP/3 782	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LAE-PEN V	PHENOXYMETHYL PENICILLIN	250MG	LABORATORY & ALLIED LTD-PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1997

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2265	NDA/MAL/HDP/3 784	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	CIPIUM	CHLORPHENIRAM INE	2MG/5ML	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2011
2266	NDA/MAL/HDP/3 787	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPENIV	PHENOXYMETHYL PENICILLIN	125MG/5ML	SPARSH BIO-TECH PVT. LTD .PLOT NO. 1, SURVEY NO. 42/243/244, VILLAGE LAKHABAVAD POST KHODIYAR COLONY DISTRICT, JAMNAGAR – 361006 GUJARAT INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2004
2267	NDA/MAL/HDP/3 789	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	LEVITRA	VARDENAFIL HCL	5MG	BAYER PHARMA AG 51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2005

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2268	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
2269	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
2270	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. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2005

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2271	NDA/MAL/HDP/3 798	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEUROTON TABLET	MULTI- INGREDIENT	N/A	AMOUN PHARMACETICAL COMPANY-1ST INDUSTRIAL ZONE, EL OBOUR CITY, CAIRO, EGYPT	EGYPT	ORAL SOLID ORDINARY COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2004
2272	NDA/MAL/HDP/3 801	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	FUNGISTIN ORAL SUSPENSION	NYSTATIN	100000 IU/ML	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2002
2273	NDA/MAL/HDP/3 802	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	LEVITRA 10MG	VARDENAFIL MONOHYDROCHL ORIDE TRIHYDRATE	10 MG	BAYER PHARMA AG 51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2005

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2274	NDA/MAL/HDP/3 803	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	DICLODYNE SUPPOSITORY	DICLOFENAC SODIUM	100MG	BLISS GVS PHARMA LTD PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA- INDIA	INDIA	RECTAL SYSTEMIC ADULT SUPPOSITORIES	1.0X5.0 SUPPOSITORY BLISTER	01/07/2007
2275	NDA/MAL/HDP/3 804	ACINO PHARMA AG	LABOREX UGANDA LIMITED	NEURORUBINE IM	VITAMIN B1+VITAMIN B6+VITAMIN B12	100MG+100MG+1 MG	MERCKLE GMBH (A MEMBER OF RATIOPHARM GROUP)LUDWIG MERCKLE STR. 3, 89143 BLAUBEUREN WEILER HAUPT PHARMA WULFING GMBH.BETHELNER LANDSTR. 18, 31028 GRONAU/LEINE	SWITZERLAND GERMANY	PARENTERAL ORDINARY I M AMPOULES	1.0X5.0X3.0 ML AMPOULE	01/07/1997
2276	NDA/MAL/HDP/3 806	INDOCO REMEDIES LTD	STAR PHARMACEUTICAL S LTD	NOCID GEL	ALUMINIUM HYDROXIDE + SIMETHICONE + MAGNESIUM	400MG/5ML + 25MG/5ML + 100MG/5ML	INDOCO REMEDIES LTDB-20, MIDC, WALUJ, AURANGABAB 431136 INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X20 0.0 ML BOTTLE	01/07/2007

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2277	NDA/MAL/HDP/3 807	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	ARTEMETHER INJECTION	ARTEMETHER	80MG/ML	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	CHINA INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE	01/07/2008
2278	NDA/MAL/HDP/3 808	NORVATIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN SUPPOSITORIES 12.5MG	DICLOFENAC SODIUM	12.5MG	DELPHARM HUNINGUE S.A.S- SITE INDUSTRIAL HUNINGUE26, RUE DE LA CHAPELLE, F- 68330, HUNINGUE	FRANCE	RECTAL SYSTEMIC PAEDIATRIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY STRIP	01/07/2006
2279	NDA/MAL/HDP/3 809	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	COLDRID DAY & NIGHT	PARACETAMOL+C HLORPHENIRAMI NE MALEATE+PHENY LEPRINE HYDROCHLORIDE + CAFFEINE	500MG+2MG+5M G+15MG	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X9.0X10.0 TABLET STRIP	01/07/2006

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2280	NDA/MAL/HDP/3 812	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	B-TONE	PHENOBARBITON E	30MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0 TABLET BLISTER	01/07/1997
2281	NDA/MAL/HDP/3 813	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	ACTIPAR	PIPERAZINE CITRATE	500MG/5ML	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X30.0 ML BOTTLE	01/07/1997
2282	NDA/MAL/HDP/3 814	MARTINDALE PHARMACEUTICAL S 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

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2283	NDA/MAL/HDP/3 817	ROYAL PHARMA	ROYAL PHARMA 2011 LIMITED	BENZYL PENICILLIN INJECTION	BENZYL PENICILLIN SODIUM	1000000 I.U	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTDNO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSH OP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 MU VIAL	01/07/2002
2284	NDA/MAL/HDP/3 818	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
2285	NDA/MAL/HDP/3 823	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	D-WORM ORAL SUSPENSION	ALBENDAZOLE	200MG/5ML	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	01/07/2009

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2286	NDA/MAL/HDP/3 825	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	UMOXIL 250	AMOXICILLIN	250MG	UNI MEDICOLABS. 21-22 PHARMACITY SELAQUI DEHRADUN 248197	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2015
2287	NDA/MAL/HDP/3 827	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORFIT-10	ATORVASTATIN	10MG	AJANTA PHARMA LIMITED PAITHANMANUFACT URING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2005
2288	NDA/MAL/HDP/3 829	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	BETACOOOL	DRIED ALUMINUM HYDROXIDE/MAG NESIUM HYDROXIDE /MAGNESIUM ALUMINUM SILICATE/SIMETHI CANE	300MG / 25MG / 50MG / 25MG	BETA HEALTHCARE INTERNATIONAL LTD - PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X50.0 TABLET STRIP	01/07/2006

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2289	NDA/MAL/HDP/3 831	ABBVIE (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	ALUVIA	LOPINAVIR+RITO NAVIR	200MG+50MG	ABBVIE DEUTSCHLAND GMBH & CO. KG.KNOLLSTASSE 50, D-67061, LUDWIGSHAFEN, GERMANY.	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X120.0 TABLET CONTAINER	01/07/2007
2290	NDA/MAL/HDP/3 833	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	LABSTATIN VAGINAL TABLETS	NYSTATIN	100.000 I.U	LABORATORY & ALLIED LTD.PLOT 209/10349 OFF MOMBASA RD NAIROBI	KENYA	VAGINAL TABLETS	1.0X3.0X5.0 PESSARY STRIP (WITH APPLICATOR)	01/07/2000
2291	NDA/MAL/HDP/3 835	GLAXOSMITHKLINE LTD	BETA HEALTHCARE UGANDA LIMITED	HEDEX CAPLETS	PARACETAMOL+A SPIRIN+CAFFEINE ANHYDROUS	200MG+400MG+5 OMG	SMITHKLINE BEECHAM (NAIROBI)NAIROBI, KENYA DINLAS PHARMA EPZ LIMITEDPLOT NO. LR 7149/121, MOMBASA ROAD, SYOKIMAU BETA HEALTHCARE INTERNATIONAL LTD - PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X20.0 TABLET PACK,1.0X110.0 TABLET PACK,1.0X100.0 TABLET PACK	01/07/1997

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2292	NDA/MAL/HDP/3 837	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,1.0X10 00.0 TABLET CONTAINER	01/07/1998
2293	NDA/MAL/HDP/3 839	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLURID	ACETAMINOPHEN + PHENIRAMINE MALEATE	500 MG + 10.5 MG	KAMPALA PHARMACEUTICALS INDUSTRIES PLOT M 444B STRETCHER NTINDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X4.0 TABLET BLISTER	01/07/2006
2294	NDA/MAL/HDP/3 840	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	TORACTIN TABLETS	CYPROHEPTADIN E	4MG	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	2.0X50.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2000

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2295	NDA/MAL/HDP/3 841	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	MEGATRIM TABLETS	CO-TRIMOXAZOLE	480MG	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED VANDALUR ROAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997
2296	NDA/MAL/HDP/3 844	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN RETARD	DICLOFENAC SODIUM	100MG	NOVARTIS PHARMA STEIN AG- SCHAFFHARVSERTRA SSE CH-4332 STEIN SWITZERLAND. NORVATIS FARMA SPA--VIA PROVINCIALE SCHITO, 131 1- 80052, TORRE ANNUNCIATA (NA) ITALY	SWITZERLAND ITALY	ORAL SOLID RETARD TABLETS	1.0X30.0 TABLET CONTAINER	01/07/1997
2297	NDA/MAL/HDP/3 845	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	CARDIPAC	AMLODIPINE	5MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2011

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2298	NDA/MAL/HDP/3 846	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	LEVITRA	VARDENAFIL HCL	20 MG	BAYER PHARMA AG 51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2005
2299	NDA/MAL/HDP/3 850	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	ANGIZAAR-H	LOSARTAN POTASSIUM + HYDROCHLOROT HIAZIDE	50MG + 12.5MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2009
2300	NDA/MAL/HDP/3 854	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	LOSARTAS 50 TABLETS	LOSARTAN POTASSIUM	50MG	INTAS PHARMACEUTICALS LTDCAMP ROAD SELAQUI DEHRADUN	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER	01/07/2003

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2301	NDA/MAL/HDP/3 859	UNIQUE PHARMACEUTICAL S LABORATORIES	PLANET PHARMACEUTICAL S UGANDA LTD	IFIMOL	PARACETAMOL	10MG/ML	UNIQUE PHARMACEUTICAL LABORATORIES- PLOT NO. 4 PASE IV, GIDC PANOLI -394 116 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2011
2302	NDA/MAL/HDP/3 860	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOLAC	LACTULOSE	3.35MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. 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
2303	NDA/MAL/HDP/3 862	TORRENT PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S LTD.	LAMITOR 100	LAMOTRIGINE	100MG	TORRENT PHAMACEUTICALS LTD TORRENT PHAMACEUTICALS LTD INDRAD 382721 DIST MEHSANA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008

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2304	NDA/MAL/HDP/3 866	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	RL	COMPOUND SODIUM LACTATE INFUSION BP	0.6/ 0.25 /0.04 / 0.027 % W/V	ABACUS PARENTERAL DRUGS LTD.PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X250.0 ML BOTTLE,1.0X500.0 ML BOTTLE	01/07/2010
2305	NDA/MAL/HDP/3 867	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	BETADERM OINTMENT	BETAMETHASONE VALERATE	0.1%W/W	ATCO LABORATORIES PVT LTDB-18,S.I.T.E KARACHI 75700, PAKISTAN	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X5.0 G TUBE	01/07/1997
2306	NDA/MAL/HDP/3 871	INTAS PHARMACEUTICAL S LIMITED	NORVIK ENTERPRISES LIMITED	DOVERIN 40	DROTAVERINE HYDROCHLORIDE	40MG	INTAS PHARMACEUTICALS LIMITEDPLOT NO. 457 / 458 SARKHEJ-BAVLA HIGHWAY, MATODA - 382 210, TALUKA - SANAND, DISTRICT - AHMEDABAD, STATE -	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008

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2307	NDA/MAL/HDP/3 872	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	ZYNCET SYRUP	CETIRIZINE HYDROCHLORIDE	5MG/5ML	THE MADRAS PHARMACEUTICALS- 137-B OLD MAHABALIPURAM ROAD KARAPAKKAM CHENNAI 600 096	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE	01/07/2006
2308	NDA/MAL/HDP/3 873	CIRON DRUGS & PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	CHLORPROMAZIN E INJECTION B.P	CHLORPROMAZIN E	25MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE	01/07/2011
2309	NDA/MAL/HDP/3 874	AJANTA PHARMA LTD 31-0	ABACUS PHARMA (AFRICA) LIMITED	RIDMAL 40/320	DIHYDROARTEMI SININ + PIPERAQUINE	40MG + 320MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X12.0 TABLET BLISTER,1.0X1.0X3. 0 TABLET BLISTER,1.0X1.0X8. 0 TABLET BLISTER,1.0X1.0X9. 0 TABLET BLISTER,1.0X1.0X6. 0 TABLET BLISTER	01/07/2010

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2310	NDA/MAL/HDP/3 875	PHAMA INTERNATIONAL CO	OMAB UGANDA LIMITED	OPTIMAL(0.05% GEL	TRETINOIN USP	0.25MG/1G	PHARMA INTERNATIONAL COMPANY .MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN	JORDAN	TOPICAL EXTERNAL GELS AND SOLS	1.0X1.0X30.0 G TUBE	01/07/2005
2311	NDA/MAL/HDP/3 881	MEDICAL UNION PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	MOXACIL	AMOXYCILLIN TRIHYDRATE	125MG/5ML	MEDICAL UNION PHARMA .COABU- SULTAN ISMAILIA EGYPT	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2009
2312	NDA/MAL/HDP/3 883	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	MYFORTIC 360	MYCOPHENOLAT E SODIUM	360MG	NOVARTIS PHARMA STEIN AGSCHAFFHARVSE TRASSE CH-4332 STEIN SWITZERLAND.	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X12.0X10.0 TABLET BLISTER	01/07/2006

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2313	NDA/MAL/HDP/3 886	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	DELOR	CLOBETASOL PROPIONATE	0.5 MG/G	PHARMA INTERNATIONAL COMPANY MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE	01/07/2004
2314	NDA/MAL/HDP/3 888	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	PYRIREN	PYRIDOXINE HYDROCHLORIDE	25MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10. 0X10.0 TABLET BLISTER	01/07/2014
2315	NDA/MAL/HDP/3 891	PHARMATHEN S.A	GOODMAN INTERNATIONAL LTD	LADININ	CIPROFLOXACIN	500MG	PHARMATHEN S.A- 6, DERVENAKION STR .153 51, PALLINI, AHICA GREECE	GREECE	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/1997

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2316	NDA/MAL/HDP/3 892	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	TETRAX	LEVAMISOLE HYDROCHLORIDE	40MG/5ML	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X15.0 ML BOTTLE	01/07/1997
2317	NDA/MAL/HDP/3 893	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	EPINEPHRINE INJECTION USP	EPINEPHRINE HCL	1MG/ML	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	CHINA INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2008
2318	NDA/MAL/HDP/3 896	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	VALCONTIN 500	SODIUM VALPROATE (CONTROLLED RELEASE)	500MG	MODI MUNDIPHARMA PVT. LTDMEERUT- MUZAFFARNAGAR ROAD, MODIPURAM – 250110 UTTAR PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	01/07/2010

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2319	NDA/MAL/HDP/3 897	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	CLAVODAR	AMOXICILLIN/CLA VULANIC ACID	875MG/125MG	DAR AL DAWANA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2010
2320	NDA/MAL/HDP/3 899	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	FEDATE SYRUP	SODIUM FEREDTATE + PYRIDOXINE + CYANOCOBALAMI N + FOLIC ACID	216.87MG + 1.5MG + 7.5MCG + 1.5MG	AJANTA PHARMA LIMITED31-0 MIDC INDUSTRIAL AREA CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA STATE	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2013
2321	NDA/MAL/HDP/3 906	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	LEROLE	PANTOPRAZOLE	40MG	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL 1*10ML 0.9%NAACL AMPOULE	01/07/2011

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2322	NDA/MAL/HDP/3 913	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	VALCONTIN	SODIUM VALPROATE	200 MG	MODI MUNDIPHARMA PVT. LTDMEERUT- MUZAFFARNAGAR ROAD, MODIPURAM – 250110 UTTAR PRADESH	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2012
2323	NDA/MAL/HDP/3 914	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	AUGMENTIN	AMOXICILLIN + CLAVULANATE POTASSIUM	875 MG + 125 MG	SMITHKLINE BEECHAM PHARMACEUTICALS, CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X1.0X7.0 TABLET BLISTER	01/07/2010
2324	NDA/MAL/HDP/3 916	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	METOCLOPRAMI DE HYDROCHLORIDE INJECTION	METOCLOPRAMI DE HYDROCHLORIDE	5MG/ML	SCOTT-EDIL PHARMACIA LTD (UNIT I)-56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE,1.0X10.0 X10.0X2.0 ML AMPOULE	01/07/2016

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2325	NDA/MAL/HDP/3 922	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	DIAZI	DIAZEPAM	5MG/ML	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2011
2326	NDA/MAL/HDP/3 924	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLUFED	PARACETAMOL+P SEUDOEPHEDRIN E HYDROCHLORIDE +TRIPOLIDINE HYDROCHLORIDE	300MG+36MG+1.5 MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10 0.0 TABLET CONTAINER,1.0X25 0.0 TABLET CONTAINER,1.0X50 0.0 TABLET CONTAINER,1.0X10. 0 TABLET BLISTER	01/07/1997
2327	NDA/MAL/HDP/3 927	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL CEPHALEXIN 125	CEPHALEXIN MONOHYDRATE	125MG/5ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2008

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2328	NDA/MAL/HDP/3 928	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	MALAREN	SULPHADOXINE + PYRIMETHAMINE	500MG/25MG	RENE INDUSTRIES LTD .PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER,1.0X50.0X3 .0 TABLET BLISTER	01/07/2004
2329	NDA/MAL/HDP/3 931	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	COARTEM 80/480	ARTEMETHER + LUMEFANTRINE	80MG +480MG	NORVATIS SAGLIK GIDA VE TARIM URENLERI SAN, VE TIC-AC-YENISEHIR MAHALLESİ IHLA VADISI SOKAK, NO.2, 34912 KURTKOY, INSTANBUL - TURKEY	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER	01/07/2014
2330	NDA/MAL/HDP/3 932	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIRAX TABLETS	CLIDINIUM BROMIDE + CHLORDIAZEPOXI DE	2.5MG + 5MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2008

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2331	NDA/MAL/HDP/3 933	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	TOZAAR-50	LOSARTAN POTASSIUM	50MG	TORRENT PHARMACEUTICAL LTD AHMEDABAD- MEHSANA HIGHWAY, TALUKA- KADI, DIST. MEHSANA , INDRAD-382721	INDIA	ORAL SOLID ORDINARY TABLETS	5.0X10.0 TABLET BLISTER	01/07/2001
2332	NDA/MAL/HDP/3 938	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	ADRENALINE INJECTION	ADRENALINE	1MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X1.0 ML AMPOULE	01/07/2013
2333	NDA/MAL/HDP/3 945	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

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2334	NDA/MAL/HDP/3 947	INTAS PHARMACUITICALS LTD	NORVIK ENTERPRISES LIMITED	RABTAS-20	RABEPRAZOLE SODIUM	20 MG	INTAS PHARMACEUTICALS LTD .PLOT NOS. 457, 458 & 191/218P SARKHEJ-BAVLA HIGHWAY MATODA SANAND AHMEDABAD GUJARAT INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND)	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2008
2335	NDA/MAL/HDP/3 948	: 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/SYR UPS/DROPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2009
2336	NDA/MAL/HDP/3 949	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	MAGNOMINT SUSPENSION	COMPOUND MAGNESIUM TRISILICATE	N/A	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/1997

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2337	NDA/MAL/HDP/3 951	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMCLOX	AMPICILLIN + CLOXACILLIN	125MG/5ML + 125MG/5ML	SPARSH BIO-TECH LTD PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2004
2338	NDA/MAL/HDP/3 954	WOCKHARDT LTD	STAR PHARMACEUTICAL S 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
2339	NDA/MAL/HDP/3 960	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	IBUPAR	PARACETAMOL/IB UPROFEN	325/400MG	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILSHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER	01/07/2008

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2340	NDA/MAL/HDP/3 963	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	COARTEM DISPERSIBLE TABLETS	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	NOVARTIS URUNLERI TURKEYENISEHIR MAHALLESİ, IHLARA VADISI SOKAK, NO. 2, TR 34912, PENDİK, INSTANBUL, 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
2341	NDA/MAL/HDP/3 965	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	OROFER SYRUP	IRON(II) HYDROXIDE POLYMALTOSE COMPLEX	50MG/5ML	EMCURE PHARMACEUTICALS LTD LANE NO.3 PHASE II,SIDCO INDUSTRIAL COMPLEX,BARI- BRAHMANA JAMMU 181 133, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X150.0 ML BOTTLE	01/07/2004
2342	NDA/MAL/HDP/3 966	DAWA LIMITED	SUPER MEDIC LTD	ASCORBIC ACID TABLETS	ASCORBIC ACID	100 MG	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER,10.0X1 0.0 TABLET BLISTER	01/07/2008

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2343	NDA/MAL/HDP/3 967	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOCLOX-125	CLOXACILLIN	125MG/5ML	MILAN LABORATORIES (INDIA) PVT LTD PLOT NOS 63, 67 & 87, JAWAHAR CO-OP. INDUSTRIAL ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2011
2344	NDA/MAL/HDP/3 969	PHARCO PHARMACEUTICAL S	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FAWAR FRUIT EFFERVESCENT GRANULES	SODIUM CARBONATE + TARTARIC ACID + CITRIC ACID	2.8G + 1.33G + 0.82G	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT, P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY EFFERVESCENT POWDERS/GRANU LES	1.0X6.5 G SACHET	01/07/2002
2345	NDA/MAL/HDP/3 970	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LECOTRIM	CO-TRIMOXAZOLE	480MG	LABORATORY & ALLIED LTD-PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10. 0X10.0 TABLET BLISTER	01/07/1997

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2346	NDA/MAL/HDP/3 971	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	VIRIAXONE-SL	CEFTRIAZONE + SULBACTAM	1G+500MG	INJECT CARE PARENTERALS PVT LTD PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 10 ML AMPOULE WFI	01/07/2013
2347	NDA/MAL/HDP/3 983	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	EXTRADOL	PARACETAMOL/C AFFEINE TABLETS	500MG/65MG	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X50.0X2 .0 TABLET BLISTER	01/07/2008
2348	NDA/MAL/HDP/3 985	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOMYCIN SUSPENSION	ERYTHROMYCIN ESTOLATE	125MG/5ML	AGOG PHARMAPLOT 33 SECTOR THE VASAI-TULUKA CO- OP ESTATE LTD INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	01/07/2008

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2349	NDA/MAL/HDP/3 987	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	ROHISOL SYRUP	LEVAMISOLE HYDROCHLORIDE	40MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X500.0 ML BOTTLE,1.0X15.0 ML BOTTLE	01/07/1997
2350	NDA/MAL/HDP/3 989	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	UNICELIB 200	CELECOXIB	200MG	UNICHEM LABORATORIES LTD- PLOT 17 & 18, PILERNE IND. ESTATE, PILERNE, BARDEZ GOA- 403511 UNICHEM LABORATORIES LTD UNIT II ,,VILLAGE, BHATAULI KALAN BADDI DIST. SOLAN (H.P) 173 205	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2003
2351	NDA/MAL/HDP/3 990	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	UNIXIL SYRUP	AMOXYCILLIN TRIHYDRATE	125MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X100.0 ML BOTTLE	01/07/1997

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2352	NDA/MAL/HDP/3 991	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOFULVIN	GRISEOFULVIN TABLETS	500MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008
2353	NDA/MAL/HDP/3 993	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	NEM SCAB	MULTI- INGREDIENT	MULTI- INGREDIENT	NEM LABORATORIES PVT LTD133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997
2354	NDA/MAL/HDP/3 996	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOTOIN TABLETS	NITROFURANTOI N BP	100MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. 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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2355	NDA/MAL/HDP/3998	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOKOFF SYRUP	TERBUTALINE SULPHATE +GUAIFENESIN+BRONHEXINE 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
2356	NDA/MAL/HDP/4000	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APIDONE SYRUP	CHLORPHENARIMINE MALEATE/DEXAMETHASONE	2MG/5ML + 0.5MG/5ML	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY, CAIRO EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X125.0 ML BOTTLE	01/07/2008
2357	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

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2358	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
2359	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
2360	NDA/MAL/HDP/4007	SANOFI PASTEUR.	LABOREX UGANDA LIMITED	SHANCHOL CHOLERA VACCINE	V.CHOLERA STRAINS- 01 INABA FORMALDEHYDE KILLED +01 OGAWA HEAT KILLED + 01 OGAWA FORMALDEHYDE KILLED + 01 INABA HEAT KILLED + 0139 FORMALDEHYDE KILLED	600 + 300 +300 +300 + 600 ELISA UNITS(EU) OF LIPOPOLYSACCHARIDE (LPS)	SANOFI HEALTHCARE INDIA PRIVATE LIMITED SURVEY 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

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2361	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,1.0X100.0 TABLET CONTAINER,1.0X50.0 TABLET CONTAINER,1.0X25.0 TABLET CONTAINER,1.0X10.0 TABLET BLISTER	01/07/1997
2362	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
2363	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,1.0X1.0X10.0 ML BOTTLE	01/07/2005

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2364	NDA/MAL/HDP/4 016	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	COMPOUND SODIUM LACATE INTRAVENOUS INFUSION	MULTI- INGREDIENT	MULTI- INGREDIENT	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTDVILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2007
2365	NDA/MAL/HDP/4 019	SEDICO PHARMACEUTICAL CO.	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FLUCAMOX 1G	AMOXICILLIN + FLUCLOXACILLIN	500 MG + 500 MG	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT	EGYPT	PARENTERAL ORDINARY VIALS	1.0X1.0 G VIAL	01/07/2007
2366	NDA/MAL/HDP/4 023	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	SINAREST LINCTUS	CHLORPHENAMIN E MALEATE+DEXTR OMETHORPHAN HYDROBROMIDE+ MENTHOL	(4MG +10MG +3MG)/10ML	CENTAUR PHARMACEUTICALS PVT LTD PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997

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2367	NDA/MAL/HDP/4 024	SEDICO PHARMACEUTICAL CO.	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SEDALAC SYRUP	LACTULOSE	3.350G/5ML	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2007
2368	NDA/MAL/HDP/4 030	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	XBETA- N	BETAMETHASONE + NEOMYCIN	0.1%W/V +0.5%W/V	ABACUS PARENTERAL DRUGS LTD PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL,1.0X5.0 ML VIAL	01/07/2011
2369	NDA/MAL/HDP/4 033	JOHNSON&JOHNS ON PTY LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	BENYLIN PAEDIATRIC SYRUP	DIPHENHYDRAMINE HYDROCHLORIDE	7MG/5ML	JOHNSON&JOHNSON PTY LTD.EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	01/07/2007

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2370	NDA/MAL/HDP/4 035	BAYER SCHERING PHARMA	SURGIPHARM (U) LIMITED	YASMIN	DROSPIRENONE + ETHINYLESTRADI OL	3MG+0.3MG	BAYER PHARMA A.GMULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X21.0 TABLET BLISTER	01/07/2010
2371	NDA/MAL/HDP/4 038	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	PREDSONE-5	PREDNISOLONE	5MG	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2012
2372	NDA/MAL/HDP/4 042	SWISS PARENTERALS PVT. LTD.	SHREEJI PHARMACEUTICAL S 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

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2373	NDA/MAL/HDP/4 047	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	NEOGAB	GABAPENTIN	300MG	HILTON PHARMA (PVT) LTD PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/2007
2374	NDA/MAL/HDP/4 055	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	BAYER ASPIRIN CARDIO	ACETYLSALICYLIC ACID	100MG	BAYER PHARMA AGD-51368 LEVERKUSEN, GERMANY	GERMANY	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2006
2375	NDA/MAL/HDP/4 060	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	TOBRADEX	TOBRAMYCIN/DE XAMETHASONE	0.3%W/V+ 0.1%W/V	ALCON COUVREUR NVRIJKSWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/1997

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2376	NDA/MAL/HDP/4 062	VIIV HEALTHCARE UK LTD-	UNITED HEALTHCARE DISTRIBUTORS LTD	KIVEXA	ABACAVIR SULFATE + LAMIVUDINE	600 MG + 300 MG	GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS)PRIORY STREET, WARE, SG12 ODJ	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X1.0X30.0 TABLET CONTAINER,1.0X3.0 X10.0 TABLET BLISTER	01/07/2006
2377	NDA/MAL/HDP/4 063	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	AVOCOMB TABLET	LAMIVUDINE/ZID OVUDINE	150MG/300MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2003
2378	NDA/MAL/HDP/4 064	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	TERAFINE	TERBINAFINE	250MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER	01/07/2010

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2379	NDA/MAL/HDP/4075	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICALS LTD	CHERICOF COUGH FORMULAR	CHLORPHENIRAMINE/DEXTROMET HOPHAN HBR/PHENYLEPH RINE 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
2380	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
2381	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

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2382	NDA/MAL/HDP/4 086	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	KELVIN SUSPENSION	PARACETAMOL	120MG/5ML	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE	01/07/2008
2383	NDA/MAL/HDP/4 091	HILTON PHARMA PVT LTD	HEALTHCARE LTD.	MYTEKA TABLETS	MONTELUKAST SODIUM	5MG	HILTON PHARMA PVT,LTD13 SECTOR 15,KORANG,IND.ARE A,8TH FLOOR PROGRESSIVE PLAZA,BEAMONT RD,KARACHI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2005
2384	NDA/MAL/HDP/4 092	PRISMA PHARMACEUTICAL S LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	FLORANORM	SACCHAROMYCES BOULARDII	250MG	BHARAT BIOTECH INTERNATIONAL LTD- TURKPALLY SHAMEX 500 078 MYDERAHAD INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X2.0X250.0 MG SACHET,1.0X10.0X2 50.0 MG SACHET	01/07/2010

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2385	NDA/MAL/HDP/4 093	LEBEN LABORATORIES LTD	MALIX PHARMA (U) LIMITED	BECLOMIN OINTMENT	BECLOMETHASON E+MICONAZOLE+ NEOMYCIN	0.025%W/W + 2%W/W + 0.5%W/W	LEBEN LAB PVT LTDL4 PHASE 111 MIDCS AKOLA 444104 MAHARAstra INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/2007
2386	NDA/MAL/HDP/4 095	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,1.0X100.0X 10.0 TABLET BLISTER	01/07/2007
2387	NDA/MAL/HDP/4 097	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	DERMOVATE	CLOBETASOL PROPIONATE	0.05%W/W	GLAXOSMITHKLINE HARMIRE GLAXOSMITHKLINE HARMIRE ROAD BARNARD CASTLE DURHAM	UNITED KINGDOM	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE,1.0X30.0 G TUBE	01/07/1997

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2388	NDA/MAL/HDP/4099	GLENMARK PHARMACEUTICALS 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-387411, GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2007
2389	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
2390	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

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2391	NDA/MAL/HDP/4 103	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	POLIO SABIN - ONE AND THREE [ORAL]	LIVE ATTENUATED POLIOMYELITIS VIRUS VACCINE OF THE SABIN STRAINS TYPE 1 +TYPE 2	10 ⁶ CCID ₅₀ +10 ⁵ . ⁸ CCI D ₅₀	GLAXO SMITHKLINE BIOLOGICALS S.ARUE DE L'INSTITUT, 89 B- 1330 RIXENSART	BELGIUM	ORAL LIQUID ORDINARY DROPS	1.0X100.0X2.0 ML VIAL (20 DOSES)	01/07/2016
2392	NDA/MAL/HDP/4 104	DAWA LIMITED	SUPER MEDIC LTD	DAWA-PROM	PROMETHAZINE HCL	25MG	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2009
2393	NDA/MAL/HDP/4 113	MICRO LABS LTD	LABOREX UGANDA LIMITED	EROSTIN 10	EBASTINE	10 MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	01/07/2005

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2394	NDA/MAL/HDP/4114	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	RINALIN SYRUP	CHLORPHENIRAMINE MALEATE	2MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/1997
2395	NDA/MAL/HDP/4115	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	PREDILONE	PREDNISOLONE	5.0 MG	REGAL PHARMACEUTICALS 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
2396	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 LIMITED PLOT NO.3, TIVIM INDUSTRIAL ESTATE KARASWADA MUPUSA-GOIA 403 526 INDIA	INDIA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL	01/07/2005

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2397	NDA/MAL/HDP/4 126	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	UNICELIB 100	CELECOXIB	100MG	UNICHEM LABORATORIES LTDUNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2003
2398	NDA/MAL/HDP/4 127	SANOFI 410 THALES	LABOREX UGANDA LIMITED	EPILIM	SODIUM VALPROATE	200MG/5ML	UNITHER LIQUID MANUFACTURING INDUSTRIE - COLOMIERS 1-3 ALLE DE LA NESTE L DEN SIGAL 31770	FRANCE	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE,1.0X300.0 ML BOTTLE	01/07/1998
2399	NDA/MAL/HDP/4 128	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	VITAREN SYRUP	VITAMIN A + VITAMIN B2 + VITAMIN B1 + VITAMIN B6 + VITAMIN C + VITAMIN E + VITAMIN B3	1500IU/5ML + 1MG/5ML + 1MG/5ML + 0.5MG/5ML + 20MG/5ML + 100 IU/5ML + 10MG/5ML	RENE INDUSTRIES LIMITEDPLOT 680 KAMULI- KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE,1.0X1.0X10 0.0 ML BOTTLE	01/07/2008

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2400	NDA/MAL/HDP/4 134	INDOCO REMEDIES LTD	STAR PHARMACEUTICAL S LTD	CITAL	DISODIUM HYDROGEN CITRATE	1.37G/5ML	INDOCO REMEDIES LTDB-20, MIDC, WALUJ, AURANGABAB 431136 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2004
2401	NDA/MAL/HDP/4 138	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYCLOX CAPSULES	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	ELYS CHEMICAL INDUSTRIES LTDROAD '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
2402	NDA/MAL/HDP/4 141	SANOFI 410 THALES	LABOREX UGANDA LIMITED	EPILIM 200	SODIUM VALPROATE	200MG	FISONS LTD (ALSO KNOWN AS SANOFI- AVENTIS)RIELL, SPAIN	SPAIN	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2001

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2403	NDA/MAL/HDP/4 143	MODI NUNDIPHARMA PVT LTD	SURGIPHARM (U) LIMITED	TAM CONTIN 0.4	TAMSULOSIN HYDROCHLORIDE	0.4MG	MODI MUNDIPHARMA PVT. LTDMEERUT- MUZAFFARNAGAR ROAD, MODIPURAM – 250110 UTTAR PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2013
2404	NDA/MAL/HDP/4 146	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOMPICLOX	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	MILAN LABORATORIES (INDIA) PVT LTD PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTR A-410209,INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2011
2405	NDA/MAL/HDP/4 147	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	NIFEDI-DENK 20 RETARD	NIFEDIPINE	20MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2000

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2406	NDA/MAL/HDP/4 148	COSMOS LIMITED	ASTRA PHARMA (U) LIMITED	AMITRIPTYLINE TABLETS	AMITRIPTYLINE	25MG	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	01/07/1998
2407	NDA/MAL/HDP/4 150	TORRENT PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S LTD.	ANGIOPRIL-25	CAPTOPRIL	25MG	TORRENT PHARMACEUTICALS LTDINDRAD-382 721, DIST.MEHSANA,INDI A.AT:VILL.MANAKPU R,TEH.NALAGARH,DI ST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER	01/07/1997
2408	NDA/MAL/HDP/4 165	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ZEFONE INJECTION	CEFTRIAZONE SODIUM	1G	SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ- BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA INJECTCARE PARENTERALS PVT. LTD.-PLOT130 SILVASSA ROAD GIDC VAPI 396195	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2001

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2409	NDA/MAL/HDP/4 171	MACK BROWN PHARMACEUTICAL S PVT LIMITED	SHURIK LTD	TOREX	MULTIINGREDIEN T	N/A	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
2410	NDA/MAL/HDP/4 172	RENE INDUSTRIES	RENE INDUSTRIES LIMITED	KOF OFF EXPECTORANT	MULTI- INGREDIENT	MULTI- INGREDIENT	RENE INDUSTRIESPLOT 680 KAMULI KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X110.0 ML BOTTLE	01/07/2005
2411	NDA/MAL/HDP/4 180	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	OSMOWIN	LACTULOSE	10G/15ML	G.S PHAMBUTOR PVT LTDG.S PHAMBUTOR PVT LTD B-172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE	01/07/2015

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2412	NDA/MAL/HDP/4 182	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	SINAREST- FORTE	MULTI INGREDIENT	MULTI INGREDIENT	CENTAUR PHARMACEUTICALS LTD PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X50.0X4 .0 TABLET STRIP	01/07/2007
2413	NDA/MAL/HDP/4 187	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	NORIGYNON	ESTRADIOL VALERATE +NORETHINDRON E ENANTHATE	5 MG+50 MG / ML	BAYER PHARMA A.GMULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE	01/07/1997
2414	NDA/MAL/HDP/4 188	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOPRAZ	PRAZIQUANTEL	600MG	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,1.0X2.0X4. 0 TABLET BLISTER,1.0X1.0X4. 0 TABLET BLISTER	01/07/2013

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2415	NDA/MAL/HDP/4 209	AUROBINDOM PHARMA LIMITED	GITTOES PHARMACEUTICAL S LIMITED	POZINEG 1000	CEFEPIME	1000MG	AUROBINDO PHARMA LIMITED, UNIT IISURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELENGANA (STATE)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL + 1*1AMP WATER FOR INJECTION	01/07/2008
2416	NDA/MAL/HDP/4 241	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AMPICILLIN SODIUM FOR INJECTION BP	AMPICILLIN SODIUM	500MG	CSPC ZHONGNUO PHARMACEUTICAL (SCJIJAZHUANG) 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
2417	NDA/MAL/HDP/4 275	F. HOFFMANN LA- ROCHE	LABOREX UGANDA LIMITED	AVASTIN 100MG/4ML	BEVACIZUMAB	100 MG/ 4ML	F.HOFFMANN-LA ROCHE LTD- GRENZACHERSTRASS E 124,CH- 4070 BASEL ROCHE DIAGNOSTICS GMBH- SANDHOFER STRASSE 116 D- 68305 MANNHEIM GERMANY	SWITZERLAND GERMANY	PARENTERAL ORDINARY VIALS	1.0X4.0 ML VIAL	01/07/2016

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2418	NDA/MAL/HDP/4 276	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	FALCI CARE	ARTESUNATE	60MG	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 5 ML NACL + 1 ML SODIUM BICARBONATE	01/07/2013
2419	NDA/MAL/HDP/4 277	NABIQASIM INDUSTRIES (PVT) LIMITED	JEET PHARMACEUTICAL S LIMITED	VIVIRON PLUS SYRUP	FERRIC AMMONIUM CITRATE +FOLIC ACID + PYRIDOXINE HCL + THIAMINE HCL + NICOTINAMIDE	50MG + 0.5MG + 2.2MG + 1.3MG +11MG	NABIQASIM INDUSTRIES (PVT) LTD-17/24,KORANGI INDUSTRIAL AREA, KORANGI, KARACHI- PAKISTAN.	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X90.0 ML BOTTLE,1.0X250.0 ML BOTTLE	01/07/2014
2420	NDA/MAL/HDP/4 279	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROTIM	TIMOLOL MALEATE	0.5% W/V	AUROLABNO. 1, SIVAGANGAI MAIN ROAD, VEERAPANJAN, MADURAI	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2016

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2421	NDA/MAL/HDP/4 280	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ABACAVIR SULFATE+LAMIVU DINE	ABACAVIR SULFATE + LAMIVUDINE	600 MG + 300 MG	MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD ,PLOT NO. 11, 12, & 13 INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III PITHAMPUR 454775,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2013
2422	NDA/MAL/HDP/4 284	F. HOFFMANN LA- ROCHE	LABOREX UGANDA LIMITED	AVASTIN 400MG/4ML	BEVACIZUMAB	400MG/4ML	F.HOFFMANN-LA ROCHE LTD- GRENZACHERSTRASS E 124,CH- 4070 BASEL ROCHE DIAGNOSTICS GMBH- SANDHOFER STRASSE 116 D- 68305 MANNHEIM GERMANY	SWITZERLAND GERMANY	PARENTERAL ORDINARY VIALS	1.0X16.0 ML VIAL	01/07/2016
2423	NDA/MAL/HDP/4 287	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANAXONE 1000	CEFTRIAXONE	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

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2424	NDA/MAL/HDP/4 291	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	VITAMIN B COMPLEX INJECTION	VITAMIN B COMPLEX	10MG/2ML	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2008
2425	NDA/MAL/HDP/4 292	F. HOFFMANN LA- ROCHE	LABOREX UGANDA LIMITED	HERCEPTIN 150MG	TRASTUZUMAB	150MG	ROCHE DIAGNOSTICS GMBH MANNHEIM- SANDHOFER STRASSE 116 -68305 MANNHEIM GERMANY.	GERMANY	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	01/07/2016
2426	NDA/MAL/HDP/4 303	PFIZER LABORATORIES (PTY)	LABOREX UGANDA LIMITED	SAYANA PRESS	MEDROXYPROGE STERONE ACETATE	104MG/0.65ML	PFIZER MANUFACTURING NV/NA, RIJKSWEG 12 2870, PUURS	BELGIUM	PARENTERAL ORDINARY I M PRE FILLED SYRINGES	1.0X200.0X0.65 ML PRE- FILLED SYRINGE	01/07/2010

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2427	NDA/MAL/HDP/4 307	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	MIKACIN	AMIKACIN SULPHATE	500MG/2ML	ARISTO PHARMACEUTICALS PVT. LIMITED PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0X8.0X2.0 ML VIAL,1.0X1.0X2.0 ML VIAL	01/07/2009
2428	NDA/MAL/HDP/4 309	HETERO DRUGS LTD	AIVEEN (U) LIMITED	LAMIVUDINE + ZIDOVUDINE	LAMIVUDINE + ZIDOVUDINE	150MG + 300MG	HETERO LABS LTD22- 110 IDA JEEDIMETLA HYDERABAD 500- 055 ANDHRA PRADESH HETERO LABS LTD (UNIT- V)SY.NO.438,439,44 0 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2010
2429	NDA/MAL/HDP/4 312	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GONAL-F	FOLLITROPIN ALFA	75IU/IE	MERCK SERONO S.P.A-VIA DELLE MAGNOLIE,15.70026 MODUGNO (BA).ITALY MERCK SERONO S.A. (MSA) - 1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND	ITALY SWITZERLAND	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1 PRE FILLED SYRINGE OF WFI	01/07/2016

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2430	NDA/MAL/HDP/4 313	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	AKUGABALIN	PREGABALIN 150MG CAPSULES	150MG	AKUMS DRUGS & PHARMACEUTICALS LTD.2, 3, 4, & 5, SEC- 6B, I.I.E., SIDCUL, RANIPUR, HARIDWAR-249403 (INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	07/01/2016
2431	NDA/MAL/HDP/4 315	DENK PHARMA GMB H &CO. KG	BENLE CONSULT LIMITED	DESLORA-DENK 5	DESLORATIDINE	5MG	DENK PHARMA GMBH & CO.KG GOLLSTR 1,84529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016
2432	NDA/MAL/HDP/4 317	DENK PHARMA GMB H &CO. KG	BENLE CONSULT LIMITED	COLOSAR-DENK 50/12.5	LOSARTAN + HYDROCHLOROT HIAZIDE	50MG + 12.5MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER,1.0X2.0X14 .0 TABLET BLISTER	01/07/2011

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2433	NDA/MAL/HDP/4 318	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	AKUGABALIN	PREGABALIN	75 MG	AKUMS DRUGS & PHARMACEUTICALS LTD19, 20,21 SECTOR 6A IIE SIDCUL RANIPUR HARIDWAR 249 403	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	07/01/2016
2434	NDA/MAL/HDP/4 320	AFRICURE PHARMACEUTICAL S (INDIA) PRIVATELIMITED	ROYAL PHARMA 2011 LIMITED	HYOSCINE BUTYL BROMIDE	HYOSCINE BUTYL BROMIDE	10MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9- 12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2005
2435	NDA/MAL/HDP/4 324	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PRASUSAFE 5	PRASUGREL	5MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1X3X10 TABLET BLISTER	01/07/2013

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2436	NDA/MAL/HDP/4 325	AJANTA PHARMA LTD 31-0	ABACUS PHARMA (AFRICA) LIMITED	ACTINAC 100	ACECLOFENAC	100MG	AJANTA PHARMA LIMITED PLOT NO. M- 55-56-57, ISEZ, PHASE II, PITHAMPUR- 454775, DISTRICT DHAR, MADHYA PRADESH STATE AJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X2.0X10.0 TABLET BLISTER	01/07/2009
2437	NDA/MAL/HDP/4 329	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGO-CPM	CHLORPHENIRAM INE MALEATE	2MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60 .0 ML BOTTLE	01/07/2010
2438	NDA/MAL/HDP/4 330	SPARSH BIO-TECH PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	FLUCLOXACILLIN CAPSULES	FLUCLOXACILLIN	250MG	SPARSH BIO-TECH PVT. LTD.-PLOT NO. 1, SURVEY NO. 242/243/244, VILLAGE LAKHABAVAD POST KHODIYAR COLONY DISTRICT, JAMNAGAR – 361006 GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE STRIP	01/07/2016

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2439	NDA/MAL/HDP/4 331	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	STEDNAC	ACECLOFENAC	100MG	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2010
2440	NDA/MAL/HDP/4 333	ZEE PHARMACEUTICAL S LTD	ZEE PHARMACEUTICAL S LIMITED	CARVIBERG	CARVEDILOL USP	6.25MG	THE MADRAS PHARMACEUTICALS 137-B,OLD MAHABALI PURAM ROAD,KARAPAKKAM ,CHENNAI INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
2441	NDA/MAL/HDP/4 334	DENK PHARM GMBH&CO.KG	BENLE CONSULT LIMITED	LOSAR-DENK 50	LOSARTAN	50MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2011

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2442	NDA/MAL/HDP/4 335	DAWA LIMITED	SUPER MEDIC LTD	CURAMOL SUSPENSION	PARACETAMOL	120MG/5ML	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2009
2443	NDA/MAL/HDP/4 339	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	SERETIDE 125 EVOHALER	SALMETEROL XINAFOATE + FLUTICASONE PROPIONATE	25MCG/125MCG	GLAXO WELLCOME PRODUCTIONZONE INDUSTRIELLE NO.2 23 RUE LAVOISER 27000 EVREUX	FRANCE	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER	01/07/2007
2444	NDA/MAL/HDP/4 348	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	MEDICLOAMP SYRUP	CLOXACILLIN+AM PICILLIN	250MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

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2445	NDA/MAL/HDP/4 350	ACINO PHARMA AG	LABOREX UGANDA LIMITED	OLFEN-75	DICLOFENAC SODIUM	75MG/2ML	MERCKLE GMBH,LUDWIG MERCKLE STRASSE3 D-89143 BLAUBEUREN HAUPT PHARMA WULFING GMBH.BETHELNER LANDSTR. 18, 31028 GRONAU/LEINE	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE	01/07/1997
2446	NDA/MAL/HDP/4 352	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REQUIN SYRUP	QUININE HYDROCHLORIDE	100MG/5ML	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2001
2447	NDA/MAL/HDP/4 356	ADCOCK INGRAM LIMITED	SURGIPHARM (U) LIMITED	FRESHEN	BISACODYL	5 MG	ADCOCK INGRAM LIMITED 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE 560099, KARNATAKA STATE, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X12.0 TABLET BLISTER	01/07/2016

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2448	NDA/MAL/HDP/4 358	A.MENARINI INDUSTRIE FARMACEUTICHE S.R.I	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	LIOTON	HEPARIN SODIUM	1000I.U/G	A. MENARINI MANUFACTURING 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
2449	NDA/MAL/HDP/4 361	: ALKEM LABORATORIES LIMITED V	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,1.0X1.0X10 .0 TABLET BLISTER	01/07/2009
2450	NDA/MAL/HDP/4 362	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	LEVOMAC 750	LEVOFLOXACIN HEMIHYDRATE	750MG	MACLEODS PHARMACEUTICALS LIMITED BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH – 174101 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2016

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2451	NDA/MAL/HDP/4 365	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ACTINAC PLUS	ACECLOFENAC + PARACETAMOL	100 MG + 500 MG	AJANTA PHARMA LIMITED PLOT NO. M- 55-56-57, ISEZ, PHASE II, PITHAMPUR- 454775, DISTRICT DHAR, MADHYA PRADESH STATE AJANTA PHARMA LIMITED B- 4/5/6, MIDC AREA, PAITHAN, 431 148 INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2009
2452	NDA/MAL/HDP/4 366	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	CLOXISPA	CLOXACILLIN	250MG	SPARSH BIO-TECH LTD PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER, 1.0X1000.0 CAPSULE CONTAINER, 1.0X10 0.0X10.0 CAPSULE BLISTER	01/07/2004
2453	NDA/MAL/HDP/4 367	ASTRA ZENECA	MACNAUGHTON LIMITED	ATACAND 8MG	CANDESARTAN	8MG	ASTRA ZENECA AB, SODERTALJEGARTUN AYEGEN, SODERTALJE	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2010

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2454	NDA/MAL/HDP/4 375	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	ZITHROMAX	AZITHROMYCIN DIHYDRATE	200MG/5ML	HAUPT PHARMA LATINA S.R.L LATINA- SS 156KM 47,600- 04100,BORGO SAN,MICHELE	ITALY	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X30.0 ML BOTTLE,1.0X15.0 ML BOTTLE	01/07/1997
2455	NDA/MAL/HDP/4 379	LEBEN LABORATORIES PVT.LTD	MALIX PHARMA (U) LIMITED	SINURHON	MULTI- INGREDIENT	5MG/ 2MG/ 500MG / 30MG	LEBEN LABORATORIES PVT. LTD PLOT NO. L-4, PHASE-III, MIDC, AKOLA- 444 104 (MS).	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X12.0X40.0 TABLET BLISTER,1.0X1.0X6. 0X20.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER	01/07/2010
2456	NDA/MAL/HDP/4 380	GLAXO WELLCOME (KENYA) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZINNAT SUSPENSION	CEFUROXIME AXETIL-	125MG/5ML	GLAXOSMITHKLINE UK LTD HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE,1.0X50.0 ML BOTTLE	01/07/1998

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2457	NDA/MAL/HDP/4 383	ZEE PHARMACEUTICAL S LTD	ZEE PHARMACEUTICAL S LIMITED	ZEEMYCIN - 150	CLINDAMYCIN HYDROCHLORIDE BP	150MG	THE MADRAS PHARMACEUTICALS 137-B,OLD MAHABALI PURAM ROAD,KARAPAKKAM ,CHENNAL INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2016
2458	NDA/MAL/HDP/4 388	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	TAZOBAK	PIPERACILLIN SODIUM + TAZOBACTAM SODIUM	4.0G + 0.5G	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA SWISS PARENTERALS LIMITED UNIT IIPLOT 402, 412-414, KERALA INDUSTRIAL ESTATE, GIDC, NEAR BAVLA, AHMEDABAD - 382220, GUJARAT -	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X4.5 G VIAL	01/07/2016
2459	NDA/MAL/HDP/4 389	PHARMACARE LTD	MEDICAL ACCESS (UGANDA) LIMITED	PREZISTA	DARUNAVIR	600MG	JANSSEN ORTHO LLC.-STATE ROAD 933 KM 0.1 MARNEY WARD GURABO PUERTO RICO 00778	UNITED STATES	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2011

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2460	NDA/MAL/HDP/4 390	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROCOL	CHLORAMPHENIC OL	0.5%W/V	AUROLABNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA	INDIA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE	01/07/2016
2461	NDA/MAL/HDP/4 392	IND SWIFT LTD	PLANET PHARMACEUTICAL S UGANDA LTD	CAPLOR	CLOPIDOGREL	75MG	IND SWIFT LTDGBU JAWAHARPUR OFF NH-21 DERABASSI DIST MOHALI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
2462	NDA/MAL/HDP/4 394	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	NS	SODIUM CHLORIDE	0.9% W/V	ABACUS PARENTERAL DRUGS LTD PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE, 1.0X250.0 ML BOTTLE	01/07/2010

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2463	NDA/MAL/HDP/4 396	MYLAN LABORATORIES LIMITED (OTL)	KIMSY MEDS LTD	ABACAVIR SULPHATE	ABACAVIR SULFATE	300MG	MYLAN LABORATORIES LTD PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR - 454775; DIST; DHAR; MADHYA PRADESH; MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2007
2464	NDA/MAL/HDP/4 398	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
2465	NDA/MAL/HDP/4 399	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	GEFIL	COMPOUND MAGNESIUM TRISILICATE	ALUMINIUM HYDROXIDE & MAGNESIUM TRISILICATE 132 &	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED VANDALUR ROAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2005

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2466	NDA/MAL/HDP/4 400	COSMOS LTD	ASTRA PHARMA (U) LIMITED	ORAL REHYDRATION SALT (DTS)	ORAL REHYDRATION SALT	N/A	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X100.0X20.6 G SACHET,1.0X100.0X 10.3 G SACHET	01/07/1997
2467	NDA/MAL/HDP/4 401	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPICEPHIN	CEFTRIAXONE 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
2468	NDA/MAL/HDP/4 402	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICAL S LIMITED	CLOTRILIN	CLOTRIMAZOLE	100MG	LINCOLN PHARMACEUTICALS LTD10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI , KHATRAJ-382721, GHANDINAGAR GUJ ARAT, INDIA	INDIA	VAGINAL TABLETS	1.0X6.0 TABLET STRIP	01/07/2014

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2469	NDA/MAL/HDP/4 404	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	FOLIGRAF	RECOMBINANT HUMAN FOLLICLE STIMULATING HORMONE	75I.U/ VIAL	BHARAT SERUMS AND VACCINES LIMITED,PLOT NO. K- 27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	01/07/2016
2470	NDA/MAL/HDP/4 406	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	SATISFIL -100	SILDENAFIL	100MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	01/07/2011
2471	NDA/MAL/HDP/4 408	REGAL PHARMACEUCALS LTD	REGAL PHARMA (U) LTD	UNISTEN CREAM	CLOTRIMAZOLE	1%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/1997

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2472	NDA/MAL/HDP/4 410	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (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
2473	NDA/MAL/HDP/4 411	ASTRAZENECA AG	MACNAUGHTON LIMITED	ATACAND PLUS	CANDESARTAN + HYDROCHLOROT HIAZIDE	16 MG + 12.5 MG	ASTRA ZENECA AB, SODERTALJEGARTUN AYEGEN, SODERTALJE	SWEDED	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2010
2474	NDA/MAL/HDP/4 412	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (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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2475	NDA/MAL/HDP/4 413	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPICEPHIN	CEFTRIAZONE	1G	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL (+ 1 GLASS AMPOULE OF 10ML WFI)	01/07/2011
2476	NDA/MAL/HDP/4 415	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	CATAFLAM 50MG TABLETS	DICLOFENAC POTASSIUM	50MG	NOVARTIS-- URUNLERI INSTABUL TURKEY NOVARTIS PHARMA SPA,- TORRE ANNUNZIATA ITALY	ITALY TURKEY	ORAL SOLID ORDINARY COATED TABLETS	10.0X10.0 TABLET BLISTER,1.0X2.0X10 .0 TABLET BLISTER	01/07/1997
2477	NDA/MAL/HDP/4 417	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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2478	NDA/MAL/HDP/4 418	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	VALORAN	CEFOTAXIME	1000MG	MEDOCHEMIE LIMITED (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL - CYPRUS.	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 VIAL CARTON	01/07/2009
2479	NDA/MAL/HDP/4 419	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIGONAL 75	HUMAN MENOPAUSAL GONADOTROPHI N	75IU/5ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL + 1 ML AMPOULE 0.9%W/V NAACL	01/07/2010
2480	NDA/MAL/HDP/4 425	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REQUIN FC	QUININE	300MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2011

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2481	NDA/MAL/HDP/4 468	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TOPRAZ 40	PANTOPRAZOLE SODIUM SESQUIHYDRATE	40MG	AUROBINDO UNIT XV PLOT NO. 17 A, E. BONANGI (VILLAGE), JAWAHARLAL NEHRU PHARMA CITY, PARAWADA MANDAL, VISAKHAPATNAM DIST, ANDHRA PRADESH -531021 INDIA AUROBINDOPHARM A LIMITED, UNIT VII, SEZ APIIC, PLOT NO.SI SURVEY	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
2482	NDA/MAL/HDP/4 480	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	KIPEL 5	MONTELUKAST	5MG	MSN LABORATORIES PVT. LIMITED PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
2483	NDA/MAL/HDP/4 483	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	WORMOL SUSPENSION	MEBENDAZOLE	100MG/5ML	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE, 1.0X100.0 L BOTTLE	01/07/1997

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2484	NDA/MAL/HDP/4 519	ARISTO PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	S-AMLOSAFE 5	AMLODIPINE BESILATE	5MG	ARISTO PHARMACEUTICALS PVT LTD PLOT NO 208 NEW INDUSTRIAL AREA NO 11 MANDIDEEP	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X3.0X1. 0X3.0X10.0 TABLET BLISTER	01/07/2007
2485	NDA/MAL/HDP/4 522	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	S-AMLOSAFE 2.5	AMLODIPINE BESILATE	2.5 MG	ARISTO PHARMACEUTICALS PVT LTD PLOT NO 208 NEW INDUSTRIAL AREA NO 11 MANDIDEEP	INDIA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X3.0X1. 0X3.0X10.0 TABLET BLISTER	01/07/2007
2486	NDA/MAL/HDP/4 523	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	BIGOMET SR 500	METFORMIN HYDROCHLORIDE	500MG	ARISTO PHARMACEUTICALS PVT. LIMITED PLOT NO. 208, NEW INDUSTRIAL AREA NO. II, MANDIDEEP PRADESH	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008

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2487	NDA/MAL/HDP/4 526	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AZ-500	AZITHROMYCIN	500MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER,1.0X20.0X3 .0 TABLET BLISTER	01/07/2011
2488	NDA/MAL/HDP/4 528	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	PIOSAFE MF 15/500	PIOGLITAZONE + METFORMIN	15 MG + 500 MG	ARISTO PHARMACEUTICALS PVT LIMITED PLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP- 462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008
2489	NDA/MAL/HDP/4 536	SEDICO PHARMACEUTICAL CO.	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FLUCAMOX	FLUCLOXACILLIN + AMOXICILLIN	250MG+250MG	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X4.0 CAPSULE STRIP	01/07/2004

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2490	NDA/MAL/HDP/4 546	KARNATAKA ANTIBIOTICS & PHARMACEUTICAL S LTD	TATA UGANDA LIMITED	CHLORAMPHENIC OL INJECTION IG	CHLORAMPHENIC OL SODIUM SUCCINATE	1G	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD #14, II PHASE PIA, BANGALORE 560058	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X100.0X1.0 G VIAL,1.0X50.0X1.0 G VIAL	01/07/1998
2491	NDA/MAL/HDP/4 553	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	ARTESUN	ARTESUNATE	30MG	GUILIN PHARMACEUTICAL CO. LTD.NO. 43 QILIDIAN ROAD, GUILIN 541004	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X30.0 MG VIAL + 1*0.5 ML SODIUM BICARBONATE	01/07/2011
2492	NDA/MAL/HDP/4 556	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM 375	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	250MG + 125MG	INDCHEMIE HEALTH SPECIALTIES PVT. LTD-(UNIT 3 BETA LACTAM BLOCK) VILLAGE: THANA, TEHSIL: BADDI, DISTRICT: SOLAN HIMACHAL PRADESH -173205 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET STRIP	01/07/2005

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2493	NDA/MAL/HDP/4 559	MSN LABORATORIES PRIVATE LIMITED,	METRO PHARMACEUTICAL S LIMITED	PREGASAFE 75	PREGABALIN	75MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2014
2494	NDA/MAL/HDP/4 561	TORRENT PHARMACEUTICAL S LTD	KARURI PHARMACEUTICAL S LTD.	LORVAS SR	INDAPAMIDE	1.5MG	TORRENT PHARMACEUTICALS LTD. AHMEDABAD- MEHSANA HIGHWAY, TAL. KADI, DIST. MEHSANA, INDRAD 382 721, GUJARAT TORRENT PHARMACEUTICALS LTD VILLAGE: BHUD & MAKHNU MAJRA, TEHSIL: BADDI – 173205, DIST: SOLAN, HIMACHAL	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2009
2495	NDA/MAL/HDP/4 568	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM 625	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	500MG + 125MG	INDCHEMIE HEALTH SPECIALTIES PVT. LTD-(UNIT 3 BETA LACTAM BLOCK) VILLAGE: THANA, TEHSIL: BADDI, DISTRICT: SOLAN HIMACHAL PRADESH -173205 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET STRIP	01/07/2005

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2496	NDA/MAL/HDP/4 571	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ASPICLOX	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	ASTRA LIFE CARE (INDIA) PVT.LTD PLOT NO. 57/P, SARKHEJ- BAVLA HIGHWAY, POST RAJODA- 382220, TALUKA BAVLA, AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE STRIP,1.0X1000.0 CAPSULE CONTAINER	01/07/1997
2497	NDA/MAL/HDP/4 575	FDC LTD	AIVEEN (U) LIMITED	PYRICORT EYE/EAR DROPS	DEXAMETHASON E+GENTAMICIN	0.1%+0.3%W/V	FDC LIMITED B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.☒	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2013
2498	NDA/MAL/HDP/4 581	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM 1000	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	875MG + 125MG	INDCHEMIE HEALTH SPECIALTIES PVT. LTD-(UNIT 3 BETA LACTAM BLOCK) VILLAGE: THANA, TEHSIL: BADDI, DISTRICT: SOLAN HIMACHAL PRADESH -173205 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET STRIP	01/07/2005

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2499	NDA/MAL/HDP/4 587	CIRON DRUGS AND PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	CIRATRO	ATROPINE	1MG/ML	CIRON DRUGS AND PHARMACEUTICALS PVT LTDN-118 M.I.D.C, TAAPUR,BOISAR,DIS T.THANE MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X1.0 ML AMPOULE	01/07/2008
2500	NDA/MAL/HDP/4 588	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	FLUCAN 200	FLUCONAZOLE	200MG	LINCOLN PHARMACEUTICAL LIMITEDTRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0 TABLET BLISTER	01/07/2011
2501	NDA/MAL/HDP/4 589	FEROZSONS LABORATORIES LTD	HEALTHCARE LTD.	LEFOXICIN-500	LEVOFLOXACIN HEMIHYDRATE	500MG	FEROZSONS LABORATORIES LTDAMANGARH- NOWSHERA, (KHYBER PAKHTOONKHWA), PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2013

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2502	NDA/MAL/HDP/4 591	S KAGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	SILVER KANT	SILVER SULPHADIAZINE USP	1%W/W	S.KANT HEALTHCARE LTD1802-18-5 GIDC PHASE III, VAPI- 396195,GUJARAT INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2009
2503	NDA/MAL/HDP/4 592	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	PENTALINK 40	PANTOPRAZOLE	40MG	LINCOLN PHARMACEUTICAL LIMITEDTRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP,1.0X3.0X10.0 TABLET BLISTER	01/07/2008
2504	NDA/MAL/HDP/4 593	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	ERYTHROKANT- 250	ERYTHROMYCIN STEARATE	250MG	S KANT HEALTHCARE LIMITED1802 – 1805, G.I.D.C., PHASE III, VAPI - 396195 GUJARAT, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2011

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2505	NDA/MAL/HDP/4 595	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	VAST-20	ATORVASTATIN	20MG	LINCOLN PHARMACEUTICAL LIMITEDTRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/2010
2506	NDA/MAL/HDP/4 598	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AZ-250	AZITHROMYCIN	250MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER	01/07/2011
2507	NDA/MAL/HDP/4 602	ELI-LILLY (SUISSE) SA	LABOREX UGANDA LIMITED	HUMALOG MIX 50	INSULIN LISPRO	100 .IU(50 I.U.+50 I.U)	LILLY FRANCE SAFRANCE	FRANCE	PARENTERAL ORDINARY S C VIALS	1.0X3.0 ML VIAL,1.0X5.0 ML VIAL	01/07/2000

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2508	NDA/MAL/HDP/4 603	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	HALOXEN - 5	HALOPERIDOL	5MG	REMEDICA LIMITED LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
2509	NDA/MAL/HDP/4 605	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGODRYL SYRUP	BROMHEXINE HCL+DEXTROMET HORPHAN HBR+AMMONIU M CHLORIDE+MENT HOL	4MG/5ML+5MG/5 ML+50MG/5ML+2. 5MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60 .0 ML BOTTLE	01/07/2009
2510	NDA/MAL/HDP/4 606	INTAS PHARMACEUTICAL S LIMITED	NORVIK ENTERPRISES LIMITED	ROVAS 10	ROSUVASTATIN	10MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

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2511	NDA/MAL/HDP/4 609	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYCORT	HYDROCORTISON E	1%W/W	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997
2512	NDA/MAL/HDP/4 611	DAFRA PHARMA LTD	MULTIPHAR UGANDA LIMITED	DAFRACLAV	AMOXYCILLIN + POTASSIUM CLAVULANATE	200MG + 28MG	BILIM ILAC SAN. VE. TIC. A.S.CERKEZKOY ORGANIZE SANAYI BOLGESI, KARAAGAC, MH. 5. SK. NO. 6, KAPAKLI - TEKIRDAG 59510	TURKEY	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X70.0 ML BOTTLE	01/07/2011
2513	NDA/MAL/HDP/4 614	GALENTIC PHARMA LTD	VITACARE LIMITED	COMPOUND BENZOIC ACID OINTMENT	BENZOIC ACID + SALICYLIC ACID	6 %W/W + 3 %W/W	GALENTIC PHARMA(INDIA) PVT LTDR- 673,MIDC TTC RABALE THANE- BELAPUR ROAD,NAVI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X25.0 G TUBE,1.0X500.0 G TUBE	01/07/2006

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2514	NDA/MAL/HDP/4 617	ASTRA ZENECA	MACNAUGHTON LIMITED	CRESTOR	ROSUVASTATIN	10MG	IPR PHARMACEUTICALS INC, LOT 17 INDUSTRIAL PARK PUERTO RICO, SAN ISIDRO, PUERTO RICO	PUERTO RICO	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2010
2515	NDA/MAL/HDP/4 619	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CHLORAMPHENIC OL SODIUM SUCCINATE	CHLORAMPHENIC OL SODIUM SUCCINATE	1G	SCOTT-EDIL PHARMACIA LTD (UNIT I)56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0X1.0 G VIAL	01/07/2009
2516	NDA/MAL/HDP/4 620	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	MALANIL PAEDIATRIC TABLET	ATOVAQUONE + PROGUANIL	62.5 MG + 25.0 MG	GLAXO WELLCOME S.A ARANDAARANDA AVDA EXTREMADURA 3, 09400 ARANDA DE DUERO BURGOS	SPAIN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X12.0 TABLET BLISTER	01/07/2007

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2517	NDA/MAL/HDP/4 622	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	CLOXAREN	CLOXACILLIN	250MG	RENE INDUSTRIESPLOT 680 KAMULI KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER	01/07/2007
2518	NDA/MAL/HDP/4 623	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	LOPERAREN	LOPERAMIDE HYDROCHLORIDE	2MG	RENE INDUSTRIAL LTDRENE INDUSTRIES LTD, PLOT 680, KAMULI- KIREKA KAMPALA UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2007
2519	NDA/MAL/HDP/4 627	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	HYCORUM CREAM	HYDROCORTISON E	1%W/W	LABORATORY AND ALLIED LTD PLOT 209/10349- MOMBASA ROAD NAIROBI	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997

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2520	NDA/MAL/HDP/4 629	DAWA LIMITED	SUPER MEDIC LTD	ORACEF	CEFALEXIN MONOHYDRATE	125MG/5ML	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1X100 ML BOTTLE	01/07/2015
2521	NDA/MAL/HDP/4 634	DENK PHARMA GMB H & CO. KG	BENLE CONSULT LIMITED	LOSAR-DENK 100	LOSARTAN	100MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2011
2522	NDA/MAL/HDP/4 641	YURIA PHARM LTD- UKRAINE	PHARMA VILLE LIMITED	RHEOSORBILACT	SORBITOL + SODIUM LACTATE + NACL + CALCIUM CHLORIDE + MAGNESIUM CHLORIDE	6G +1.9G +0.6G + 0.01G +0.03G + +0.02	YURIA-PHARM LLC MANUFACTURING SITE NO. 1108, KOBZARSKA STREET, CHERKASY, 18030	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X200.0 ML BOTTLE,1.0X400.0 ML BOTTLE	01/07/2013

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2523	NDA/MAL/HDP/4 645	ASTRA ZENECA	MACNAUGHTON LIMITED	CRESTOR	ROSUVASTATIN CALCIUM	20MG	IPR PHARMACEUTICALS INC, LOT 17 INDUSTRIAL PARK PUERTO RICO, SAN ISIDRO, PUERTO RICO	PUERTO RICO	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2010
2524	NDA/MAL/HDP/4 646	YURIA PHARM LTD- UKRAINE	PHARMA VILLE LIMITED	LEFLOCIN	LEVOFLOXACIN	5MG/ML	YURIA-PHARM LLC MANUFACTURING SITE NO. 1108, KOBZARSKA STREET, CHERKASY, 18030	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X150.0 ML BOTTLE, 1.0X1.0X10 0.0 ML BOTTLE	01/07/2013
2525	NDA/MAL/HDP/4 650	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	DUOTRAV	TRAVOPROST + TIMOLOL MALEATE	40MG/ML + 5MG/ML	ALCON COUVREUR NVRIJKSWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X1.0X2.5 ML VIAL	01/07/2010

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2526	NDA/MAL/HDP/4 652	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),1.0X10. 0 ML VIAL (20 DOSE VIAL)	01/07/1997
2527	NDA/MAL/HDP/4 657	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	VOLAR 300MG	GABAPENTIN	300MG	DAR AL DAWADAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2013
2528	NDA/MAL/HDP/4 658	PT SANBE FARMA	MEDVIN PHARMA LIMITED	MEROSAN 0.5	MEROPENEM	0.5G	PT SANBE FARMAJI LEUWIGAJAH I62 CIMINDI CIMAHI WEST JAVA INDONESIA	INDONESIA	PARENTERAL ORDINARY DRY VIALS	1.0X0.5 G VIAL	01/07/2014

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2529	NDA/MAL/HDP/4 661	YURIA PHARM LTD- UKRAINE	PHARMA VILLE LIMITED	FLUCONAZOLE-UF	FLUCONAZOLE	2MG/ML	YURIA-PHARM LLC MANUFACTURING SITE NO. 1108, KOBZARSKA STREET, CHERKASY, 18030	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X50.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2013
2530	NDA/MAL/HDP/4 666	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	ANTIPLEX	CLOPIDOGREL BISULFATE	30MG	DAR AL DAWANA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
2531	NDA/MAL/HDP/4 669	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (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

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2532	NDA/MAL/HDP/4 670	MEDOPHARM PRIVATE LIMITED	PLANET PHARMACEUTICAL S 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
2533	NDA/MAL/HDP/4 675	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	DICLOGESIC RETARD 100	DICLOFENAC SODIUM	100MG	DAR AL DAWADAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X6.0 CAPSULE BLISTER	01/07/2013
2534	NDA/MAL/HDP/4 677	: 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/SYR UPS/DROPS	1.0X1.0X30.0 ML BOTTLE,1.0X70.0 ML BOTTLE	01/07/2011

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2535	NDA/MAL/HDP/4 678	: ALKEM LABORATORIES LIMITEDV	ABACUS PHARMA (AFRICA) LIMITED	ZOCEF-500	CEFUROXIME AXETIL	500MG	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY 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
2536	NDA/MAL/HDP/4 680	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANCEPH DS	CEPHALEXIN	125MG/5ML	SANCE LABORATORIES PVT. LTD.VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT- 686573, KERALA, INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2011
2537	NDA/MAL/HDP/4 690	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYPEN	PHENOXYMETHYL PENICILLIN	250MG	ELYS CHEMICAL INDUSTRIES LTDROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997

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2538	NDA/MAL/HDP/4 694	MERCK SHARP & DOHME INTAPHARMA	SURGIPHARM (U) LIMITED	ROTATEQ	ROTAVIRUS LIVE REASSORTANT VIRUS G1+G2+G3+G4 &P1	2.2M IU+2.8M IU+2.2M IU+2.0M IU	MERK & CO. INCSUMNEYTOWN PIKE, P.O BOX 4, WEST POINT, PENNSYLVANIA, U.S. 19486, USA	UNITED STATES	ORAL LIQUID ORDINARY EMULSIONS	1.0X10.0 ML BOTTLE	01/07/2011
2539	NDA/MAL/HDP/4 697	PT SAMBE FARMA	MEDVIN PHARMA LIMITED	SANBE CLANEKSI	AMOXICILLIN + CLAVULANIC ACID	1000 MG + 200 MG	PT SANBE FARMAJI LEUIGAJAH NO. 162 CIMINDI, INDONESIA	INDONESIA	PARENTERAL ORDINARY VIALS	1.0X6.0 VIAL CARTON	01/07/2011
2540	NDA/MAL/HDP/4 700	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	MEDIZOLE	METRONIDAZOLE	125MG/5ML	MEDIPHARM INDUSTRIES (E.A) LTD PLOT 65, KAKAJJO ROAD, BWEYOGERERE	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2006

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2541	NDA/MAL/HDP/4 701	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
2542	NDA/MAL/HDP/4 702	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABTOL 20%W/V	MANNITOL	200MG/ML	ABACUS PARENTERAL DRUGS LTD. PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2011
2543	NDA/MAL/HDP/4 703	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABGYL	METRONIDAZOLE	500MG	ABACUS PARENTERAL DRUGS LTD. PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	01/07/2011

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2544	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
2545	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
2546	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

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2547	NDA/MAL/HDP/4 707	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	DICLOMOL INJECTION	DICLOFENAC SODIUM	25MG/ML	WIN MEDICARE PVT LIMITEDMEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X3.0 ML AMPOULE	01/07/1998
2548	NDA/MAL/HDP/4 710	COSMOS LTD	ASTRA PHARMA (U) LIMITED	MEDOPRESS TABLETS 250MG	METHYLDOPA	250MG	COSMOS LIMITED..RANGWE ROAD, OFF LUNGA LUNGA ROAD, INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1998
2549	NDA/MAL/HDP/4 712	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	MEFINAL-500	MEFENAMIC ACID	500MG	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILSHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009

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2550	NDA/MAL/HDP/4715	BLUE CROSS LABORATORIES LIMITED	STAR PHARMACEUTICALS LTD	MEFTAL FORTE	MEFENAMIC ACID + PARACETAMOL	500MG + 450MG	BLUE CROSS LABORATORIES LTD-17, VERNA INDUSTRIAL ESTATE,VERNA GOA-403722	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X2.0X10.0 TABLET BLISTER	01/07/2008
2551	NDA/MAL/HDP/4717	BLUE CROSS LABORATORIES LIMITED	STAR PHARMACEUTICALS LTD	MEFTAL-SPAS	MEFENAMIC ACID + DICYCLIMINE HYDROCHLORIDE	250MG + 10MG	BLUE CROSS LABORATORIES LTD-17, VERNA INDUSTRIAL ESTATE,VERNA GOA-403722	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X20.0 TABLET BLISTER,1.0X2.0X3.0X10.0 TABLET BLISTER,1.0X10.0X3.0X10.0 TABLET BLISTER	01/07/2008
2552	NDA/MAL/HDP/4718	MEGA LIFSCIENCES (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

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2553	NDA/MAL/HDP/4 719	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	ACNOTIN 10	ISOTRETINOIN	10MG	MEGA LIFE SCIENCES PUBLIC COMPANY LIMITED384 SOIB PATTANA 3 RD BANGPOO INDUSTRIAL ESTATE SAMUTPRAKARN 10280	THAILAND	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2011
2554	NDA/MAL/HDP/4 721	PT SAMBE FARMA	MEDVIN PHARMA LIMITED	MEGABAL	MECOBALAMIN	5000MCG	PT SANBE FARMA,UNIT 1JI INDUSTRI NO.9 LEUWIGAJAH CIMINDI CIMAH WEST JAVA,INDONESIA	INDONESIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	01/07/2011
2555	NDA/MAL/HDP/4 723	REGAL PHARMACEUCIALS LTD	REGAL PHARMA (U) LTD	MEGYL SUSPENSION	METRONIDAZOLE BENZOATE	200MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/1997

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2556	NDA/MAL/HDP/4 725	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	MEGYL TABLET	METRONIDAZOLE	200MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X250.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	01/07/1997
2557	NDA/MAL/HDP/4 726	MACK BROWN PHARMACEUTICAL S PVT LIMITED	SHURIK LTD	ADB MIN MULTIPOWER	MULTI- INGREDIENT	MULTI- INGREDIENT	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X300.0 ML BOTTLE	01/07/1997
2558	NDA/MAL/HDP/4 731	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

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2559	NDA/MAL/HDP/4 738	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	CILOXAN	CIPROFLOXACIN	0.3%W/V	ALCON COUVREUR NVRIKSWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/1997
2560	NDA/MAL/HDP/4 739	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	MERO	MEROPENEM	1G	SWISS PARENTERALS LIMITED (UNIT-2) PLOT NO. 402, 412- 414 KERALA INDUSTRIAL ESTATE, GIDC, NEAR BAVLA, AHMEDABAD,38222 0, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2011
2561	NDA/MAL/HDP/4 744	DAFRA PHARMA N.V/S.A	MULTIPHAR UGANDA LIMITED	MERONIA 500	MEROPENEM	500MG	DEMO SA21ST KM NATIONAL ROAD, ATHENS, LAMIA 14568 KRYONERI, ATHENS	GREECE	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL	01/07/2013

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2562	NDA/MAL/HDP/4 745	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
2563	NDA/MAL/HDP/4 748	MEDICAL UNION PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	ACICONE-S CHEWABLE TABLET	MAGALDRATE+SI METHICONE	720MG+25MG	MEDICAL UNION PHARMA .COABU- SULTAN ISMAILIA EGYPT	EGYPT	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X5.0X4.0 TABLET BLISTER	01/07/2006
2564	NDA/MAL/HDP/4 749	PT SANBE FARMA	MEDVIN PHARMA LIMITED	MEROSAN	MEROPENEM	1G	PT SANBE FARMAJI LEUWIGAJAH I62 CIMINDI CIMAHI WEST JAVA INDONESIA	INDONESIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2012

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2565	NDA/MAL/HDP/4 751	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	FEROL	FERROUS SULPHATE	200MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER,1.0X100.0X 10.0 TABLET BLISTER	01/07/2009
2566	NDA/MAL/HDP/4 757	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	METFORMIN- DENK 500	METFORMIN	500MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	01/07/1998
2567	NDA/MAL/HDP/4 758	DENK PHARMA GMB H & CO. KG	BENLE CONSULT LIMITED	METFORMIN DENK 1000	METFORMIN	1000MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER	01/07/2011

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2568	NDA/MAL/HDP/4 759	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	CIPRODAR	CIPROFLOXACIN	500MG	DAR AL DAWADAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2009
2569	NDA/MAL/HDP/4 766	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOBEN SUSPENSION	MEBENDAZOLE	100MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2001
2570	NDA/MAL/HDP/4 769	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOBEX	MEBENDAZOLE	100MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER,1.0X100.0X 10.0 TABLET BLISTER	01/07/2009

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2571	NDA/MAL/HDP/4 774	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FERROFOL VIT-Z	FERROUS SULPHATE+FOLIC ACID+ASCORBIC ACID+THIAMINE MONONITRATE+R IBOTLAVINE+PYRI DOXINE HCL+NICOTINAMI DE+ZINC	150MG+0.5MG+50 MG+2MG+2MG+1 MG+10MG+25MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X6.0 CAPSULE BLISTER	01/07/2014
2572	NDA/MAL/HDP/4 775	SKAGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	CIPROKANT-500	CIPROFLOXACIN	500MG	S KANT HEALTH CARE LTD PLOT 1802 - 1805	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010
2573	NDA/MAL/HDP/4 781	CYANO PHARMA(P)	RENE PHARMACY LTD	CYANO IRON TABLETS	FERROUS SULPHATE	200MG	CYANO PHARMA(P)115-C IND ESTATE POLO GROUND INDORE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2001

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2574	NDA/MAL/HDP/4 784	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	D50	GLUCOSE INTRAVENOUS INFUSION	50%W/V	ABACUS PARENTERAL DRUGS LIMITEDBLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2011
2575	NDA/MAL/HDP/4 788	JASSEN-CILAG (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	DAKTARIN ORAL GEL	MICONAZOLE NITRATE	20MG/G	SPECPHARM HOLDINGS 15TH ROAD HALFWAY HOUSE	SOUTH AFRICA	ORAL TOPICAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/1997
2576	NDA/MAL/HDP/4 789	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	DALACIN C	CLINDAMYCIN HYDROCHLORIDE	300MG	FAREVA AMBOISE - ZONE INDUSTRIELLE, 29 ROUTE DES INDUSTRIES, 37530 POCE SUR CISSE, FRANCE	FRANCE	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CARTON,1.0X2.0X8. 0 CAPSULE STRIP	01/07/1997

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2577	NDA/MAL/HDP/4 790	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	DALACIN C	CLINDAMYCIN HYDROCHLORIDE	150MG	FAREVA AMBOISE - ZONE INDUSTRIELLE, 29 ROUTE DES INDUSTRIES, 37530 POCE SUR CISSE, FRANCE	FRANCE	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X8.0 CAPSULE STRIP,1.0X100.0 CAPSULE CARTON	01/07/1997
2578	NDA/MAL/HDP/4 792	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	DALACIN C	CLINDAMYCIN PHOSPHATE	150MG/ML	PFIZER GLOBAL MANUFACTURING BELGIUM NVRIJKSWEG 12, 2870 PUURS - BELGIUM	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X4.0 ML VIAL,1.0X2.0 ML VIAL	01/07/1997
2579	NDA/MAL/HDP/4 794	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	DALADOL	DICLOFENAC SODIUM + PARACETAMOL	50MG+500MG	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2012

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2580	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
2581	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
2582	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

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2583	NDA/MAL/HDP/4 801	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	DAZEL KIT	FLUCONAZOLE + AZITHROMYCIN + SECNIDAZOLE	150MG + 1G + 1G	AJANTA PHARMA LIMITED PAITHANMANUFACT URING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2009
2584	NDA/MAL/HDP/4 804	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	CLAVODAR	AMOXICILLIN + CLAVULANIC	200MG + 28MG /5ML	DAR AL DAWANA'UR PLANT AMMAN	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X70.0 ML BOTTLE	01/07/2012
2585	NDA/MAL/HDP/4 806	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOFER	FERROUS SULPHATE+FOLIC ACID	200MG + 0.25MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10 0.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2009

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2586	NDA/MAL/HDP/4 807	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOFORMIN	METFORMIN	500MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2011
2587	NDA/MAL/HDP/4 809	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOCORT SKIN CREAM	HYDROCORTISON E	0.1%W/W	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2013
2588	NDA/MAL/HDP/4 811	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOGYL	METRONIDAZOLE	200MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER,1.0X100.0X 10.0 TABLET BLISTER	01/07/2009

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2589	NDA/MAL/HDP/4 812	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOMETROL SUSPENSION	METRONIDAZOLE BENZOATE	125MG/5ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2001
2590	NDA/MAL/HDP/4 813	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOMETROL TABLETS (THANE)	METRONIDAZOLE	200MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X10 0.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER,10.0X1 0.0 TABLET BLISTER	01/07/1998
2591	NDA/MAL/HDP/4 815	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	FERROLIC-LF	FERROUS SULPHATE +FOLIC ACID	200MG+0.4MG	LABORATORY & ALLIED LTD PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2014

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2592	NDA/MAL/HDP/4 817	CYANO PHARMA(P)	RENE PHARMACY LTD	METOCLOPRAMI DE TABLETS	METOCLOPRAMI DE	10MG	CYANO PHARMA(P)115-C IND ESTATE POLO GROUND INDORE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2001
2593	NDA/MAL/HDP/4 818	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	FERROUS SULPHATE	FERROUS SULPHATE	200MG	LABORATORY & ALLIED LTD PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1997
2594	NDA/MAL/HDP/4 819	FDC LIMITED	AIVEEN (U) LIMITED	ELECTRAL 21.8G	ORAL REHYDRATION SALT	21.8G	FDC LIMITED B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.☐	INDIA	ORAL LIQUID ORDINARY UNIT DOSE POWDERS	1.0X21.8 G SACHET	01/07/2000

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2595	NDA/MAL/HDP/4 821	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	METPURE-XL 50	METOPROLOL	50MG	EMCURE PHARMACEUTICALS LIMITED LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI- BRAHMANA JAMMU ,181133	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2009
2596	NDA/MAL/HDP/4 823	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	METRIS INFUSION	METRONIDAZOLE	5MG/ML	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTDVILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/1997
2597	NDA/MAL/HDP/4 826	UNIQUE PHARMACEUTICAL S LTD	PLANET PHARMACEUTICAL S UGANDA LTD	METROGYL DENTA GEL	METRONIDAZOLE + CHLORHEXIDINE	1%W/W + 0.25%W/W	UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)-216-219 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X20.0 G TUBE	01/07/2004

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2598	NDA/MAL/HDP/4 828	UNIQUE PHARMACEUTICAL S LABORATORIES	PLANET PHARMACEUTICAL S UGANDA LTD	METROGYL GEL	METRONIDAZOLE	1%W/W	UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)-304-308 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH	INDIA	TOPICAL EXTERNAL EMULSION GELS	1.0X30.0 G TUBE (ALUMINIUM TUBE),1.0X30.0 G TUBE (LAMINATED TUBE)	01/07/2001
2599	NDA/MAL/HDP/4 830	UNIQUE PHARMACEUTICAL S LABORATORIES	PLANET PHARMACEUTICAL S UGANDA LTD	METROGYL INJECTION	METRONIDAZOLE	5MG/ML	UNIQUE PHARMACEUTICAL LABORATORIES, (A DIVISION OF J.B CHEMICALS & PHARMACEUTICALS LTD PLOT NO 4, PHASE IV, GIDC INDUSTRIAL AREA, PANOLI 394 116 UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS &	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/1997
2600	NDA/MAL/HDP/4 832	UNIQUE PHARMACEUTICAL S LABORATORIES	PLANET PHARMACEUTICAL S UGANDA LTD	METROGYL SUSPENSION	METRONIDAZOLE	200MG/5ML	UNIQUE PHARMACEUTICAL LABORATORIES PLOT NO. 215-219, G.I.D.C. INDUSTRIAL AREA, PANOLI — 394 116, GUJARAT, INDIA. J.B. CHEMICALS AND PHARMACEUTICALS LTD .128/1, GIDC, ANKLESHWAR 393 002, GUJARAT	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/1997

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2601	NDA/MAL/HDP/4 834	AUROBINDO PHARMA LTD UNIT VII	GITTOES PHARMACEUTICAL S LIMITED	FINAGEN	FINASTERIDE	5MG	AUROBINDO PHARMA LIMITED, UNIT IISURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELENGANA (STATE)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2004
2602	NDA/MAL/HDP/4 836	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	METRON	METRONIDAZOLE	200MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X 10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2009
2603	NDA/MAL/HDP/4 838	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	METRONIDAZOLE	METRONIDAZOLE BENZOATE	125MG/5ML	MEDICAMEN BIOTECH LTDSP- 1192, A & B, PHASE -IV, INDUSTRIAL AREA BHIWADI -301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2014

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2604	NDA/MAL/HDP/4 839	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	ANOMEX	ZINC OXIDE+LIDOCAIN E+HYDROCORTIS ONE+ALLANTOIN	5%W/W+3%W/W+ 0.25%W/W+0.5% W/W	BLISS GVS PHARMA LTD PLOT NO 10, SURVEY NO 38/1, DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST. THANE, MAHARASHTRA- INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY BLISTER, 1.0X2.0X5. 0 SUPPOSITORY BLISTER	01/07/2007
2605	NDA/MAL/HDP/4 841	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROMETRO FC	METRONIDAZOLE	200MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793) PLOT 9- 12, DEWAN & SONS INDUSTRIAL. AREA, VEOOR, PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007
2606	NDA/MAL/HDP/4 854	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	METROREN FC	METRONIDAZOLE	200MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2014

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2607	NDA/MAL/HDP/4 855	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICAL S LTD	ASCORIL EXPECTORANT	SALBUTAMOL SULPHATE + BROMHEXINE HYDROCHLORIDE + GUAIFENESIN + MENTHOL	(2MG + 4MG + 100MG + 1MG)/10ML	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2000
2608	NDA/MAL/HDP/4 856	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	METROREN	METRONIDAZOLE	200MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X20.0X1 0.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2001
2609	NDA/MAL/HDP/4 858	RENE INDUSTRIES	RENE INDUSTRIES LIMITED	METROREN SUSPENSION	METRONIDAZOLE BENZOATE	200MG/5ML	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2001

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2610	NDA/MAL/HDP/4 863	MEDICAL UNION PHARMACUITICALS	KARURI PHARMACEUTICAL S LTD.	MICONAZ ORAL GEL	MICONAZOLE	2%W/W	MEDICAL UNION PHARMA .COABU- SULTAN ISMAILIA EGYPT	EGYPT	ORAL TOPICAL GELS AND SOLS	1.0X20.0 G TUBE	01/07/2003
2611	NDA/MAL/HDP/4 865	MEDICAL UNION PHARMACUITICALS	KARURI PHARMACEUTICAL S LTD.	MICONAZ CREAM	MICONAZOLE NITRATE	2%W/W	MEDICAL UNION PHARMA .COABU- SULTAN ISMAILIA EGYPT	EGYPT	VAGINAL CREAMS	1.0X20.0 G TUBE	01/07/2003
2612	NDA/MAL/HDP/4 867	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	MICONA ORAL GEL	MICONAZOLE	20MG	CENTAUR PHARMACEUTICALS PVT LTD -PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X40.0 G TUBE,1.0X20.0 G TUBE	01/07/2003

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2613	NDA/MAL/HDP/4 868	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	FLUCANIR	FLUCONAZOLE	2MG/ML	ACULIFE HEALTHCARE PVT LTDVILLAGE SACHANA, TALUKA, VIRAMGAM, DIST. AHMEDABAD 382150, GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2011
2614	NDA/MAL/HDP/4 872	DAWA LIMITED	SUPER MEDIC LTD	MICLOCIN CREAM	MICONAZOLE NITRATE + CLOBETASOL PROPRIONATE + GENTAMICN	2%W/W+0.5%W/ W+0.1W/W	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2013
2615	NDA/MAL/HDP/4 873	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	FLUCAS	FLUCONAZOLE	200MG	ASTRA LIFE CARE (INDIA) PVT.LTDPLOT NO. 57/P, SARKHEJ- BAVLA HIGHWAY, POST RAJODA- 382220, TALUKA BAVLA, AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0 CAPSULE BLISTER	01/07/2011

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2616	NDA/MAL/HDP/4 874	SANOFI-AVENTIS	LABOREX UGANDA LIMITED	CLEXANE	ENOXAPARIN SODIUM	100MG/ML	SANOFI WINTHROP INDUSTRIE180 RUE JEAN JAURE'S BP 94702, MAISONS- ALFORT CEDEX	FRANCE	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X2.0X0.6 ML PRE FILLED SYRINGE	01/07/2009
2617	NDA/MAL/HDP/4 875	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
2618	NDA/MAL/HDP/4 876	SANOFI-AVENTIS	LABOREX UGANDA LIMITED	CLEXANE	ENOXAPARIN SODIUM	100MG/ML	SANOFI WINTHROP INDUSTRIE180 RUE JEAN JAURE'S BP 94702, MAISONS- ALFORT CEDEX	FRANCE	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X2.0X0.8 ML PRE FILLED SYRINGE	01/07/2009

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2619	NDA/MAL/HDP/4 877	SANOFI-AVENTIS	LABOREX UGANDA LIMITED	CLEXANE	ENOXAPARIN SODIUM	100MG/ML	SANOFI WINTHROP INDUSTRIE180 RUE JEAN JAURE'S BP 94702, MAISONS- ALFORT CEDEX	FRANCE	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X2.0X0.4 ML PRE FILLED SYRINGE	01/07/2009
2620	NDA/MAL/HDP/4 880	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	MISOPROST 200	MISOPROSTOL	200MCG	CIPLA LTD .CIPLA GOA UNIT 8 L-147 TO L-147/1 L-147-3 TO L-138 VERNA INDUSTRIAL ESTATE VERNA GOA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER,1.0X7.0X4. 0 TABLET BLISTER,1.0X15.0X4 .0 TABLET BLISTER	01/07/2014
2621	NDA/MAL/HDP/4 891	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	ASPEC TABLET	ASPIRIN+PARACE TAMOL+CAFFEINE ANHYDROUS	150MG+250MG+3 00MG	REGAL PHARMACEUTICALS LTDOFF BABA DOGO RD, RUARAKA, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X10 0.0 TABLET CONTAINER	01/07/1997

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2622	NDA/MAL/HDP/4 895	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	CLOMIFERT	CLOMIPHENE	50MG	DAR AL DAWADAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2010
2623	NDA/MAL/HDP/4 903	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	CMT-TABLETS	MAGNESIUM TRISILICATE+DRIE D ALUMINIUM HYDROXIDE+PEPP ERMINT OIL	250MG+120MG+0. 003ML	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. 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
2624	NDA/MAL/HDP/4 904	NOVO NORDISK	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	MIXTARD 30	INSULIN HUMAN	100 I.U./ML	NOVO NORDISK PRODUCTION SAS45 AVENUE D'ORLEANS, 28000 CHARTRES, FRANCE NOVO NORDISK PHARMANOVO ALLE	DENMARK FRANCE	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL	01/07/1997

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2625	NDA/MAL/HDP/4 905	XEPA-SOUL PATTINSON	DELMAW ENTERPRISES LIMITED	AVORAX CREAM	ACYCLOVIR	5%W/W	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE	01/07/1997
2626	NDA/MAL/HDP/4 906	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	AVORAX TABLETS	ACYCLOVIR	200MG	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X5.0 TABLET STRIP	01/07/1997
2627	NDA/MAL/HDP/4 907	XEPA-SOUL PATTINSON	DELMAW ENTERPRISES LIMITED	AVORAX TABLETS	ACYCLOVIR	400MG	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X5.0 TABLET STRIP	01/07/1997

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2628	NDA/MAL/HDP/4 908	NOVO NORDISK	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MIXTARD 30 PENFILL	BIPHASIC ISOPHANE INSULIN (HUMAN)	100 I.U./ML	NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDAAV. "C", 1413, DISTRITO INDUSTRIAL - 390404 004 MONTES CLAROS, MINAS GERAIS - BRAZIL NOVO NORDISK A/S NOVO ALLE DK-2880 BAGSVAERD	DENMARK BRAZIL	PARENTERAL ORDINARY CARTRIDGES	1.0X1.5 ML FLEXPEN,1.0X5.0X3. 0 ML FLEXPEN	01/07/1997
2629	NDA/MAL/HDP/4 909	AXA PARENTERALS LTD	VITACARE LIMITED	AXAGYL	METRONIDAZOLE	0.5%W/V	AXA PARENTERAL LIMITEDPLOT NO.936,937&939, VILL. KISHANPUR, JAMALPUR,ROORKEE 247667, DISTT. HARIDWAR (UTTARAKHAND) INDIA.	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2015
2630	NDA/MAL/HDP/4 910	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	FLUZOL	FLUCONAZOLE	200MG	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

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2631	NDA/MAL/HDP/4 911	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	MOFILET-500	MYCOPHENOLAT E MOFETIL	500MG	EMCURE PHARMACEUTICALS LIMITED LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI- BRAHMANA JAMMU ,181133	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2008
2632	NDA/MAL/HDP/4 915	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	FOGYL-S TABLETS	METRONIDAZOLE	200MG	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED VANDALUR ROAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/1997
2633	NDA/MAL/HDP/4 917	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL EVILINE FORTE SUSPENSION	MAGNESSIUM HYDROXIDE +ALUMINIUM HYDROXIDE+SIME THICONE	400MG/5ML+400 MG/5ML+40MG/5 ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X120.0 ML BOTTLE	01/07/2010

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2634	NDA/MAL/HDP/4 918	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	FOGYL SUSPENSION	METRONIDAZOLE BENZOATE	200MG/5ML	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED VANDALUR ROAD	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/1997
2635	NDA/MAL/HDP/4 919	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL FUSIDIC ACID- B CREAM	FUSIDIC ACID+BETAMETH ASONE 17 VALERATE	2%,W/W,+0.1% W/W	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2008
2636	NDA/MAL/HDP/4 920	LEBEN LABORATORIES LTD	MALIX PHARMA (U) LIMITED	FOLIBEN	FOLIC ACID	5MG	LEBEN LAB PVT LTDL4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X20.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2011

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2637	NDA/MAL/HDP/4 922	KOPRAN LIMITED	TATA UGANDA LIMITED	CIPROQUIN-500	CIPROFLOXACIN	500MG	KOPRAN LIMITEDVILLAGE- SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	10.0X10.0 TABLET BLISTER	01/07/1999
2638	NDA/MAL/HDP/4 924	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	MULTIVIT TABLET	MULTIVITAMIN	MULTI- INGREDIENT	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2001
2639	NDA/MAL/HDP/4 926	LABORATORY&ALLI ED 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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2640	NDA/MAL/HDP/4 927	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	AZOPT	BRINZOLAMIDE	10MG/ML	ALCON COUVREUR NVRIJKSWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML BOTTLE	01/07/2009
2641	NDA/MAL/HDP/4 929	MARTINDALE AND AURUM PHARMACEUTICAL	LABOREX UGANDA LIMITED	MORPHINE INJECTION	MORPHINE	15MG/ML	MARTINDALE PHARMACEUTICAL LIMITED BAMP TON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/1997
2642	NDA/MAL/HDP/4 932	MARTINDALE AND AURUM PHARMACEUTICAL	LABOREX UGANDA LIMITED	MORPHINE INJECTION	MORPHINE	10MG/ML	MARTINDALE PHARMACEUTICAL LIMITED BAMP TON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/1997

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2643	NDA/MAL/HDP/4 933	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	AZUDOX	DOXYCYCLINE HYDROCHLORIDE	100MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD PLOT NO. M444B, STRETCHER ROAD, NTINDA, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CONTAINER,1.0X10. 0 CAPSULE BLISTER,1.0X500.0 CAPSULE CONTAINER,1.0X25 0.0 CAPSULE CONTAINER,1.0X10 00.0 CAPSULE CONTAINER	01/07/1997
2644	NDA/MAL/HDP/4 936	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	COMBIFEN	IBUPROFEN + PARACETAMOL	400MG + 500MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2011
2645	NDA/MAL/HDP/4 937	JASSEN-CILAG (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	MOTILIUM	DOMPERIDONE	10MG	JANSSEN- CILAG DOMAINE DE MAIGREMONT, 27100 VAL DE REUIL - FRANCE	FRANCE	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X20.0 TABLET BLISTER,1.0X30.0 TABLET BLISTER	01/07/1997

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2646	NDA/MAL/HDP/4 939	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	FOLIREN	FOLIC ACID	5MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2005
2647	NDA/MAL/HDP/4 940	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	FOLON	FOLIC ACID	5MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2006
2648	NDA/MAL/HDP/4 943	ASTRAZENECA	MACNAUGHTON LIMITED	NOLVADEX	TAMOXIFEN	20MG	ASTRAZENECA UK LIMITED ASTRAZENECA UK LIMITED SILK ROAD BUSINESS PARK, MACCLES FIELD,CHESHIRE SK 10 2NA,	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/1997

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2649	NDA/MAL/HDP/4 944	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	BENA EXPECTORANT	DIPHENHYDRAMINE HCL + AMMONIUM CHLORIDE + SODIUM CITRATE	14MG + 135MG + 57.5MG	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X120.0 ML BOTTLE	01/07/1997
2650	NDA/MAL/HDP/4 946	ESAPHARM SRL	BYAMAKA PHARMACEUTICAL COMPANY LTD	MOVATE	CLOBETASOL	0.05%W/W	ESAPHARMA SRL VIA DE GASPERI, 13- 20066 MELZO (MILAN) ITALY	ITALY	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	01/07/1999
2651	NDA/MAL/HDP/4 949	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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2652	NDA/MAL/HDP/4 951	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
2653	NDA/MAL/HDP/4 952	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
2654	NDA/MAL/HDP/4 953	MEGA LIFSCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	NAT-B	MULTI- INGREDIENT	MULTI- INGREDIENT	MEGA LIFE SCIENCES PUBLIC COMPANY LIMITED384 SOIB PATTANA 3 RD BANGPOO INDUSTRIAL ESTATE SAMUTPRAKARN 10280	THAILAND	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2009

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2655	NDA/MAL/HDP/4 955	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	COMPOUND SODIUM LACTATE INFU.	COMPOUND SODIUM LACTATE	MULTI INGREDIENT	ACULIFE HEALTHCARE PVT. LTDVILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/1997
2656	NDA/MAL/HDP/4 956	UNIQUE PHARMACEUTICAL S LABORATORIES	PLANET PHARMACEUTICAL S UGANDA LTD	CONTRAPAQUE 350	IOHEXOL	350MG	UNIQUE PHARMACEUTICAL LABORATORIES, (A DIVISION OF J.B CHEMICALS & PHARMACEUTICALS LTD PLOT NO 4, PHASE IV, GIDC INDUSTRIAL AREA, PANOLI 394 116	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL	01/07/2010
2657	NDA/MAL/HDP/4 957	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICAL S LTD	MUMFER	IRON (111) POLYMALTOSE COMPLEX + FOLIC ACID	100MG + 500MCG	GLENMARK PHARMACEUTICALS LTD PLOT E PLOT NO. E-37, 39, MIDC AREA, SATPUR, NASIK - 422 007, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2004

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2658	NDA/MAL/HDP/4 958	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BENZOSED	MIDAZOLAM	1MG/ML	TROIKAA PHARMACEUTICALS LTD .SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X5.0 ML VIAL	01/07/2011
2659	NDA/MAL/HDP/4 959	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	CONTUS PAEDIATRIC LINCTUS	CHLORPHENIRAM INE / PHENYLEPHRINE / DEXTROMETHOR PHAN	1MG/ 5MG/ 10MG	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X50.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2011
2660	NDA/MAL/HDP/4 962	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	BETAD	BETAMETHASONE DIPROPIONATE	0.05%W/W	S.KANT HEALTHCARE LTD PLOT 1802, 1805, GIDC PHASE III VAPI 39179, GUJARAT	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE,1.0X1.0X15.0 G TUBE	01/07/2010

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2661	NDA/MAL/HDP/4 964	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	CONTUS PLUS PAEDIATRIC SUSPENSION	CHLORPHENAMIN E+PHENYLEPHRIN E+PARACETAMOL	1MG+5MG+160MG	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. 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
2662	NDA/MAL/HDP/4 965	BETA HEALTHCARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	BETAFEN SYRUP	IBUPROFEN	100MG/5ML	BETA HEALTHCARE INTERNATIONAL LTD - PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2001
2663	NDA/MAL/HDP/4 966	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	CONTUS-650	CHLORPHENIRAM INE + PHENYLEPHRINE + PARACETAMOL	2MG + 5MG + 650MG	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X50.0X1 .0X6.0 TABLET BLISTER, 1.0X1.0X10.0 TABLET BLISTER	01/07/2010

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2664	NDA/MAL/HDP/4 968	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	FRUSEMIDE INJECTION	FUROSEMIDE	10MG/ML	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2008
2665	NDA/MAL/HDP/4 969	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	BENZATHINE PENICILLIN	BENZATHINE PENICILLIN	2.4 M.U	CSPC ZHONGNUO PHARMACEUTICAL (SCJIJAZHUANG) 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
2666	NDA/MAL/HDP/4 971	AFRICURE PHARMACEUTICAL S (INDIA) PRIVATE LIMITED	AFRICURE PHARMACEUTICAL S U LIMITED	FRUSEMIDE TABLETS	FUROSEMIDE	40MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITEDPLOT 9- 12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP,1.0X1000.0 TABLET CONTAINER	01/07/1997

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2667	NDA/MAL/HDP/4 972	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	COOLMINT LISTERINE	MENTHOL + ALCOHOL 95%	0.02% + 4.58ML	JOHNSON&JOHNSO N PTY LTD.EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY LIQUIDS	1.0X250.0 ML CONTAINER,1.0X50 0.0 ML CONTAINER	01/07/2001
2668	NDA/MAL/HDP/4 973	MERCK	UNITED HEALTHCARE DISTRIBUTORS LTD	PERGOVERIS	FOLLITROPIN ALFA/LUTROPIN ALFA	150 I.U/75 I.U	MERCK SERONO S.A. (MSA) -1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND	ITALY SWITZERLAND	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 ML VIAL + 1*1ML VIAL OF WFI	01/07/2014
2669	NDA/MAL/HDP/4 974	COSMOS LTD	ASTRA PHARMA (U) LIMITED	FRUSEMIDE TABLETS BP 40MG	FUROSEMIDE	40MG	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	01/07/1998

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2670	NDA/MAL/HDP/4 976	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
2671	NDA/MAL/HDP/4 979	CIRON DRUGS & PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	FUROSEMIDE	FUROSEMIDE	10MG/ML	CIRON DRUGS AND PHARMACEUTICALS PVT LTDN-118 M.I.D.C, TAAPUR,BOISAR,DIS T.THANE MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE	01/07/2010
2672	NDA/MAL/HDP/4 982	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSMAG TABLETS	MAGNESIUM TRISILICATE	370MG	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X100.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	01/07/1998

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2673	NDA/MAL/HDP/4 983	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
2674	NDA/MAL/HDP/4 998	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	HYAN	LEVONORGESTRE L	0.03MG	MYLAN LABORATORIES LIMITED..PLOT NO.20 & 21, PHARMEZ, SARKHEJ- BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL- SANAND, AHMEDABAD, GUJARAT, INDIA 382213 MYLAN LABORATORIES LIMITED.-PLOT NO.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X28.0 TABLET BLISTER	01/07/2006
2675	NDA/MAL/HDP/4 999	UNIQUE PHARMACEUTICAL LABORATORIES	PLANET PHARMACEUTICAL S UGANDA LTD	PAMIDOL*370	IOPAMIDOL	755.3MG/ML	UNIQUE PHARMACEUTICAL LABORATORIES, (A DIVISION OF J.B CHEMICALS & PHARMACEUTICALS LTD PLOT NO 4, PHASE IV, GIDC INDUSTRIAL AREA, PANOLI 394 116	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL,1.0X1.0X100.0 ML VIAL	01/07/2010

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2676	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
2677	NDA/MAL/HDP/5004	GLAXOSMITHKLINE LIMITED LIKONI	BETA HEALTHCARE UGANDA LIMITED	COFTA TABLETS	MULTI-INGREDIENT	N/A	GLAXOSMITHKLINE LIMITED - 78392-00507, VIWANDANI LIKONI ROAD NAIROBI KENYA BETA HEALTHCARE INTERNATIONAL LTD - PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY LOZENGES	1.0X100.0 TABLET CARTON,1.0X50.0 TABLET CARTON,1.0X150.0 TABLET CARTON	01/07/1997
2678	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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2679	NDA/MAL/HDP/5 008	UNIMED INDIA	ASTRA PHARMA (U) LIMITED	COLDAFEX	MULTI- INGREDIENT	MULTI- INGREDIENT	UNIMED INDIA86,MAROL COOPERATIVE ESTATE, M.V ROAD ANDHERE(E)MUMBA I 400059	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2005
2680	NDA/MAL/HDP/5 010	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	ZARIN CREAM	MICONAZOLE NITRATE	2%W/W	XEPA-SOUL PATTINSON (MALAYSIA) SDA BHD1-5, CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997
2681	NDA/MAL/HDP/5 011	UNIMED INDIA	ASTRA PHARMA (U) LIMITED	COLDAFEX TABLETS	MULTI- INGREDIENT	MULTI- INGREDIENT	UNIMED INDIA86,MAROL COOPERATIVE ESTATE, M.V ROAD ANDHERE(E)MUMBA I 400059	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X4.0 TABLET STRIP,1.0X10.0X10. 0 TABLET BLISTER	01/07/1997

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2682	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
2683	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
2684	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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2685	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
2686	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
2687	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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2688	NDA/MAL/HDP/5 028	THE MENTHOLATUM COMPANY LTD TWY	HARLEYS UGANDA LIMITED	DEEP HEAT SPRAY	MULTI- INGREDIENT	MULTI- INGREDIENT	COLEP LAUPHEIM GMBH & CO KG- FOCKESTRASSE 12, 88471, LAUPHEIM	GERMANY	TOPICAL EXTERNAL PRESSURISED AEROSOLS	1.0X150.0 ML CANNISTER	01/07/1997
2689	NDA/MAL/HDP/5 030	PFIZER LAB LTD	LABOREX UGANDA LIMITED	SOLU-MEDROL	METHYLPREDNIS OLONE HEMISUCCINATE	125MG/2ML	PFIZER GLOBAL MANUFACTURING BELGIUM NVRIJKSWEG 12, 2870 PUURS - BELGIUM	BELGIUM	PARENTERAL ORDINARY DRY VIALS	1.0X2.0 ML VIAL,1.0X8.0 ML VIAL	01/07/1997
2690	NDA/MAL/HDP/5 031	THE MENTHOLATUM COMPANY LTD	HARLEYS UGANDA LIMITED	DEEP HEAT RUB	MULTI- INGREDIENT	MULTI- INGREDIENT	THE MENTHOLATUM COMPANY LTD, TWYFORD,1 REDWOOD AVENUE, PEEL PARK CAMPUS EAST KILBRIDE, G74 SCOTLAND	UNITED KINGDOM	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X35.0 G TUBE,1.0X67.0 G TUBE,1.0X100.0 G TUBE	01/07/1997

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2691	NDA/MAL/HDP/5032	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	DELAISED DRY COUGH SYRUP (NON DROWSY)	DEXTROMETHOR PHAN	7.5MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2004
2692	NDA/MAL/HDP/5033	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	MEBFIL TABLETS	MEBENDAZOLE	100MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDA LUR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/1997
2693	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

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2694	NDA/MAL/HDP/5036	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	DEPO PROGESTIN	MEDROXYPROGESTERONE ACETATE	150MG	PT HARSEN LABORATORIES, JL RAYA - JL RAYA BOGOR, KM 24.6, JAKARTA TIMUR 13750	INDONESIA	PARENTERAL ORDINARY VIALS	1.0X20.0 VIAL CARTON,1.0X25.0X1.0 ML VIAL	01/07/2010
2695	NDA/MAL/HDP/5038	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	M-CAM TABLETS	MELOXICAM	15MG	UNICHEM LABORATORIES LIMITED UNICHEM LABORATORIES LIMITED. UNIT II, VILLAGE BHATAULI KALAN, BADDI, DIST. SOLAN PIN CODE 173 205, HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X5.0X10.0 TABLET BLISTER	01/07/2002
2696	NDA/MAL/HDP/5040	PFIZER LABORATORIES (PTY) LTD BELGIUM	LABOREX UGANDA LIMITED	DEPO-MEDROL	METHYLPREDNISOLONE ACETATE	40MG/ML	PFIZER GLOBAL MANUFACTURING BELGIUM NVRIJKSWEG 12, 2870 PUURS - BELGIUM	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL,1.0X2.0 ML VIAL,1.0X5.0 ML VIAL	01/07/1997

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2697	NDA/MAL/HDP/5 041	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	MAXITROL	DEXAMETHASON E/NEOMYCIN/POL YMYXIN B	0.1%W/W +0.1%W/W+6000 I.U	ALCON COUVREUR NVRIJKSWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC OINTMENTS	1.0X3.5 G TUBE	01/07/1997
2698	NDA/MAL/HDP/5 042	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSATRIM DS TABLETS	CO-TRIMOXAZOLE	960MG	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X50 0.0 TABLET CONTAINER,1.0X10 0.0 TABLET CONTAINER	01/07/1998
2699	NDA/MAL/HDP/5 043	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	MAXITROL	DEXAMETHASON E/NEOMYCIN/POL YMYXIN B	0.1%W/W+3500I.U /ML+6000I.U/ML	ALCON COUVREUR NVRIJKSWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/1997

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2700	NDA/MAL/HDP/5044	PFIZER LABORATORIES (PTY) LTD BELGIUM	LABOREX UGANDA LIMITED	DEPO-PROVERA	MEDROXYPROGESTERONE ACETATE	150MG/ML	PFIZER GLOBAL MANUFACTURING BELGIUM NVRIJKSWEG 12, 2870 PUURS - BELGIUM	BELGIUM	PARENTERAL ORDINARY I M VIALS	1.0X3.5 ML VIAL,1.0X1.0 ML VIAL	01/07/1997
2701	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
2702	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

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2703	NDA/MAL/HDP/5 053	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	DERMX	ECONAZOLE/ TRIAMCINOLONE/ GENTAMYCIN	1%/0.1%/0.1%	S KANT HEALTH CARE LTD PLOT 1802 - 1805	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2011
2704	NDA/MAL/HDP/5 055	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	DERMOVATE	CLOBETASOL PROPIONATE	0.05%W/W	GLAXOSMITHKLINE HARMIRE GLAXOSMITHKLINE HARMIRE ROAD BARNARD CASTLE DURHAM	UNITED KINGDOM	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE, 1.0X25.0 G TUBE	01/07/1997
2705	NDA/MAL/HDP/5 064	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	MANNITOL INFUSION	MANNITOL	20%W/V	ACULIFE HEALTHCARE PVT. LTD VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2011

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2706	NDA/MAL/HDP/5065	N.V. ORGANON	SURGIPHARM (U) LIMITED	MARVELON	DESOGESTREL/ETHINYLESTRADIOL	150MG/30MG	N.V. ORGANONKLOOSTER STRAAT 6, 5349 AB OSS, THE NETHERLAND	NETHERLANDS	ORAL SOLID ORDINARY TABLETS	1.0X100.0X1.0X28.0 TABLET BLISTER	01/07/2015
2707	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
2708	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

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2709	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
2710	NDA/MAL/HDP/5073	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	DEXONA EYE/EAR DROP	DEXAMATHASON E 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
2711	NDA/MAL/HDP/5074	ZYDUS LIFESCIENCES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DEXONA INJECTION	DEXAMETHASON E DISODIUM PHOSPHATE	4MG/ML	SAKAR HEALTH CARE PVT LTD-10/13 CHONGODAR SARKHEJ BAVLA ROAD DIST AHMABAD 382213 GUJARATI	INDIA	PARENTERAL ORDINARY VIALS	1.0X6.0X2.0 ML VIAL,16.0X6.0X2.0 ML VIAL	01/07/1997

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2712	NDA/MAL/HDP/5076	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	DEXTRACIN EYE DROPS	DEXAMETHASON E + NEOMYCIN	0.1MG + 0.5MG	XEPA-SOUL PATTINSON (MALAYSIA) SDA BHD1-5, CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA	MALAYSIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/1997
2713	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
2714	NDA/MAL/HDP/5079	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	GLEMONT CT 5	MONTELUKAST	5MG	GLENMARK PHARMACEUTICALS LTD .VILLAGE KISHANPURA, BADDI-NALAGARH ROAD, TEHSIL BADDI, DISTRICT SOLAN HP 173205	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014

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2715	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
2716	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,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
2717	NDA/MAL/HDP/5092	MICRO LABS LTD 92 SIPCOT	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DIAPRIDE	GLIMEPIRIDE	2MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011

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2718	NDA/MAL/HDP/5 095	MICRO LABS LTD	LABOREX UGANDA LIMITED	DIAPRIDE PLUS	GLIMEPIRIDE + METFORMIN	1MG + 500MG	MICRO LABS LTD 92 SIPCOT 92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
2719	NDA/MAL/HDP/5 096	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	SCABION	CROTAMITON + SULPHUR	10 G + 2G/100G	ATCO LABS LTD,B- 18, S.I.T.E, KARACHI	PAKISTAN	TOPICAL EXTERNAL OINTMENTS	1.0X60.0 ML BOTTLE	01/07/2003
2720	NDA/MAL/HDP/5 099	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,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2005

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2721	NDA/MAL/HDP/5 100	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S 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
2722	NDA/MAL/HDP/5 102	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE 500MG	METFORMIN	500MG	NKUNZI PHARMACEUTICALS (PTY) LTD.259 DAVIDSON ROAD CNR PEDDIE STREET, WADEVILLE EST. 1 GERMISTON 1422 MERCK SANTÉ2, RUE DU PRESOIR VERT F 45400, SEMOY	FRANCE SOUTH AFRICA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X500.0 TABLET CONTAINER,1.0X6.0 X15.0 TABLET BLISTER,1.0X30.0 TABLET BLISTER	01/07/2010
2723	NDA/MAL/HDP/5 103	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE 1000MG	METFORMIN	1000MG	NKUNZI PHARMACEUTICALS (PTY) LTD -259 DAVIDSON ROAD, WADEVILLE, EXT 1, GERMINSTON, SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X15.0 TABLET BLISTER	01/07/2010

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2724	NDA/MAL/HDP/5 104	NOVO NORDISK PHARMA GULF FZ- LC	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	LEVEMIR FLEXPEN	INSULIN DETEMIR	100 I.U./ML	NOVO NORDISK PRODUCTION SAS45 AVENUE D'ORLEANS, 28000 CHARTRES, FRANCE NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDAAV. "C", 1413, DISTRITO INDUSTRIAL - 390404 004 MONTES CLAROS, MINAS GERAIS - BRAZIL	DENMARK BRAZIL FRANCE	PARENTERAL ORDINARY PRE- FILLED PENS	1.0X5.0X3.0 ML PREFILLED PEN	01/07/2014
2725	NDA/MAL/HDP/5 106	ESAPHARM SRL	BYAMAKA PHARMACEUTICAL COMPANY LTD	LEMONVATE CREAM	CLOBETASOL PROPIONATE	0.05%W/W	ESAPHARMA SRLVIA DE GASPERI, 13- 20066 MELZO (MILAN) ITALY	ITALY	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	01/07/2003
2726	NDA/MAL/HDP/5 107	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	INDOREN CAPSULES	INDOMETHACIN	25MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER, 1.0X1000.0 CAPSULE CONTAINER	01/07/2000

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2727	NDA/MAL/HDP/5 109	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	LEBASMA ORAL SOLUTION	SALBUTAMOL	2MG/5ML	LEBEN LAB PVT LTD L4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2011
2728	NDA/MAL/HDP/5 110	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	GLUCOSE INFUSION BP	DEXTROSE	5%W/V	ACULIFE HEALTHCARE PVT. LTD VILLAGE 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
2729	NDA/MAL/HDP/5 112	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	DICLOMOL SR TABLETS	DICLOFENAC SODIUM	100MG	WIN MEDICARE PVT LIMITED MEERUT, MUZAFFARNAGER ROAD, MODIPURAM - 250110, UTTAR PRADESH -INDIA	INDIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1998

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2730	NDA/MAL/HDP/5 115	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	INDOS-25	INDOMETHACIN	25MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1000.0 CAPSULE CONTAINER,20.0X5. 0 CAPSULE BLISTER,1.0X10.0X1 0.0 CAPSULE BLISTER	01/07/2000
2731	NDA/MAL/HDP/5 117	VENUS REMEDIES LIMITED	HARLEYS UGANDA LIMITED	LASTINEM	IMIPENEM + CILASTATIN	500MG + 500MG	VENUS REMMEDIESUNIT II HILLTOP INDUSTRIAL ESTATES JHARMAJRI EPIP PHASE 1 BHOTOLI KALA BADDI INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	01/07/2011
2732	NDA/MAL/HDP/5 119	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	KONTRAC 200	MISOPROSTOL	200MCG	FOURRTS INDIA LABORATORIES PVT. LIMITEDVANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X2.0 TABLET STRIP,1.0X10.0X10. 0 TABLET BLISTER	01/07/2009

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2733	NDA/MAL/HDP/5 120	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	GLYFORMIN 500 TABLETS	METFORMIN	500MG	REMEDICA LIMITED LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER	01/07/1999
2734	NDA/MAL/HDP/5 121	UNIQUE PHARMACEUTICAL S LABORATORIES	PLANET PHARMACEUTICAL S UGANDA LTD	DICLORAN GEL	DICLOFENAC DIETHYLAMMONI UM	1%W/W	UNIQUE PHARMACEUTICALS LABS (A DIV OF J.B CHEMICALS & PHARMACEUTICAL LTD)-304-308 ,GIDC , PANOLI 394116	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X50.0 G TUBE,1.0X20.0 G TUBE	01/07/1997
2735	NDA/MAL/HDP/5 122	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	KOFAREST SYRUP	SALBUTAMOL SULPHATE/AMBR OXOL SULPHATE/GUAFFE NESIN/MENTHOL	2MG+30MG+100M G+5MG/10ML	CENTAUR PHARMACEUTICALS LTD PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2007

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2736	NDA/MAL/HDP/5 124	GLAXOSMITHKLINE LTD BELGIUM	UNITED HEALTHCARE DISTRIBUTORS LTD	INFANRIX-HEXA	DIPHThERIA TOXOID+TETANU S TOXOID+PERTUSS IS TOXOID(PT)+FILA MENTOUS HAEMAGGLUTINI N(FHA)+PERTACTI N(69KDA OMP)+HBSAG PURIFIED,INACTIV ATED POLIO VIRUS TYPE I-INACTIVATED	MIN 30 I.U.+MIN 40 I.U.+25MG+25MG+ 8MG+10MG,40DU +8DU+32DU+10M G	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
2737	NDA/MAL/HDP/5 125	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	GLYGESIC FORTE RHUMETIC CREAM	MULTI INGREDIENT	N/A	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1998
2738	NDA/MAL/HDP/5 128	MERCK (PTY) LTD	ABACUS PHARMA (AFRICA) LIMITED	GOFEN 400 CLEARCAP	IBUPROFEN	400MG	MEGA LIFESCENCES LTD.384 PATTANA 3 ROAD BANGPOO INDUSTRIAL ESTATE SUMUTPRAKAN	THAILAND	ORAL SOLID ORDINARY CAPSULES	6.0X1.0X10.0 CAPSULE BLISTER	01/07/2009

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2739	NDA/MAL/HDP/5 129	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICAL S LIMITED	KLEEN ENEMA	DISODIUM BISPHOSPHATE/ SODIUM PHOSPHATE	19.2G+7.2G/ 120ML	NABIQASIM INDUSTRIES (PVT) LIMITED17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN	PAKISTAN	RECTAL SYSTEMIC ENEMA LIQUIDS	1.0X135.0 ML BOTTLE	01/07/2006
2740	NDA/MAL/HDP/5 130	UNIQUE PHARMACEUTICAL S LTD	PLANET PHARMACEUTICAL S UGANDA LTD	DICLORAN MS GEL	DICLOFENAC+ME THYL SALICYLATE+MEN THOL	1%W/W+10%W/W +5%W/W	UNIQUE PHARMACEUTICALS LABS (A DIV OF J.B CHEMICALS & PHARMACEUTICAL LTD)-304-308 ,GIDC , PANOLI 394116	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/2005
2741	NDA/MAL/HDP/5 131	NOVO NORDISK	PHILLIPS PHARMACEUTICAL S (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

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2742	NDA/MAL/HDP/5 133	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GONAL-F PEN 900IU/1.5ML(66M CG/1.5ML)	FOLLITROPIN ALFA	66MCG/1.5ML	MERCK SERONO SPA (BARI)-VIA DELLE MAGNOLIE, 15 (LOC FRAZ ZONA INDUSTRIALE) 70026, MODUGNO, BARI MERCK SERONO S.A. (MSA) - 1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND	ITALY SWITZERLAND	PARENTERAL ORDINARY PRE- FILLED PENS	1.0X1.0 CARTRIDGE PREFILLED PEN + 20 NEEDLES FOR INJECTION,1.0X1.0 CARTRIDGE PREFILLED PEN + 8 NEEDLES FOR INJECTION.	01/07/2015
2743	NDA/MAL/HDP/5 134	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	GOODMORNING COUGH TABLETS	MULTIINGREDIEN T	N/A	BETA HEALTHCARE INTERNATIONAL LTD - PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CARTON	01/07/1997
2744	NDA/MAL/HDP/5 135	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	KETOZ	KETOCONAZOLE	2%W/W	SK ANT HEALTHCARE LTD1802-1805 GIDC PHASE III, VAPI- 396195 GUJARAT, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X30.0 G TUBE	01/07/2010

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2745	NDA/MAL/HDP/5 136	BETA HEALTHCARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	GOODMORNING LUNG TONIC	MULTIINGREDIEN T	N/A	BETA HEALTHCARE INTERNATIONAL LTD - PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X50.0 ML BOTTLE	01/07/1997
2746	NDA/MAL/HDP/5 139	NOVO NORDISK	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	INSULATARD HM PENFILL	ISOPHANE INSULIN (HUMAN)	100I.U/ML	NOVO NORDISK PRODUCTION SAS45 AVENUE D'ORLEANS, 28000 CHARTRES, FRANCE NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDAAV. "C", 1413, DISTRITO INDUSTRIAL - 390404 004 MONTES CLAROS, MINAS GERAIS - BRAZIL	DENMARK BRAZIL FRANCE	PARENTERAL ORDINARY CARTRIDGES	1.0X5.0X3.0 ML PREFILLED PEN,1.0X5.0X1.5 ML PREFILLED PEN	01/07/1997
2747	NDA/MAL/HDP/5 140	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	DIFLUCAN	FLUCONAZOLE	200MG	FAREVA AMBOISE - ZONE INDUSTRIELLE, 29 ROUTE DES INDUSTRIES, 37530 POCE SUR CISSE, FRANCE	FRANCE	ORAL SOLID ORDINARY CAPSULES	1.0X7.0 CAPSULE BLISTER	01/07/1997

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2748	NDA/MAL/HDP/5 142	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	INTAMINE CREAM	MEPYRAMINE MALEATE	2%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE,1.0X400.0 G TUBE	01/07/1997
2749	NDA/MAL/HDP/5 143	ASTRA ZENECA	MACNAUGHTON LIMITED	BETALOC ZOK - 25MG	METOPROLOL	25MG	ASTRA ZENECA ABGARTUNAVGEN SE 151 58 SODAERTAJJE SWEDEN	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER	01/07/2011
2750	NDA/MAL/HDP/5 146	ASTRA ZENECA	MACNAUGHTON LIMITED	BETALOC ZOK - 100MG	METOPROLOL	100MG	ASTRA ZENECA ABSE 151 85 SODERTALJE, SWEDEN (GARTUNAVAGEN & SNACKVIKEN)	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2011

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2751	NDA/MAL/HDP/5 147	ASTRA ZENECA	MACNAUGHTON LIMITED	BETALOC ZOK - 50MG	METOPROLOL	50MG	ASTRA ZENECA ABGARTUNAVGEN SE 151 58 SODAERTAJJE SWEDEN	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2011
2752	NDA/MAL/HDP/5 149	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	GRAVINATE SYRUP	DIMENHYDRINAT E	12.5MG/4ML	SEARLE COMPANY LTD - F-319, S.I.T.E., OPP. KESC POWER STATION, KARACHI	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/1997
2753	NDA/MAL/HDP/5 150	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICAL S LTD	KETO PLUS SHAMPOO	KETOCONAZOLE + ZINC PYRITHIONE	2%W/W + 1%W/W	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL LIQUID SOAPS/WASHES	1.0X60.0 ML BOTTLE	01/07/2003

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2754	NDA/MAL/HDP/5 153	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	GRAVINATE TABLETS	DIMENHYDRINAT E	50MG	SEARLE PAKISTAN LTD..F-319, S.I.T.E., OPP. KESC POWER STATION, KARACHI	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997
2755	NDA/MAL/HDP/5 154	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	BETASIL PAEDIATRIC SYRUP	IPECACUANHA TINCTURE	0.5ML	BETA HEALTHCARE INTERNATIONAL LTD - PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X50.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1997
2756	NDA/MAL/HDP/5 155	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	BETAVEL	MULTI- INGREDIENT	N/A	NEM LABORATORIES PVT LTD133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997

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2757	NDA/MAL/HDP/5 157	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	BETAVEL N	BETAMETHASONE +NEOMYCIN SULPHATE	1MG+5MG	NEM LABORATORIES PVT LTD133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL CREAMS	1.0X3.0 G TUBE,1.0X15.0 G TUBE	01/07/1997
2758	NDA/MAL/HDP/5 161	AFRICURE PHARMACEUTICAL S (INDIA) PRIVATELIMITED	ROYAL PHARMA 2011 LIMITED	GRISEOSIM-500	GRISEOFULVIN	500MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9- 12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
2759	NDA/MAL/HDP/5 164	COSMOS LTD	ASTRA PHARMA (U) LIMITED	BROMSAL EXPECTORANT	SALBUTAMOL SULPHATE+BROM HEXINE HYDROCHLORIDE +GUAIFENESIN+M ENTHOL	1MG+2MG+50MG +0.5MG	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2010

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2760	NDA/MAL/HDP/5 165	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
2761	NDA/MAL/HDP/5 167	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	BRUSTAN TABLETS	IBUPROFEN + PARACETAMOL	400MG + 325MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED INDUSTRIAL AREA 3, A.B. ROAD, DEWAS 455001, MADHYA PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,2.0X10.0 TABLET BLISTER	01/07/1998
2762	NDA/MAL/HDP/5 169	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GVGYL SUPPOSITORY	METRONIDAZOLE BP	500MG	BLISS GVS PHARMA LTD PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA- INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY BLISTER	01/07/2007

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2763	NDA/MAL/HDP/5 170	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	CANDITRAL CAPSULE	ITRACONAZOLE	100MG	GLENMARK PHARMACEUTICALS LTD PLOT NO E -37, 39 ,D	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0 CAPSULE STRIP, 1.0X10.0X1.0X4.0 CAPSULE STRIP	01/07/2000
2764	NDA/MAL/HDP/5 171	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	KETAMAX-50	KETAMINE	50MG/ML	TROIKAA PHARMACEUTICALS LIMITED C-1 SARA INDUSTRIAL ESTATE, SELAQUI, DEHRADUN- 248197, UTTARAKHAND, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	01/07/2011
2765	NDA/MAL/HDP/5 176	BAYER AG	SURGIPHARM (U) LIMITED	CANESTEN	CLOTRIMAZOLE	100MG	BAYER AG D-51368 LEVERKUSEN GERMANY	GERMANY	VAGINAL TABLETS	1.0X6.0 TABLET STRIP	01/07/1997

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2766	NDA/MAL/HDP/5 177	YURIA PHARM LTD	PHARMA VILLE LIMITED	ISONIAZID	ISONIAZID	100MG/5ML	YURIA-PHARM LLC MANUFACTURING SITE NO. 1108, KOBZARSKA STREET, CHERKASY, 18030	UKRAINE	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2013
2767	NDA/MAL/HDP/5 179	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFIX 200MG CAPSULES	CEFIXIME TRIHYDRATE	200MG	PHARMA INTERNATIONAL CO.,AL-QASTAL AREA, AIRPORT ROAD, 11941, AMMAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X8.0 CAPSULE BLISTER	01/07/2007
2768	NDA/MAL/HDP/5 180	REGAL PHARMACEUCIALS LTD	REGAL PHARMA (U) LTD	ISORYN DROPS (PAEDRIATRIC)	EPHEDRINE HYDROCHLORIDE	5MG/ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	NASAL TOPICAL DROPS	1.0X15.0 ML BOTTLE	01/07/1997

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2769	NDA/MAL/HDP/5 182	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	ISORYN DROPS (ADULT)	EPHEDRINE HYDROCHLORIDE	10MG/ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	NASAL TOPICAL DROPS	1.0X15.0 ML BOTTLE	01/07/1997
2770	NDA/MAL/HDP/5 183	PHARCO B PHARMACEUTICAL S	WIDE SPECTRUM ENTERPRISES (U) LIMITED	GYNOZOL VAGINAL CAPSULES	MICONAZOLE NITRATE	400MG	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT, P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	VAGINAL SUPPOSITORIES	1.0X3.0 CAPSULE BLISTER	01/07/2000
2771	NDA/MAL/HDP/5 184	PHARCO PHARMACEUTICAL S	WIDE SPECTRUM ENTERPRISES (U) LIMITED	GYNOZOL VAGINAL CREAM	MICONAZOLE NITRATE	2%W/W	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT, P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	VAGINAL CREAMS	1.0X40.0 G TUBE	01/07/2000

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2772	NDA/MAL/HDP/5 186	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ISOTROY 250	ISOFLURANE	250ML	TROIKAA PHARMACEUTICALS LTDTHOL VILLAGE, DIST. MEHSANA- 382728, GUJARAT, INDIA	INDIA	OTHER SYSTEMIC LIQUID INHALATIONS	1.0X250.0 ML BOTTLE	01/07/2014
2773	NDA/MAL/HDP/5 187	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	HEALIT SKIN OINTMENT	BACITRACIN+POL YMYXIN B SO4+NEOMYCIN+ LIDOCAINE	500UNITS+5000UN ITS+3.5MG+40MG/ G	ATCO LABORATORIES PVT LTDB-18,S.I.T.E KARACHI, PAKISTAN	PAKISTAN	TOPICAL EXTERNAL OINTMENTS	1.0X10.0 G TUBE	01/07/2007
2774	NDA/MAL/HDP/5 188	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	ITRAZ CAPSULES	ITRACONAZOLE	100MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X5.0 CAPSULE BLISTER,1.0X6.0X10 .0 CAPSULE BLISTER	01/07/2009

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2775	NDA/MAL/HDP/5 200	COSMOS LTD	ASTRA PHARMA (U) LIMITED	HYDRALAZINE TABLETS B.P 25MG.	HYDRALAZINE HYDROCHLORIDE	25MG	COSMOS LIMITED- RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1998
2776	NDA/MAL/HDP/5 201	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM BENDAZOLE	MEBENDAZOLE	100MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X250.0 TABLET CONTAINER,1.0X50 0.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1997
2777	NDA/MAL/HDP/5 205	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM-VENT	SALBUTAMOL	4MG	KAMPALA PHARMACEUTICALS INDUSTIESPLOT 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

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2778	NDA/MAL/HDP/5 207	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	DIGOXIN TABLETS	DIGOXIN	0.25MG	NEM LABORATORIES PVT. LIMITED133 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
2779	NDA/MAL/HDP/5 211	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	DINAC GEL	DICLOFENAC	1%W/W	S KANT HEALTHCARE LTD1802-1805 GIDC PHASE III VAPI 396 195 GUJARAT	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE	01/07/2009
2780	NDA/MAL/HDP/5 214	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	NIRMET	METRONIDAZOLE	500MG/100ML	ACULIFE HEALTHCARE PVT. LTDVILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2010

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2781	NDA/MAL/HDP/5 215	J.B CHEMICALS & PHARMACEUTICAL S LTD	PLANET PHARMACEUTICAL S UGANDA LTD	METROGYL TABLETS	METRONIDAZOLE	200MG	J.B. CHEMICALS AND PHARMACEUTICALS LTD .128/1, GIDC, ANKLESHWAR 393 002, GUJARAT GLOBELA PHARMA PVT.LTD.357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X20.0X5 .0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X5.0 X2.0X10.0 TABLET BLISTER	01/07/2001
2782	NDA/MAL/HDP/5 221	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	DICLOFENAC SODIUM	DICLOFENAC SODIUM	75MG/3ML	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X3.0 ML AMPOULE,1.0X10.0 X3.0 ML AMPOULE	01/07/2006
2783	NDA/MAL/HDP/5 222	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	EMTRICITABINE+T ENOFOVIR DF	EMTRICITABINE/T ENOFOVIR	200MG/300MG	MYLAN LABORATORIES LTD- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD ,PLOT NO. 11, 12, & 13 INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III PITHAMPUR 454775,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	07/07/2008

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2784	NDA/MAL/HDP/5 224	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	EMTRICITABINE+T ENOFOVIR DISOPROXIL FUMERATE	EMTRICITABINE/T ENOFOVIR DISOPROXIL FUMERATE	200MG/300MG	AUROBINDO PHARMA LTD UNIT IIIAUROBINDO PHARMA LTD UNIT III SURVEY NO. 313 BACHUPALLY VILLAGE QUTHUBULLAPUR MANDAL RANGA REDDY DISTRICT (A.P)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2009
2785	NDA/MAL/HDP/5 226	HETERO DRUGS LTD	AIVEEN (U) LIMITED	EMTRICITABINE+T ENOFOVIR DISOPROXIL FUMERATE	EMTRICITABINE+T ENOFOVIR DISOPROXIL FUMERATE	200MG/300MG	HETERO LABS LTD (UNIT- V)SY.NO.438,439,44 0 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA HETERO DRUGS LTDUNIT-111 NO 22- 110 I.D.A JEEDIMETTA HYDRABAD 500055	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2013
2786	NDA/MAL/HDP/5 228	CENTAUR PHARMACEUTICAL S PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	DICLOGENTA	DICLOFENAC SODIUM+GENTA MICIN SULPHATE	1MG/ML+3MG/ML	CENTAUR PHARMACEUTICALS PVT LTD -PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2009

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2787	NDA/MAL/HDP/5 231	INTAS, PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	ENAPRIL 10	ENALAPRIL MALEATE	10MG	INTAS PHARMACEUTICALS LTD PLOT 457/458, SARKHEJ BAVLA HIGHWAY MATODA 382 210 TAL: SANAND, AHMEDABAD, INDIA INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
2788	NDA/MAL/HDP/5 232	INTAS, PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	ENAPRIL-5	ENALAPRIL MALEATE	5MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2006
2789	NDA/MAL/HDP/5 233	CADILA PHARMACEUTICAL S LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	ENVAS 10 MG TABLETS	ENALAPRIL	10MG	CADILA PHARMACEUTICALS LIMITED 1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997

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2790	NDA/MAL/HDP/5 234	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
2791	NDA/MAL/HDP/5 235	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,	INDIA	ORAL SOLID RETARD ENTERIC- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,5.0X2.0 X10.0 TABLET BLISTER	01/07/1997
2792	NDA/MAL/HDP/5 243	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

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2793	NDA/MAL/HDP/5 245	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	FABUTAS-40	FEBUXOSTAT	40MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
2794	NDA/MAL/HDP/5 248	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM-AMPI	AMPICILLIN	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE CONTAINER,1.0X10 0.0 CAPSULE CONTAINER,1.0X10 00.0 CAPSULE CONTAINER,1.0X50 0.0 CAPSULE CONTAINER,1.0X25 0.0 CAPSULE CONTAINER	01/07/1997
2795	NDA/MAL/HDP/5 249	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	ENCIFER	IRON SUCROSE	100MG/5ML	SAMRUDH PHARMACEUTICALS PVT LTDJ-174, J-168 & J-168/1, MIDC, TARAPUL, BOISAR, DIST THANE-401506 EMCURE PHARMACEUTICALS LTD PLOT NO. P-1 ITBT PARK PHASE II MIDC HINJWADI PUNE 411057	INDIA	PARENTERAL ORDINARY INFUSION AMPOULES	1.0X5.0X5.0 ML AMPOULE	01/07/2013

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2796	NDA/MAL/HDP/5 250	PHARCO PHARMACEUTICAL S	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCOLIN SYRUP	SALBUTAMOL + AMMONIUM CHLORIDE	2MG/5ML +100MG/5ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT, P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/1998
2797	NDA/MAL/HDP/5 255	GLAXOSMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ENO LEMONFRUIT SALT	MULTI- INGREDIENT	MULTI- INGREDIENT	GLAXO SMITH KLINE LTDLIKONI RD, INDUSTRIAL AREA,NAIROBI KENYA	KENYA	ORAL LIQUID ORDINARY EFFERVESCENT POWDERS/GRANU LES	1.0X8.0X4.5 G SACHET,1.0X10.0X4 .5 G SACHET,1.0X48.0X4 .5 G SACHET,1.0X4.0X4. 5 G SACHET,1.0X24.0X4 .5 G SACHET	01/07/1997
2798	NDA/MAL/HDP/5 260	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	ERYMYCIN	ERYTHROMYCIN ESTOLATE	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997

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2799	NDA/MAL/HDP/5 269	INTAS, PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	DIVAA OD 500	DIVALPROEX	500MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2010
2800	NDA/MAL/HDP/5 271	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	ERYTHYL SYRUP	ERYTHROMYCIN ETHYL SUCCINATE	125MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997
2801	NDA/MAL/HDP/5 272	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	DIX	DIGOXIN	0.25MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2011

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2802	NDA/MAL/HDP/5 279	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DOSIN	DOXAZOCIN	2MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2011
2803	NDA/MAL/HDP/5 281	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	EFAVIRENZ+EMTR ICITABINE+TENOF OVIR 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
2804	NDA/MAL/HDP/5 282	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	DORFEN	ACECLOFENAC	100MG	TRIVENI FORMULATIONS LIMITED -PLOT NO 52-54,62-64 ALEAP INDUSTRIAL ESTATE SURAMPALLI (V) VIJAYAWADA A.P	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014

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2805	NDA/MAL/HDP/5 283	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	IBUMEX GEL	IBUPROFEN	5%W/W	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL EMULSION GELS	1.0X25.0 G TUBE	01/07/2001
2806	NDA/MAL/HDP/5 284	HETERO LABS LTD	AIVEEN (U) LIMITED	EFAVIRENZ+EMTR ICITABINE+TENOF OVIR	EFAVIRENZ + EMTRICITABINE + TENOFVIR	600MG + 200MG + 300MG	HETERO LABS LTD(UNIT V).JADCHERLA (M),MAHABOONAG AR DIST, ANDHRA PRADESH,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2012
2807	NDA/MAL/HDP/5 287	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	EFAVIRENZ + LAMIVUDINE + TENOFVIR DISOPROXIL FUMERATE	EFAVIRENZ + LAMIVUDINE + TENOFVIR DISOPROXIL FUMERATE	600MG + 300MG + 300MG	AUROBINDO PHARMA LIMITED (SEZ, UNIT – VII), SURVEY NO.411, 425, 434, 435 & 458, APIIC, PLOT NO. SI GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHERLA MANDAL, MAHABOON NAGAR DISTRICT, HYDERABAD, ANDHRA PRADESH 500090, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2014

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2808	NDA/MAL/HDP/5 288	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	IBUMEX SUSPENSION	IBUPROFEN	100MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	100.0 ML BOTTLE,60.0 ML BOTTLE,1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/1997
2809	NDA/MAL/HDP/5 291	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	IBUMEX TABLET	IBUPROFEN	200MG	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	10.0X10.0 TABLET BLISTER,1.0X20.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER	01/07/1997
2810	NDA/MAL/HDP/5 292	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	DOMI 10	DOMPERIDONE	10MG	LINCOLN PHARMACEUTICAL LIMITEDTRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2011

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2811	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
2812	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
2813	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

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2814	NDA/MAL/HDP/5 299	PHARMA INTERNATIONAL.C O	OMAB UGANDA LIMITED	KENAZOLE	KETOCONAZOLE	20MG/ML	PHARMA INTERNATIONAL COMPANY ,.AL- QASTAL INDUSTRIAL AREA/AMMAN	JORDAN	TOPICAL EXTERNAL LIQUID SOAPS/WASHES	1.0X100.0 ML BOTTLE	01/07/2014
2815	NDA/MAL/HDP/5 300	CADILA PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	DOLAC	KETOROLAC TROMETHAMINE	30MG	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2015
2816	NDA/MAL/HDP/5 302	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	IBUGO-COMBI	IBUPROFEN + PARACETAMOL + CAFFEINE	200MG + 325MG + 30MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER,1.0X10.0X1 0.0 CAPSULE BLISTER,1.0X100.0X 10.0 CAPSULE BLISTER	01/07/2014

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2817	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
2818	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
2819	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

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2820	NDA/MAL/HDP/5 316	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DYNAPAR	DICLOFENAC SODIUM + PARACETAMOL	50MG + 500MG	TROIKAA PHARMACEUTICALS LTD .SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
2821	NDA/MAL/HDP/5 317	MACK BROWN	SHURIK LTD	DR MAC'S COUGH FORMULA	TERBUTALINE SULPHATE+BROM HEXINE HYDROCHLORIDE +GUAIFENESIN+M ENTHOL	2.5MG+8.0MG+10 0MG+5MG	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2003
2822	NDA/MAL/HDP/5 318	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DYNAPAR AQ (1ML)	DICLOFENAC SODIUM	75MG/ML	TROIKAA PHARMACEUTICALS LTD .SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE	01/07/2009

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2823	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
2824	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
2825	NDA/MAL/HDP/5323	STEDMAN PHARMACEUTICALS LTD	VEERAM HEALTHCARE (U) LIMITED	DREZ	IODINATED POVIDONE + METRONIDAZOLE	1.0% W/V + 5.0% W/V	STEDMAN PHARMACEUTICALS PVT LTD...C-4, SIDCO PHARMACEUTICAL COMPLEX ALATHUR, THIRUPORUR	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X60.0 ML CONTAINER,1.0X30.0 ML CONTAINER,1.0X100.0 ML CONTAINER,1.0X500.0 ML CONTAINER	01/07/2010

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2826	NDA/MAL/HDP/5 324	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	IBUFIL 400	IBUPROFEN	400MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDA LUR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1998
2827	NDA/MAL/HDP/5 326	UNIQUE PHARMACEUTICAL S LABORATORIES	PLANET PHARMACEUTICAL S UGANDA LTD	ECODAX G CREAM	ECONAZOLE NITRATE + GENTAMYCIN + BECLAMETASONE	1%+0.1%+0.025%	UNIQUE PHARMACEUTICAL LABORATORIESPLOT NO. 215-219, G.I.D.C. INDUSTRIAL AREA,PANOLI — 394 116, GUJARAT, INDIA.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE,1.0X100.0 G TUBE	01/07/1997
2828	NDA/MAL/HDP/5 327	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	IBUFIL 200	IBUPROFEN	200MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDA LUR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997

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2829	NDA/MAL/HDP/5 329	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	IBUFEN TABLETS	IBUPROFEN	200MG	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/1997
2830	NDA/MAL/HDP/5 330	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	DREZ-V	MICONAZOLE + METRONIDAZOLE	2.0%W/W + 1.0%W/W	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/2011
2831	NDA/MAL/HDP/5 333	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	IBUFEN	IBUPROFEN	200MG	KPI (KAMPALA PHARMACEUTICAL INDUSTRIES LTD PLOT M444 B STRETCHER ROAD NTINDA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X100.0X10.0 TABLET BLISTER,500.0 TABLET CONTAINER,1000.0 TABLET CONTAINER,250.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1997

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2832	NDA/MAL/HDP/5 338	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	HYDROSIL TABLETS	ALUMINIUM HYDROXIDE+MAG NESIUM HYDROXIDE+SIME THICONE	200MG+200MG+2 0MG	XEPA-SOUL PATTINSON (MALAYSIA) SDA BHD1-5, CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X20.0 TABLET BLISTER	01/07/1997
2833	NDA/MAL/HDP/5 341	LABORATORY&ALLI ED LTD	HARLEYS UGANDA LIMITED	HYDOPA	METHYLDOPA	250MG	LABORATORY & ALLIED LTD PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997
2834	NDA/MAL/HDP/5 346	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFUTIL 500	CEFUROXIME AXETIL	500MG	PHARMA INTERNATIONAL COMPANY MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET CONTAINER	01/07/2014

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2835	NDA/MAL/HDP/5 347	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	CEFUTIL 250	CEFUROXIME AXETIL	250MG	PHARMA INTERNATIONAL COMPANY MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2014
2836	NDA/MAL/HDP/5 348	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	CELEPID 20	INTRAVENOUS FAT EMULSION	20%W/V	OTSUKA PHARMACEUTICAL INDIA PRIVATE 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
2837	NDA/MAL/HDP/5 352	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICAL S LTD	MUMFER	IRON(111) POLYMALTOSE COMPLEX	50MG/5ML	GLENMARK PHARMACEUTICALS LTD PLOT E PLOT NO. E-37, 39, MIDC AREA, SATPUR, NASIK - 422 007, MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X150.0 ML BOTTLE	01/07/2005

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2838	NDA/MAL/HDP/5 356	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	BURNNEM	MULTI- INGREDIENT	N/A	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/1997
2839	NDA/MAL/HDP/5 358	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	CADISTIN EXPECTORANT	CHLORPHENIRAM INE MALEATE + GUAIFENESIN + AMMONIUM CHLORIDE + SODIUM CITRATE + LEVOMENTHOL + TERPIN HYDRATE + TOLU BALSAM + VASAKA SYRUP	(2MG + 80MG + 100MG + 44MG + 0.8MG + 4MG + 6MG + 0.133ML)/5ML	SAKAR HEALTHCARE PVT 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
2840	NDA/MAL/HDP/5 361	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	CALFIC	MULTI- INGREDIENT	N/A	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997

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2841	NDA/MAL/HDP/5 362	ASTRA ZENECA	MACNAUGHTON LIMITED	CASODEX 150MG	BICALUTAMIDE	150MG	ASTRAZENECA MACCLESFIELDCHES HIRE	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	2.0X14.0 TABLET STRIP	01/07/2001
2842	NDA/MAL/HDP/5 363	ASTRA ZENECA	MACNAUGHTON LIMITED	CASODEX 50MG	BICALUTAMIDE	50MG	BULK CORDEN PHARMA GMBHOTT HAHN STRASSE ,68723 GERMANY ASTRA ZENECA UK LIMITEDA STRAZENE CA 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
2843	NDA/MAL/HDP/5 366	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	CEFIM	CEFIXIME	400MG	HILTON PHARMA (PVT) LTD PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X5.0 CAPSULE STRIP	01/07/2005

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2844	NDA/MAL/HDP/5 367	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	CEFIM	CEFIXIME	100MG/5ML	HILTON PHARMA (PVT) LTD PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X30.0 ML BOTTLE	01/07/2005
2845	NDA/MAL/HDP/5 368	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	CEFIX 100MG/5ML DRY SUSPENSION	CEFIXIME	100MG/5ML	PHARMA INTERNATIONAL CO.AMMAN JORDAN PLANT AL-QARTAL MARKETING DEPARTMENT ALBUJAH COMPLEX, ALJUBAIHA	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE,1.0X30.0 ML BOTTLE	01/07/2007
2846	NDA/MAL/HDP/5 370	COSMOS LTD	ASTRA PHARMA (U) LIMITED	HYOSCINE BUTYLBROMIDE	HYOSCINE N- BUTYLBROMIDE	10 MG	COSMOS LIMITED RANGWA ROAD, OFF LUNGA LUNGA ROAD, INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X1000.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2010

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2847	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
2848	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,1.0X10.0X10.0 CAPSULE BLISTER	01/07/2008
2849	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

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2850	NDA/MAL/HDP/5 381	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	ADIFLAM GEL	DICLOFENAC DIETHYLAMINE	1.16%W/W	LEBEN LABORATORIES PVT. LTD PLOT NO. L-4, PHASE-III, MIDC, AKOLA- 444 104 (MS).	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/2008
2851	NDA/MAL/HDP/5 386	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	UDIHEP TABLETS	URSODEOXYCHOL IC ACID	150MG	WIN- MEDICARE LTDMODIPURAM - 250 110,UTTAR PRAADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2001
2852	NDA/MAL/HDP/5 388	IPCA LABORATOIES LTD	MEDVIN PHARMA LIMITED	LARINATE-60	ARTESUNATE	60MG	IPCA LABORATORIES LTD,- SEJAVTA,RATLAM 457-002 REG.OFF.48 KANDIVLI IND.ESTATE MUMBAI 400067	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 1*5 ML SODIUM CHLORIDE INJECTION + 1*1 ML AMPOULE OF SODIUM BICARBONATE INJECTION	01/07/2011

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2853	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,1.0X30.0X6.0 TABLET BLISTER,1.0X1.0X12.0 TABLET BLISTER,1.0X1.0X18.0 TABLET BLISTER,1.0X30.0X12.0 TABLET BLISTER,1.0X30.0X18.0 TABLET	01/07/2011
2854	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
2855	NDA/MAL/HDP/5392	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	AMLO-DENK 10	AMLODIPINE MESILATE MONOHYDRATE	10MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2008

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2856	NDA/MAL/HDP/5 393	DENK PHARMA GMB H & CO. KG	BENLE CONSULT LIMITED	AMLO-DENK 5	AMLODIPINE MESILATE MONOHYDRATE	5MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2008
2857	NDA/MAL/HDP/5 394	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	FINAZOL	ALBENDAZOLE	400MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDA LUR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	01/07/2007
2858	NDA/MAL/HDP/5 395	MICRO LABS LTD	LABOREX UGANDA LIMITED	OFLOX	OFLOXACIN	200MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

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2859	NDA/MAL/HDP/5 400	GLAXOSMITHKLINE TRADING SERVICES LTD, IRELAND	UNITED HEALTHCARE DISTRIBUTORS LTD	ALBEN SUSPENSION	ALBENDAZOLE	400MG/10ML	PANACEA BIOTEC LTD MALPUR, BADDI, TEHSIL, NALAGARH, DIST. SOLAN (H.P) – 173 205	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	01/07/1999
2860	NDA/MAL/HDP/5 404	INTAS, PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	HIFENAC P	ACECLOFENAC + PARACETAMOL	100 MG + 500 MG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI- 248197, DEHRADUN (UTTARAKHAND)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
2861	NDA/MAL/HDP/5 406	INTAS, PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	HIFENAC SR	ACECLOFENAC	200 MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2007

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2862	NDA/MAL/HDP/5 407	THEMIS PHARMACEUTICAL S	STAR PHARMACEUTICAL S 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
2863	NDA/MAL/HDP/5 410	MEDICAL UNION PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	UNICTAM 1500	AMPICILLIN + SULBACTAM	1000 MG + 500 MG	MEDICAL UNION PHARMACEUTICALS LTD - ABU SULTAN, CR 13363 ISMAILLIA, EGYPT	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	01/07/2009
2864	NDA/MAL/HDP/5 414	ACINO PHARMA AG	LABOREX UGANDA LIMITED	XYLO-ACINO 0.1%	XYLOMETAZOLINE	0.1 % W/V	MERCKLE GMBH,LUDWIG MERCKLE STRASSE3 D-89143 BLAUBEUREN	GERMANY	NASAL TOPICAL DROPS	1.0X1.0X10.0 ML BOTTLE	01/07/2007

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2865	NDA/MAL/HDP/5415	CENTAUR PHARMACEUTICALS 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
2866	NDA/MAL/HDP/5416	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
2867	NDA/MAL/HDP/5417	PHARMA INTERNATIONAL.C O	OMAB UGANDA LIMITED	CIPROPHARM	CIPROFLOXACIN	500MG	PHARMA INTERNATIONAL COMPANYMAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2007

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2868	NDA/MAL/HDP/5418	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	PAEDIATRIC CO-TRIMOXAZOLE	CO-TRIMOXAZOLE	240MG/5ML	MACLEODS PHARMACEUTICALS LTD(BLOCK N2)VILLAGE THEDA,P.O LODHI MAJRA,TEHSIL BADDI,HIMACHAL PRADESH 174101	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2005
2869	NDA/MAL/HDP/5419	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGO-CPM	CHLORPHENIRAMINE	4MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER	01/07/2005
2870	NDA/MAL/HDP/5423	HETERO LABS LTD	AIVEEN (U) LIMITED	EFAVIRENZ+LAMIVUDINE+TENOFIVIR	EFAVIRENZ+LAMIVUDINE+TENOFIVIR	600MG/300MG/300MG	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 LTD UNIT-111 NO 22-110 I.D.A JEEDIMETTA HYDRABAD 500055	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER,1.0X90.0 TABLET JAR,1.0X100.0 TABLET JAR	01/07/2013

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2871	NDA/MAL/HDP/5 425	ROYAL GROUP	HARLEYS UGANDA LIMITED	PARACETAMOL	PARACETAMOL	500MG	HEBEI (JIHENG GRP) PHARMACEUTICALS CO.LTD-INDIA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
2872	NDA/MAL/HDP/5 427	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	NIRCIP	CIPROFLOXACIN	200MG/100MG	ACULIFE HEALTHCARE PVT. LTDVILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2010
2873	NDA/MAL/HDP/5 428	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	CIPFIL 500	CIPROFLOXACIN	500MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITEDVANDA LUR ROAD,KELAMBAKKA M-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007

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2874	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. THANE INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X100.0 TABLET CARTON	01/07/2006
2875	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. THANE INDIA	INDIA	ORAL SOLID ORDINARY OTHER SPECIAL FORMS	1.0X2.0X20.5 G SACHET + 1.0*10.0 TABLET BLISTER	01/07/2016
2876	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

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2877	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
2878	NDA/MAL/HDP/5441	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL NASATAB TABLETS	PARACETAMOL+C HLORPHENIRAMINE+PSEUDOEPHEDRINE	500MG+4MG+60MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X100.0 TABLET BLISTER, 1.0X10.0X100.0 TABLET BLISTER	01/07/2008
2879	NDA/MAL/HDP/5442	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	CHLORAMPHENICOL OPHTHALMIC OINTMENT USP 1%	CHLORAMPHENICOL	1%W/W	NEM LABORATORIES PVT LTD 133 KRISHNA INDUSTRIAL ESTATE VASAI (E) DIST THANE 401 210 MAHARASHTRA	INDIA	OPHTHALMIC OINTMENTS	1.0X20.0X3.5 G TUBE	01/07/2013

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2880	NDA/MAL/HDP/5 445	ESKAYEF PHARMACEUTICAL S LTD	SWASTIK PHARMACEUTICAL LTD	AZITHRAX 500	AZITHROMYCIN DIHYDRATE	500 MG	ESKAYEF BANGLADESH LTD- 400, TONGI INDUSTRIAL AREA, SQUIB ROAD TONGI- GAZIPUR BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X6.0 TABLET BLISTER,1.0X1.0X3. 0 TABLET BLISTER	01/07/2014
2881	NDA/MAL/HDP/5 447	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	DICLOFENAC	DICLOFENAC SODIUM	50MG	TRIVENI FORMULATION LTD PLOT NO.52,53,54,63,62,6 4, ALEAP INDUSTRIAL ESTATE SURAMPALI, AP-INDIA – 521212	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CARTON,1.0X10.0X 10.0 TABLET BLISTER	01/07/2012
2882	NDA/MAL/HDP/5 449	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	CLOFENAC 50	DICLOFENAC SODIUM	50MG	HOVID BERHAD (CHEMOR SITE)-LOT 56442, 71/2, JALAN IPOH/CHEMOR 31200, PERAK. MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010

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2883	NDA/MAL/HDP/5 457	RAJESHI PLASTICS	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	FALCIMON 100/270 B/L	ARTESUNATE+AM ODIAQUINE	100MG+270MG	CIPLA LTD UNIT IIA- 42 MIDC PATALGANGA DISTRICT RAIGAD MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X25.0X3 .0 TABLET BLISTER,1.0X25.0X6 .0 TABLET BLISTER	01/07/2014
2884	NDA/MAL/HDP/5 458	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	FALCIMON 50/135 B/L	ARTESUNATE+AM ODIAQUINE	50MG+135MG	CIPLA LTD UNIT IIA- 42 MIDC PATALGANGA DISTRICT RAIGAD MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER,1.0X25.0X3 .0 TABLET BLISTER	01/07/2014
2885	NDA/MAL/HDP/5 460	GUILIN PHARMACEUTICAL S CO.LTD	TRIDEM PHARMA UGANDA LIMITED	ASAQ GPSC	ARTESUNATE+AM ODIAQUINE	50MG+135MG	GUILIN PHARMACEUTICALS CO. LTDNO 43 QULIDIAN ROAD GUILIN GUANGXI CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0X20.0 TABLET BLISTER,1.0X25.0X3 .0 TABLET BLISTER,1.0X25.0X6 .0 TABLET BLISTER	01/07/2011

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2886	NDA/MAL/HDP/5 464	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S 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,1.0X1.0X6. 0 TABLET BLISTER,1.0X1.0X12 .0 TABLET	01/07/2007
2887	NDA/MAL/HDP/5 467	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMSIDAR	SULFADOXINE/PY RIMETHAMINE	525MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CARTON,1.0X250.0 TABLET CONTAINER,1.0X50 0.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	01/07/1997
2888	NDA/MAL/HDP/5 469	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	NIMOTOP	NIMODIPINE	0.2MG/ML	SOLUPHARM GMBH INDUSTRIESTRASSE 3, 34212 MELSUNGEN BAYER PHARMA AG 51368 LEVERKUSEN GERMANY	GERMANY	PARENTERAL ORDINARY I V VIALS	1.0X50.0 ML VIAL	01/07/2009

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2889	NDA/MAL/HDP/5 471	MICRO LABS LTD	LABOREX UGANDA LIMITED	AVAS 40	ATORVASTATIN	40MG	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
2890	NDA/MAL/HDP/5 472	CLARIS OTSUKA LIMITED	REDDYS PHARMA LIMITED	NS	SODIUM CHLORIDE	0.9%W/V	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTDVILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X250.0 ML BOTTLE,1.0X500.0 ML BOTTLE,1.0X100.0 ML BAG	01/07/2007
2891	NDA/MAL/HDP/5 473	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TROYPOFOL	PROPOFOL	1%W/V	TROIKAA PHARMACEUTICALS LTD .C-1 SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL	01/07/2012

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2892	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
2893	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 PORTUGAL	PORTUGAL	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL + 10 ML WFI	01/07/2002
2894	NDA/MAL/HDP/5478	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	BECORT 50	BECLMETHASONE 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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2895	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
2896	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
2897	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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2898	NDA/MAL/HDP/5 486	EMCURE PHARMACEUTICAL S 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
2899	NDA/MAL/HDP/5 489	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
2900	NDA/MAL/HDP/5 495	AGOG PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	AGOCAL TABLETS	CALCIUM LACTATE	300MG	AGOG PHARMA LTD PLOT NO.33, SECTOR II, VASAI, TALUKA INDL CO-OP ESTATE LTD, GAURAI PADA, VASAI (E) DIST. 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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2901	NDA/MAL/HDP/5496	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
2902	NDA/MAL/HDP/5497	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
2903	NDA/MAL/HDP/5591	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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2904	NDA/MAL/HDP/5 619	CADILA PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S LTD.	RABELOX 20	RABEPRAZOLE SODIUM	20MG	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X1.0X10.0 TABLET STRIP	01/07/2006
2905	NDA/MAL/HDP/5 644	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	FORTIFIED PROCAINE PENICILLIN	FORTIFIED PROCAINE PENICILLIN	4 MEGA UNITS	CSPC ZHONGNUO PHARMACEUTICAL (SCJIJAZHUANG) 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
2906	NDA/MAL/HDP/5 648	KARNATAKA ANTIBIOTICS & PHARMACEUTICAL S 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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2907	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
2908	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,1.0X10.0X10.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER	01/07/2016
2909	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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2910	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,1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE JAR	01/07/2017
2911	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
2912	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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2913	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
2914	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,1.0X10.0X10.0 TABLET BLISTER	01/07/2009
2915	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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2916	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
2917	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
2918	NDA/MAL/HDP/6070	DEVA HOLDING A.S	SHREEJI PHARMACEUTICALS LIMITED	VAZKOR	AMLODIPINE BESILATE	10MG	DEVA HOLDING A.S SCERKEZKOY ORGANIZE SANAYI BOLGESI, KARAAGAC MAH., ATATURK CAD., NO.: 32 KAPAKLI TEKIRDAG	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X9.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	01/07/2017

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2919	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
2920	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
2921	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 NACL AMPOULE + 1*1 ML OF 5%W/V NAHCO3 AMPOULE	01/07/2017

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2922	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
2923	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
2924	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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2925	NDA/MAL/HDP/6081	TIANJIN MNCHIP TECHNOLOGIES CO.,LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ANTALGEX T	PARACETAMOL/TAMADOL 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
2926	NDA/MAL/HDP/6082	EXPHAR SA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CROMSOL	SODIUM CROMOGLYCATE	2%W/V	AHLCONPARENTERALS (INDIA) LIMITEDDSP-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
2927	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,1.0X10.0X10.0 TABLET BLISTER	01/07/2017

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2928	NDA/MAL/HDP/6 092	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPOTCLAV 1000	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	875 MG + 125 MG	SPARSH BIO-TECH PVT. LIMITED PLOT NO. 1; SURVEY NO. 242/243/244, LAKHA BAVAD, JAMNAGAR- 361 006, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017
2929	NDA/MAL/HDP/6 093	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPOTCLAV 625	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	500 MG + 125 MG	SPARSH BIO-TECH PVT. LIMITED PLOT NO. 1; SURVEY NO. 242/243/244, LAKHA BAVAD, JAMNAGAR- 361 006, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2017
2930	NDA/MAL/HDP/6 094	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPOTCLAV 375	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	250 MG + 125 MG	SPARSH BIO-TECH PVT. LTD PLOT NO. 1; SURVEY NO. 242/243/244, LAKHABAVAD, JAMNAGAR-361 006, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2017

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2931	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
2932	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
2933	NDA/MAL/HDP/6101	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TELPRESS-H 40/12.5	TELMISARTAN + HYDROCHLOROT HIAZIDE	40MG + 12.5MG	PSYCHOTROPICS INDIA LTD PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017

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2934	NDA/MAL/HDP/6 102	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TELPRESS 80	TELMISARTAN	80MG	PSYCHOTROPICS INDIA LTD PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
2935	NDA/MAL/HDP/6 103	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	OZACE MD 5	OLANZAPINE	5MG	PSYCHOTROPICS INDIA LTD PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017
2936	NDA/MAL/HDP/6 105	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	AZOPIL 200	AZITHROMYCIN	200MG/5ML	PSYCHOTROPICS INDIA LTD PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND KESAR PHARMA PVT LTD PLOT SURVEY NO. 50/2. VILLAGE BILSHWARPURA CHHATRAL - 382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1X15 ML BOTTLE	01/07/2017

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2937	NDA/MAL/HDP/6 106	SQUARE PHARMACEUTICAL S LTD	GAMA PHARMACEUTICAL S (U) LIMITED	TREVOX 500	LEVOFLOXACIN HEMIHYDRATE	500MG	SQUARE PHARMACEUTICALS LTDKALIAKOIR	BANGLADESH	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2017
2938	NDA/MAL/HDP/6 107	SQUARE PHARMACEUTICAL S LTD	GAMA PHARMACEUTICAL S (U) LIMITED	SULPREX	IPRATROPIUM BROMIDE+SALBU TAMOL SULPHATE	500MCG/2.5ML+2. 5MG/2.5ML	SQUARE PHARMACEUTICALS LIMITEDKALIAKOIR GAZIPUR – 1750, BANGLADESH	BANGLADESH	LUNG ADMINISTRATION LIQUID FOR INHALATION	1.0X10.0 AMPOULE CARTON	01/07/2017
2939	NDA/MAL/HDP/6 114	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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2940	NDA/MAL/HDP/6 115	I-CARE PHARMA LTD	SUPER MEDIC LTD	TIZOL	TINIDAZOLE	500MG	MEDICO REMEDIES PVT LTD,.8 & 9 DEWAN AND SONS, UDYOG NAGAR, PALGHAR, DIST. THANE-401404, MAHARSHITRA	INDIA	ORAL SOLID ORDINARY TABLETS	1X4 TABLET STRIP	01/07/1997
2941	NDA/MAL/HDP/6 117	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	GRAN-DENK	GRANISETRON HYDROCHLORIDE	1MG/ML	SIEGFRIED HAMELN GMBHLANGES FELD 13,31789 HAMELN SOLUPHARM GMBH INDUSTRIESTRASSE 3, 34212 MELSUNGEN	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X5.0 ML AMPOULE,1.0X5.0X 3.0 ML AMPOULE	01/07/2017
2942	NDA/MAL/HDP/6 118	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	L-TRIM DS	SULPHAMETHOX AZOLE + TRIMETHOPRIM	800MG + 160MG	LEBEN LABORATORIES PVT. LTD PLOT NO. L-4, PHASE-III, MIDC, AKOLA- 444 104 (MS).	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017

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2943	NDA/MAL/HDP/6 120	NATIONAL HEALTHCARE PVT LTD	VITACARE LTD	KMINE	KETAMINE HYDROCHLORIDE	50MG/ML	NATIONAL HEALTHCARE PVT LTD-CHHATAPIPRA 3 BARA NEPAL	NEPAL	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	01/07/2017
2944	NDA/MAL/HDP/6 121	İLKO İLAÇ SANAYI VE TİCARET A. Ş.	CORE ACCESS LTD	DEXIREN	DEKTOPROFEN TROMETAMOL	25MG	İLKO İLAÇ SANAYI VE TİCARET A. Ş3. ORGANİZE SANAYI 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
2945	NDA/MAL/HDP/6 126	MEDICAL UNION PHARMACEUTICAL S	KARURI PHARMACEUTICAL S LTD.	DERMOTRACIN	NEOMYCIN SULPHATE + BACITRACIN	165,000 IU + 12,500 IU	MEDICAL UNION PHARMACEUTICAL CO.PLANT: ABU- SULTAN, ISMAILIA, EGYPT	EGYPT	TOPICAL EXTERNAL PRESSURISED AEROSOLS	1.0X150.0 ML CANNISTER	01/07/2016

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2946	NDA/MAL/HDP/6 127	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	INTELENCE	ETRAVIRINE	25MG	JANSSEN-CILAG S.P.A.VIA C. JANSSEN BORGIO S. MICHELE 04100 LATINA	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET BOTTLE	01/07/2016
2947	NDA/MAL/HDP/6 129	VIIV HEALTHCARE UK LTD-	UNITED HEALTHCARE DISTRIBUTORS LTD	TRIUMEQ	DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE	50MG + 600MG + 300MG	GLAXOSMITHKLINE PHARMACEUTICALS SAGRUNWALDZKA 189 STREET, 60-322 POZNANA GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS)PRIORY STREET, WARE HERTFORDSHIRE SG12 0DJ, UK	UNITED KINGDOM POLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2016
2948	NDA/MAL/HDP/6 132	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	KETOVID	KETOCONAZOLE	2%W/W	HOVID BHD 121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	TOPICAL EXTERNAL LIQUID SOAPS/WASHES	1.0X120.0 ML BOTTLE	01/07/2016

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2949	NDA/MAL/HDP/6 134	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	ZAMADOL P	TRAMADOL HYDROCHLORIDE +ACETAMINOPHE N	37.5MG+325MG	MACLEODS PHARMACEUTICALS LIMITED BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH - 174101 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
2950	NDA/MAL/HDP/6 135	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TRIXONE-S	CEFTRIAZONE SODIUM+SULBAC TAM	1000MG+500MG	ZEISS PHARMA LIMITED-IGC,SIDCO, PHASE II, SAMBA, JAMMU - 184121,(J&K)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL	01/07/2016
2951	NDA/MAL/HDP/6 137	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	LUPRODEX	LEUPROLIDE ACETATE	3.75MG	BHARAT SERUMS AND VACCINES LIMITED,PLOT NO. K- 27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X1.0 ML VIAL + 1*2ML GLASS AMPOULE OF DILUENT (EACH ML CONTAINS 50MG OF D-MANNITOL AND WFI TO Q.S) + 1 DISPOSABLE SYRINGE, 2 NEEDLES AND 2 ALCOHOL SWABS	01/07/2016

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2952	NDA/MAL/HDP/6 141	UNOSOURCE PHARMA LTD	MEDVIN PHARMA LIMITED	ACEWEL	ACECLOFENAC	100MG	AKUMS DRUGS & PHARMACEUTICALS LTD19, 20,21 SECTOR 6A IIE SIDCUL RANIPUR HARIDWAR 249 403	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2016
2953	NDA/MAL/HDP/6 142	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOCARB	ACTIVATED CHARCOAL	0.25GM	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET BOTTLE,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2016
2954	NDA/MAL/HDP/6 143	IESUS GROUP	SHREEJI PHARMACEUTICAL S LIMITED	CONTRACTUBEX	EXTRACT CEPAE FLUID +HEPARIN SODIUM+ALLANT OIN	10G+5000 I.U+1G/100G	MARCYRL PHARMACEUTICAL INDUSTRIES.EL OBOUR CITY CAIRO	EGYPT	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE	01/07/2016

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2955	NDA/MAL/HDP/6 158	DEVA HOLDING A.S	SHREEJI PHARMACEUTICAL S LIMITED	DESEFIN	CEFTRIAZONE SODIUM	1G	DEVA HOLDING A.SCERKEZKOY ORGANIZE SANAYI BOLGESI, KARAAGAC MAH., ATATURK CAD., NO.: 32 KAPAKLI TEKIRDAG	TURKEY	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2016
2956	NDA/MAL/HDP/6 167	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	AKUROSE	IRON SUCROSE	20MG/ML	AKUMS DRUGS & PHARMACEUTICALS LTD. -PLANT III,PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL,RANIPUR, 249 403	INDIA	PARENTERAL ORDINARY INFUSION AMPOULES	1.0X5.0X5.0 ML AMPOULE	07/01/2016
2957	NDA/MAL/HDP/6 169	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	INTELENCE	ETRAVIRINE	100MG	JANSSEN-CILAG S.P.A.VIA C. JANSSEN BORGO S. MICHELE 04100 LATINA	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET BOTTLE	01/07/2016

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2958	NDA/MAL/HDP/6 170	SQUARE PHARMACEUTICAL S LTD	GAMA PHARMACEUTICAL S (U) LIMITED	ALACOT 0.1% EYE DROPS	OLOPATADINE HYDROCHLORIDE	0.1%W/V	SQUARE PHARMACEUTICALS LIMITED-KALIAKOIR GAZIPUR – 1750, BANGLADESH	BANGLADESH	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	07/01/2016
2959	NDA/MAL/HDP/6 176	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	G-GLUTAMIN	VITAMIN B1 +B6+B12 WITH L- GLUTAMIC ACID	100MG+50MG+10 0MCG+50MG	BLISS GVS PHARMA LTD PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA- INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2010
2960	NDA/MAL/HDP/6 179	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	ON.SETRON-DENK 4MG ODT	ONDANSETRON	4MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X6.0 TABLET BLISTER	01/07/2016

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2961	NDA/MAL/HDP/6 181	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
2962	NDA/MAL/HDP/6 182	SQUARE PHARMACEUTICAL S LTD	GAMA PHARMACEUTICAL S (U) LIMITED	ALARID	KETOTIFEN FUMARATE	0.025%W/V	SQUARE PHARMACEUTICALS LTD DHAKA UNIT KALIAKOIR GAZIPUR	BANGLADESH	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2016
2963	NDA/MAL/HDP/6 184	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ATOXIA 60MG	ETORICOXIB	60MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTDP.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL- RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016

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2964	NDA/MAL/HDP/6 185	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	DOLOFORTE DENK	TRAMADOL HYDROCHLORIDE + PARACETAMOL	37.5MG + 325MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2016
2965	NDA/MAL/HDP/6 186	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ATOXIA 90MG F.C. TABLETS	ETORICOXIB	90MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTDP.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL- RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016
2966	NDA/MAL/HDP/6 187	ALLY PHARMA OPTIONS PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	FLOXCIP	CIPROFLOXACIN HYDROCHLORIDE	500MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328 - 1330, VILLAGE MANPURA. TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH, 174101 - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X10X10 TABLET BLISTER	01/07/2016

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2967	NDA/MAL/HDP/6 188	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICAL S (U) LIMITED	GIZLAN 150	IRBESARTAN	150MG	DAR AI DAWANA UR PLANT,AMMAN,JOR DAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
2968	NDA/MAL/HDP/6 189	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
2969	NDA/MAL/HDP/6 190	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	D-LYTE	ANHYDROUS GLUCOSE+SODIU M CHLORIDE+TRISO DIUM CITRATE+POTASSI UM CHLORIDE,ANHYD ROUS GLUCOSE+SODIU M CHLORIDE+TRISO DIUM CITRATE+POTASSI UM	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 LTDPLOT 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

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2970	NDA/MAL/HDP/6 191	AMOUN PHARMACEUTICAL S COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	KAPRON AMPOULE	TRANEXAMIC ACID	500MG/5ML	AMOUN PHARMACEUTICAL CO. S.A.E-1ST INDUSTRIAL ZONE A, PLOTS NO. 1B,2,3,4,5 BLOCK 13015, EL-OBOUR CITY, KALYOUBIA CAIRO EGYPT	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X6.0X5.0 ML AMPOULE	01/07/2016
2971	NDA/MAL/HDP/6 201	SPARSH BIO-TECH PVT.LTD.	ABACUS PHARMA (AFRICA) LIMITED	SPAMOXIFLOX	AMOXICILLIN TRIHYDRATE + FLUCLOXACILLIN SODIUM	250MG + 250MG	SPARSH BIO-TECH PVT. LIMITED PLOT NO. 1; SURVEY NO. 242/243/244, LAKHA BAVAD, JAMNAGAR- 361 006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE STRIP	01/07/2016
2972	NDA/MAL/HDP/6 207	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	GO!GEL	DICLOFENAC DIETHYLAMINE+ METHYL SALICYLATE	1.16%W/W + 10%W/W	S KANT HEALTHCARE LTD PLOT NO. 1802- 1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT.	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/2016

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2973	NDA/MAL/HDP/6 211	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	CLOFAINS	PARACETAMOL/D ICLOFENAC SODIUM	500MG/50MG	MILAN LABORATORIES (INDIA) PVT LTD PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTR A-410209,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016
2974	NDA/MAL/HDP/6 217	INDIAN IMMUNOLOGICALS LTD	TATA UGANDA LIMITED	ELOVAC -B	HEPATITIS B (RDNA)	20MCG/ML	HUMAN BIOLOGICALS INSTITUTE (A DIVISION OF INDIAN IMMUNOLOGICALS LTD) RAKSHAPURAM GACHIBOWLI POST HYDERABAD 500032	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0X1.0 ML VIAL (1 DOSE VIAL)	01/07/2016
2975	NDA/MAL/HDP/6 218	ASTRA ZENECA	MACNAUGHTON LIMITED	FORXIGA	DAPAGLIFLOZIN	10MG	ASTRAZENECA PHARMACEUTICALS LP4601 HIGHWAY 62 EAST, MOUNT VERNON, IN 47620- 1500 - UNITED STATES OF AMERICA	UNITED STATES	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2016

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2976	NDA/MAL/HDP/6 220	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	METHYLDOPA	METHYLDOPA	250MG	NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E, DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
2977	NDA/MAL/HDP/6 223	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROPROST- RT	LATANOPROST	0.005%W/V	AUROLAB.SIVAGANG AI MAIN ROAD, VEERAPANJAN, MADURAI 625 020 TAMIL INDIA	INDIA	OPHTHALMIC DROPS	1.0X2.5 ML BOTTLE	01/07/2016
2978	NDA/MAL/HDP/6 227	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ISONIAZID	ISONIAZID	300MG	MYLAN LABORATORIES LIMITED.PLOT NO. H- 12 & H-13 MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD. – 431136, MAHARASHTRA STATE, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2016

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2979	NDA/MAL/HDP/6 228	CACHET PHAMACUITICALS PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	ACINET	AMOXICILLIN + POTASSIUM CLAVULANATE	500 MG + 125 MG	INDCHEMIE HEALTH SPECIALITIES PVT. LTDVILLAGE-THANA, BADDI, DIST. SOLAN, HIMACHAL PRADESH- 173 205.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X2.0X7. 0 TABLET BLISTER	01/07/2016
2980	NDA/MAL/HDP/6 229	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	CO-FLUAMPICIL CAPSULES BP 500MG	FLUCLOXACILLIN SODIUM + AMPICILLIN TRIHYDRATE	250MG +250MG	SPARSH BIO-TECH PVT. LIMITEDPLOT NO. 1;SURVEY NO. 242/243/244,LAKHA BAVAD,JAMNAGAR- 361 006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE STRIP	01/07/2016
2981	NDA/MAL/HDP/6 230	CACHET PHAMACUITICALS PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	EMITINO	ONDANSETRON	4MG	CACHET PHARMACEUTICALS PVT LTD THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016

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2982	NDA/MAL/HDP/6 231	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP DISPERSIBLE	DIHYDROARTEMI SININ/PIPERAQUI NE	20MG/160MG	GUILIN PHARMACEUTICAL CO LTDNO.43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X2.0X3.0 TABLET BLISTER,1.0X3.0X35 .0 TABLET BLISTER	01/07/2016
2983	NDA/MAL/HDP/6 234	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP DISPERSIBLE	DIHYDROARTEME SININE/ PIPERAQUINE PHOSPHATE	40MG/320MG	GUILIN PHARMACEUTICAL CO.,LTDNO 43 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
2984	NDA/MAL/HDP/6 235	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ANGINET 160MG	VALSARTAN	160MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTDP.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL- RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016

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2985	NDA/MAL/HDP/6 237	HETERO LABS LTD	AIVEEN (U) LIMITED	LOPINAVIR/RITON AVIR	LOPINAVIR/ RITONAVIR	100MG/25MG	HETERO LABS LTD22- 110 IDA JEEDIMETLA HYDERABAD 500- 055 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X120.0 TABLET BOTTLE,1.0X60.0 TABLET CONTAINER	01/07/2016
2986	NDA/MAL/HDP/6 238	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	NEBILONG -AM	NEBIVOLOL HYDROCHLORIDE + AMLODIPINE BESILATE	5MG + 5MG	MICRO LABS LTD 92 SIPCOT 92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
2987	NDA/MAL/HDP/6 239	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GSUNATE	ARTESUNATE	60MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY 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 NA CL + 1*1 ML OF 5%W/V SODIUM BICARBONATE	01/07/2016

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2988	NDA/MAL/HDP/6 242	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP	DIHYDROARTEME SININ/PIPERAQUI NE PHOSPHATE	80MG/640MG	GUILIN PHARMACEUTICAL CO LTDNO.43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER,1.0X6.0X25 .0 TABLET BLISTER	01/07/2016
2989	NDA/MAL/HDP/6 243	ABBVIE (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	SURVANTA	BERACTANT	100MG/4ML	ABBVIE NORTH CHICAGO FACILITY1401 SHERDAN ROAD NORTH CHICAGO FACILITY ILLINOIS 60064 -4000	UNITED STATES	TOPICAL EXTERNAL INSTILLATION VIALS	1.0X4.0 ML VIAL,1.0X8.0 ML VIAL	01/07/2016
2990	NDA/MAL/HDP/6 244	CACHET PHAMACUITICALS PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	CABALIN	PREGABALIN	75MG	CACHET PHARMACEUTICALS PVT LTDVILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X12.0 CAPSULE BLISTER,1.0X3.0X10 .0 CAPSULE BLISTER	01/07/2016

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2991	NDA/MAL/HDP/6 245	BIOLOGICAL E. LTD	ABACUS PHARMA (AFRICA) LIMITED	COSCOPIN LINCTUS	NOSCAPINE + CHLORPHENIRAM INE MALEATE + SODIUM CITRATE + AMMONIUM CHLORIDE	7MG+2 MG+ 3.25 MG+28 MG/5 ML.	BIOLOGICAL E. LTD PLOT NO.31 & 32 PHARMA CITY SELAQUI INDUSTRIAL AREA SELAQUI DEHRADUN- 248 197 UTTARAKHAND,INDI A	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2016
2992	NDA/MAL/HDP/6 246	CIRON DRUGS & PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	LUTHER	ARTEMETHER	80MG/ML	CIRON DRUGS AND PHARMACEUTICALS PVT. LTDN-118, N119, N113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, INDIA	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE	01/07/2016
2993	NDA/MAL/HDP/6 247	MILAN LABORATORIES LTD (INDIA) PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	MILOXY 250-DT	AMOXICILLIN TRIHYDRATE	250MG	MILAN LABORATORIES (INDIA) PVT LTD PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA	INDIA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X2.0X10 .0 TABLET BLISTER,1.0X1.0X10 .0 TABLET BLISTER	01/07/2016

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2994	NDA/MAL/HDP/6 249	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL METRONIDAZOLE - 200 TABLETS	METRONIDAZOLE	200MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
2995	NDA/MAL/HDP/6 250	REMINGTON PHARMACEUTICAL INDUSTRIES PVT LTD	HEALTHCARE LTD.	ROCIP EYE DROPS	CIPROFLOXACIN HYDROCHLORIDE	3MG/ML	REMINGTON PHARMACEUTICAL INDUSTRIES (PVT) LTD18 KM MULTAN ROAD LAHORE 53800 PAKISTAN	PAKISTAN	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2016
2996	NDA/MAL/HDP/6 256	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AZIMAX- 250	AZITHROMYCIN DIHYDRATE	250MG	HOVID BHDLOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0X10.0 TABLET BLISTER	01/07/2016

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2997	NDA/MAL/HDP/6 257	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	EDURANT	RILPIVIRINE	25MG	JANSSEN CILAG S.P.AVIA C.JANSSEN, BORGIO	ITALY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2016
2998	NDA/MAL/HDP/6 264	ACINO PHARMA AG -	LABOREX UGANDA LIMITED	PARACONICA 1000 MG IV	PARACETAMOL	10MG/ML	S.M FARMACEUTICI SRLZONA INDUSTRIALE, 85050 TITO- POTENZA (PZ) ITALY	ITALY	PARENTERAL ORDINARY I V VIALS	1.0X100.0 ML VIAL	01/07/2016
2999	NDA/MAL/HDP/6 267	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	TRAMADOL DENK 50	TRAMADOL HYDROCHLORIDE	50MG	LOSAN PHARMA GMBH OTTO-HAHN- STR 13 79395 NEUENBURG	GERMANY	ORAL SOLID ORDINARY EFFERVESCENT TABLETS	1.0X10.0 TABLET BOTTLE	01/07/2016

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3000	NDA/MAL/HDP/6 270	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	FEBUMAC 80	FEBUXOSTAT	80MG	MACLEODS PHARMACEUTICALS LTD - VILLAGE THEDA P.O LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH INDIA 174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER,1.0X2.0X14 .0 TABLET BLISTER	01/07/2017
3001	NDA/MAL/HDP/6 275	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICAL S LIMITED	BENZYL BENZOATE APPLICATION BP	BENZYL BENZOATE	25%W/V	SEV PHARMACEUTICALS LTD, PLOT 100 MASAKA ROAD ,NALUKOLONGO KAMPALA,UGANDA.	UGANDA	TOPICAL EXTERNAL EMULSIONS	1.0X100.0 ML BOTTLE	27/11/2018
3002	NDA/MAL/HDP/6 279	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CIFF-200 DT	CEFIXIME TRIHYDRATE	200MG	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X10.0 TABLET STRIP	27/11/2018

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3003	NDA/MAL/HDP/6 281	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	HOMAGON	CHLORPHENAMIN E MALEATE + CAFFEINE ANHYDROUS + PSEUDOEPHEDRI NE HYDROCHLORIDE + PARACETAMOL	4MG + 30MG + 30MG + 400MG	LABORATORY AND ALLIED LTD PLOT 209/10349- MOMBASA ROAD NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER, 1.0X10.0X1 0.0 CAPSULE BLISTER	07/11/2018
3004	NDA/MAL/HDP/6 282	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	MEBUX-40	FEBUXOSTAT	40MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	07/11/2018
3005	NDA/MAL/HDP/6 283	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (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

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3006	NDA/MAL/HDP/6 288	THEON PHARMACEUTICAL S LTD	AIVEEN (U) LIMITED	THEOFIX-100 DS	CEFIXIME TRIHYDRATE	100MG/5ML	THEON PHARMACEUTICALS LIMITED. VILLAGE SAINI MAJRA, TEHSIL NALAGARH, DISTT. SOLAN, HIMACHAL PRADESH 174 101 INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1X1X60 ML BOTTLE	17/12/2018
3007	NDA/MAL/HDP/6 292	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VENAXAN 250 MG	LEVOFLOXACIN HEMIHYDRATE	250MG	SOUTH EGYPT DRUG INDUSTRIES CO-1ST INDUSTRIAL ZONE, 6 OCTOBER CITY, EGYPT.	EGYPT	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X5.0 TABLET BLISTER	27/11/2018
3008	NDA/MAL/HDP/6 293	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	NEUROGAB 150	PREGABALIN	150MG	"MACLEODS PHARMACEUTICALS LTD,-BLOCK N2, VILLAGE THEDA, POST OFFICE LODHIMAJRA, TEHSIL BADDI, DISTRICT SOLAN, HIMACHAL PRADESH – 174101 INDIA."	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	27/11/2018

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3009	NDA/MAL/HDP/6 294	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	NEXAVAR	SORAFENIB TOSYLATE	200MG	BAYER PHARMA AG 51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X28.0 TABLET BLISTER	07/11/2018
3010	NDA/MAL/HDP/6 300	GUILIN PHARMACEUTICAL (SHANGHAI) CO., LTD	TRIDEM PHARMA UGANDA LIMITED	AMOXICILLIN	AMOXICILLIN	250MG	SINOPHARM WEIQIDA PHARMACEUTICAL CO., LTD-OSD WORKSHOP OF ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, SECOND MEDICAL ZONE DATONG, SHANXI, CHINA	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X2.0 X10.0 CAPSULE BLISTER, 1.0X10.0X10.0 CAPSULE BLISTER	31/01/2018
3011	NDA/MAL/HDP/6 302	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	PLENOX	OFLOXACIN	200MG	AKUMS DRUGS & PHARMACEUTICALS LTD19-20,21, SECTOR 6-4, SIDCUL, IIE, RANIPUR HARIDWAR-249403	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	27/03/2019

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3012	NDA/MAL/HDP/6 304	UNOSOURCE PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	UNOSURE 72	LEVONORGESTRE L	1.5MG	AKUMS DRUGS & PHARMACEUTICALS LTD .PLOT NO. 47, 48, SECTOR 6A, IIE, SIDCUL HARIDWAR, UTTRAKHAND – 249403, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0 TABLET BLISTER	27/03/2019
3013	NDA/MAL/HDP/6 314	YELURI FORMULATIONS PVT LTD	SUPER MEDIC	ELMOX-CV 625	AMOXICILLIN TRIHYDRATE+CLA VULANATE POTASSIUM	500MG+125MG	YELURI FORMULATIONS PVT. LTD-SY. NO. 296 / 7 / 6 IDA BOLLARAM,MEDAK DIST.502325, TELANGANA,INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X5.0 TABLET BLISTER,1.0X2.0X10 .0 TABLET BLISTER	30/05/2018
3014	NDA/MAL/HDP/6 327	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENESTEN-V	CLOTRIMAZOLE	100MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X6.0 PESSARY BLISTER	27/11/2018

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3015	NDA/MAL/HDP/6 332	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMOXIREN DT 250	AMOXICILLIN TRIHYDRATE	250MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	27/11/2018
3016	NDA/MAL/HDP/6 334	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	ENDOPROST 250MCG/1ML	CARBOPROST TROMETHAMINE	250MCG/ML	BHARAT SERUM AND VACCINES LIMITED PLOT NO. K- 27 ADDITIONAL MIDC AMBERNATH (EAST) INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X1.0 ML VIAL	27/03/2019
3017	NDA/MAL/HDP/6 338	BIOTON S.A.	BHL HEALTHCARE LIMITED	GENSULIN M30 (30/70)	INSULIN HUMAN OF RECOMBINANT DNA ORIGIN (30% SOLUBLE INSULIN + 70% ISOPHANE INSULIN)	100 IU/ML	BIOTON S.AMACIERZYSZ, POZNANSKA 12 STR., 05-850 OZAROW MAZOWIECKI	POLAND	PARENTERAL ORDINARY S C VIALS	1.0X1.0X10.0 ML VIAL, 1.0X5.0X3.0 ML CARTRIDGE	27/03/2019

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3018	NDA/MAL/HDP/6 339	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OXY-POL	OXYTETRACYCLIN E HCL + POLYMYXIN B SULPHATE	5MG+10000IU/G	EGYPTIAN INT.PHARMACEUTIC AL INDUSTRIES CO. E.I.P.C.O --10TH OF RAMADAN CITY – INDUSTRIAL AREA B1 P.O BOX: 149 TENTH EGYPT	EGYPT	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE	30/05/2018
3019	NDA/MAL/HDP/6 340	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	AXYLIN CAPSULES	AMPICILLIN TRIHYDRATE + CLOXACILLIN SODIUM	250MG +250 MG	LABORATORY & ALLIED LTD PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	31/01/2018
3020	NDA/MAL/HDP/6 341	MACLEODS PHARMACEUTICAL S LTDS LTD	VITACARE LIMITED	ROSUMAC 20	ROSUVASTATIN CALCIUM	20MG	MACLEODS PHARMACEUTICALS LTD., NO. 25-27 PLOT NO. 25-26-27, SURVEY NO.366, PREMIER INDUSTRIAL ESTATE , DAMAN - 396210, KACHIGAM, DAMAN	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	31/01/2018

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3021	NDA/MAL/HDP/6 342	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIFENAC EYE DROPS	DICLOFENAC SODIUM SALT	1MG/ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B EGYPT	EGYPT	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	30/05/2018
3022	NDA/MAL/HDP/6 343	BIOTON S.A.	BHL HEALTHCARE LIMITED	GENSULIN N	ISOPHANE HUMAN HUMAN OF RECOMBINANT DNA ORIGIN	100 IU/ML	BIOTON S.AMACIERZYSZ, POZNANSKA 12 STR., 05-850 OZAROW MAZOWIECKI	POLAND	PARENTERAL ORDINARY S C VIALS	1.0X1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE	27/03/2019
3023	NDA/MAL/HDP/6 344	S KAGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	LACTEASE	LACTULOSE SOLUTION	66.7% W/W	S KANT HEALTHCARE LTD PLOT NO. 1802- 1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT.	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE	26/09/2018

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3024	NDA/MAL/HDP/6 345	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MAGNABIOTIC 600MG VAIL	AMOXICILLIN SODIUM/ CLAVULANATE POTASSIUM	500MG/100MG	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	25/07/2018
3025	NDA/MAL/HDP/6 346	BIOTON S.A.	BHL HEALTHCARE LIMITED	GENSULIN R	SOLUBLE HUMAN INSULIN OF RECOMBINANT DNA ORIGIN	100 IU/ML	BIOTON S.AMACIERZYSZ, POZNANSKA 12 STR., 05-850 OZAROW MAZOWIECKI	POLAND	PARENTERAL ORDINARY S C VIALS	1.0X1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE	27/03/2019
3026	NDA/MAL/HDP/6 348	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	COMPOUND SODIUM LACTATE INTRAVENOUS INFUSION BP	SODIUM LACTATE SOLUTION +SODIUM CHLORIDE + CALCIUM CHLORIDE + POTASSIUM CHLORIDE	0.533 GM +0.600 GM + 0.027G+ 0.040 GM/100ML	ABARIS HEALTHCARE PVT. LTD-PLOT NO: 1407- 1411 VILLAGE: RAJPUR TALUKA: KADI, DIST.: MEHSANA 382 740, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	28/03/2018

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3027	NDA/MAL/HDP/6 349	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GSUNATE -120	ARTESUNATE	120MG	BLISS INDASI LIFESCINCES PRIVATE LIMITED - PLOT 73-76 SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN 396 210, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1*10ML 0.9%W/W SODIUM CHLORIDE SOLUTION AMPOULE + 1*2ML 5.0%W/W SODIUM BICARBONATE SOLUTION AMPOULE	26/09/2018
3028	NDA/MAL/HDP/6 350	MEGA LIFESCINCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	INVEL	METRONIDAZOLE + MICONAZOLE NITRATE	500MG + 100MG	BLISS GVS PHARMA LIMITED10,11 & 12,DEWAN UDYOG NAGAR,ALIYALI,PAL GHAR,MAHARASHTR A 401404,INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X7.0 SUPPOSITORY STRIP	27/03/2019
3029	NDA/MAL/HDP/6 352	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	OMIPIN-20	OMEPRAZOLE	20MG	BRAWN LABORATORIES LTD .13, NIT, INDUSTRIAL AREA, FARIDABAD- 121001, HARYANA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	28/03/2019

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3030	NDA/MAL/HDP/6353	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	DOLUTEGRAVIR/LAMIVUDINE/TENOFOVIR DISOPROXIL FUMARATE TABLETS 50MG/300MG/300MG	DOLUTEGRAVIR+LAMIVUDINE+TENOFVIR DISOPROXIL FUMARATE TABLETS	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
3031	NDA/MAL/HDP/6354	EXPHAR SA.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TIMOSOL [®]	TIMOLOL MALEATE	O.5%W/V	AHLCONPARENTERALS (INDIA) LIMITED DSP-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
3032	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

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3033	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
3034	NDA/MAL/HDP/6365	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	EASY PILL	LEVONORGESTREL	1.5MG	CORONA REMEDIES PVT LTDCORONA HOUSE, C MONDEAL BUSINESS PARK, NR. GURUDWARA GOVINDDHAM LANE, SG HIGHWAY, THALTEJ, AHMEDABAD 380059, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0 TABLET BLISTER	27/03/2019
3035	NDA/MAL/HDP/6368	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

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3036	NDA/MAL/HDP/6369	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVXIM SUSPENSION	CEFIXIME TRIHYDRATE	100MG/5ML	ASSOCIATED BIOTECH-VILLAGE : KISHANPURA, GURU MAJRA, BADDI, DISTT. SOLAN, INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE	31/01/2018
3037	NDA/MAL/HDP/6374	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, 1.0X10.0X10.0 TABLET BLISTER	28/03/2018
3038	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

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3039	NDA/MAL/HDP/6 377	REGAL PHARMA U LIMITED	REGAL PHARMA U LIMITED	EPHICOL CAPSULES	CHLORPHENIRAM INE MALEATE+ PARACETAMOL+ CAFFEINE ANHYDROUS+ PHENYLEPHRINE HCL	2MG+500 MG+30 MG+5MG	REGAL PHARMACEUTICALS LTD..PLOT 7879/18 OFF BABA DOGO ROAD, RUARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X12.0 CAPSULE BLISTER	01/07/2017
3040	NDA/MAL/HDP/6 380	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MAGNABIOTIC 1200MG VIAL	AMOXICILLIN + CLAVULANIC ACID	1000MG+120MG	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.2 G VIAL	25/07/2018
3041	NDA/MAL/HDP/6 381	MANKIND PHARM LTD	TATA UGANDA LIMITED	SERTAKIND	SERTACONAZOLE NITRATE	2.0%W/W	CURETECH SKINCAREPLOT NO. 33 & 34, PHASE IV, BHATOLI KALAN, BADDI DISTT. SOLAN (HP) 173205	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X10.0 G TUBE,1.0X20.0 G TUBE	27/03/2019

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3042	NDA/MAL/HDP/6 383	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	EXXIB	CELECOXIB	200MG	GRACURE PHARMACEUTICALS LIMITED E- 1105, RIICO INDUSTRIAL AREA, PHASE-III BHIWADI, PIN- 301019 DIST. ALWAR, RAJASTHAN, INDI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	31/01/2018
3043	NDA/MAL/HDP/6 385	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	AMOXIKID-250	AMOXICILLIN	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD PLOT NO. M444B, STRETCHER ROAD, NTINDA, KAMPALA	UGANDA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X10.0 TABLET STRIP	25/07/2018
3044	NDA/MAL/HDP/6 386	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	JUSDEE 60K GRANULES	COLECALCIFEROL	60000 IU	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X8.0X1.0 G SACHET	30/05/2018

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3045	NDA/MAL/HDP/6 389	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	METRONIDAZOLE BP	METRONIDAZOLE	0.5%W/V	ABARIS HEALTHCARE PVT. LTD-PLOT NO: 1407- 1411 VILLAGE: RAJPUR TALUKA: KADI, DIST.: MEHSANA 382 740, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	28/03/2018
3046	NDA/MAL/HDP/6 390	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	ROSUMAC 10	ROSUVASTATIN CALCIUM	10MG	MACLEODS PHARMACEUTICALS LTD ,.PHASE I & II, PLOT NO. 25-27 SURVEY NO. 366, PREMIERE INDUSTRIAL ESTATE, KACHIGAN, DAMAN- 396210	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	06/02/2019
3047	NDA/MAL/HDP/6 392	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MET XL 50	METOPROLOL SUCCINATE	50 MG	AJANTA PHARMA LTD .B-4//5/6, MIDC INDUSTRIALAREA, PAITHAN-431 128, AURANGBAD	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	30/05/2018

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3048	NDA/MAL/HDP/6 395	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	FLOXSOL [®]	NORFLOXACIN	0.3%W/V	AHLCON PARENTERALS (INDIA) LIMITEDSP- 917-918, PHASE 111, BHIWADI -301019, ALWAR, RAJASTHAN INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML VIAL	28/05/2019
3049	NDA/MAL/HDP/6 400	MERIDIAN ENTERPRISES PRIVATE LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	FENSUPP-100	DICLOFENAC SODIUM	100MG	MERIDIAN ENTERPRISES PVT. LTD-PLOT NO. 418, G.I.D.C.,KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	RECTAL SYSTEMIC ADULT SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY STRIP	01/07/2017
3050	NDA/MAL/HDP/6 401	MERIDIAN ENTERPRISES PRIVATE LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	SUPPOL 250 SUPPOSITORIES	ACETAMINOPHEN	250MG	MERIDIAN ENTERPRISES PVT. LTD PLOT NO. 418, G.I.D.C.,KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP	01/07/2017

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3051	NDA/MAL/HDP/6 404	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	STEDNAC GEL	ACECLOFENAC + LINSEED OIL + METHYL SALICYLATE	1.5%W/W + 3.0W/W +10.0%W/W	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE,1.0X15.0 G TUBE,1.0X50.0 G TUBE,1.0X100.0 G TUBE	01/07/2017
3052	NDA/MAL/HDP/6 405	ZIM LABORATORIES LTD	REDDYS PHARMA LIMITED	CLOPRAZ	CLOPIDOGREL BISULFATE	75MG	ZIM LABORATORIES LTDB-21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X3X10 TABLET BLISTER	01/07/2017
3053	NDA/MAL/HDP/6 407	ZIM LABORATORIES LTD	REDDYS PHARMA LIMITED	ZIMCOX 200	CELECOXIB	200 MG	ZIM LABORATORIES LTDB-21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA,	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	29/11/2017

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3054	NDA/MAL/HDP/6 408	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DECOZAL	XYLOMETAZOLINE HCL	0.1%W/V	AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	JORDAN	NASAL TOPICAL METERED DOSE AEROSOLS	1.0X10.0 ML BOTTLE	28/05/2019
3055	NDA/MAL/HDP/6 414	CIPLA LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	IMATIB 100	IMATINIB MESYLATE	100MG	CIPLA LTD, GOA UNIT V & UNIT XL- 139, S-103&M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	28/05/2019
3056	NDA/MAL/HDP/6 415	CIPLA LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	IMATIB 400	IMATINIB MESYLATE	400MG	CIPLA LTD, GOA UNIT V & UNIT XL- 139, S-103&M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	28/05/2019

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3057	NDA/MAL/HDP/6 416	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	PAN-D	PANTOPRAZOLE + DOMPERIDONE	40MG + 30MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	29/05/2019
3058	NDA/MAL/HDP/6 419	SEGURA PHARMA PRIVATE LTD	ABACUS PHARMA (AFRICA) LIMITED	CLINICEF CV	CEFIXIME + POTASSIUM CLAVULANATE	200MG + 125MG	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD - UNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE-247668. DIST.-HARIDWAR, UTTARAKHAND	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	26/09/2018
3059	NDA/MAL/HDP/6 422	INTERNATIONAL ORGANIZATION FOR MIGRATION	AIVEEN (U) LIMITED	EMADON	ONDANSETRON	4MG	CORONA REMEDIES PVT LTD-VILLAGE JATOLI,POST OFFICE - OACHGHAT, TEHSIL SOLAN, DIST. OLAN HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017

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3060	NDA/MAL/HDP/6423	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
3061	NDA/MAL/HDP/6424	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	ASCORIL LS	LEVOSALBUTAMOL 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
3062	NDA/MAL/HDP/6425	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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3063	NDA/MAL/HDP/6 426	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	SODIUM CHLORIDE INTRAVENOUS INFUSION BP	SODIUM CHLORIDE	0.9%W/V	ABARIS HEALTHCARE PVT. LTD-PLOT NO: 1407- 1411 VILLAGE: RAJPUR TALUKA: KADI, DIST.: MEHSANA 382 740, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2017
3064	NDA/MAL/HDP/6 430	IPCA LABORATOIES LTD	MEDVIN PHARMA LIMITED	LUMERAX DT 20/120	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	IPCA LABORATORIES LIMITED .PLOT 225/1, VILLAGE ATHAL, DANDRA AND NAGAR HAVELI UNION TERRITORY, SILVASSA-396 230	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X30.0X1.0X6.0 TABLET BLISTER,1.0X30.0X1 .0X12.0 TABLET BLISTER	27/03/2019
3065	NDA/MAL/HDP/6 431	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BRUMOX 125	AMOXICILLIN TRIHYDRATE	125MG/5ML	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017

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3066	NDA/MAL/HDP/6 432	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	UMBI-GEL	CHLORHEXIDINE GLUCONATE	4 % W/W	KAMPALA PHARMACEUTICALS INDUSTRIES (1996)LTDSTRETCH R ROAD PLOT M444B NTINDA KAMPALA	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X50.0X1.0X5.0 G TUBE	27/03/2019
3067	NDA/MAL/HDP/6 433	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	FICYC CREAM	ACICLOVIR	5%W/W	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE	01/07/2017
3068	NDA/MAL/HDP/6 435	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	FIMABUTE 200	CEFIXIME TRIHYDRATE	200MG	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	01/07/2017

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3069	NDA/MAL/HDP/6437	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
3070	NDA/MAL/HDP/6438	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
3071	NDA/MAL/HDP/6439	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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3072	NDA/MAL/HDP/6 440	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	CEFIWEL 400	CEFIXIME TRIHYDRATE	400MG	MALIK LIFESCENCES PRIVATE LIMITED PLOT NO. 16, NH 58, VARDHMAN INDUTRIAL ESTATE, VILLAGE BAHADARPUR SAINI HARIDWAR, UTTARAKHAND- 247667	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	28/03/2018
3073	NDA/MAL/HDP/6 441	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	OFLOXACIN INTRAVENOUS INFUSION	OFLOXACIN	0.2%W/V	ABARIS HEALTHCARE PVT. LTD-PLOT NO: 1407- 1411 VILLAGE: RAJPUR TALUKA: KADI, DIST.: MEHSANA 382 740, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1X100 ML BOTTLE	30/05/2018
3074	NDA/MAL/HDP/6 442	ZIM LABORATORIES LTD	REDDYS PHARMA LIMITED	AZITO SUSPENSION	AZITHROMYCIN DIHYDRATE	200 MG/5ML	ZIM LABORATORIES LTDB-21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA,	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X30.0 ML BOTTLE, 1.0X15.0 ML BOTTLE	31/01/2018

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3075	NDA/MAL/HDP/6 443	MICRO LABS	MALIX PHARMA (U) LIMITED	SINURHON SUSPENSION	CHLORPHENIRAM INE + PHENYLEPHRINE + PARACETAMOL	1MG + 5MG + 125MG	LEBEN LABORATORIES PVT LTD .L-14 PHASE III MIDC AKOLA 444 104	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	27/03/2019
3076	NDA/MAL/HDP/6 447	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	AZIBRU 500	AZITHROMYCIN DIHYDRATE	500MG	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0 TABLET BLISTER	01/07/2017
3077	NDA/MAL/HDP/6 448	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIZOLONE- DEPOT 40 MG/ 1 ML VIAL	METHYLPREDNIS OLONE ACETATE	40 MG/ ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B1,EGYPT	EGYPT	PARENTERAL ORDINARY VIALS	1.0X1.0X1.0 ML VIAL	25/07/2018

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3078	NDA/MAL/HDP/6 449	EVA PHARMA FOR PHARMACEUTICAL S & MEDICAL APPLIANCES	GAMA PHARMACEUTICAL S (U) LIMITED	DES Lorat Syrup	DES Loratidine	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
3079	NDA/MAL/HDP/6 454	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MAGRILAN 20MG	FLUOXETINE HYDROCHLORIDE	20MG	MEDOCHEMIE (FACTORY AZ).-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	29/01/2019
3080	NDA/MAL/HDP/6 455	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	FICYC TABLETS	ACYCLOVIR	200MG	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017

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3081	NDA/MAL/HDP/6 456	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	GLUCOSE INTRAVENOUS INFUSION BP (5% W/V)	GLUCOSE ANHYDROUS	5%W/V	ABARIS HEALTHCARE PVT. LTD-PLOT NO: 1407- 1411 VILLAGE: RAJPUR TALUKA: KADI, DIST.: MEHSANA 382 740, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2017
3082	NDA/MAL/HDP/6 459	MACLEODS PHARMACEUTICAL S LTDS LTD	VITACARE LIMITED	MACSUNATE AQ FORTE	ARTESUNATE + AMODIAQUINE	100MG + 270MG	MACLEODS PHARMACEUTICALS LTD .,PHASE I & II, PLOT NO. 25-27 SURVEY NO. 366, PREMIERE INDUSTRIAL ESTATE, KACHIGAN, DAMAN- 396210	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER,1.0X25.0X3 .0 TABLET BLISTER,1.0X25.0X6 .0 TABLET BLISTER,1.0X6.0 TABLET BLISTER	27/03/2019
3083	NDA/MAL/HDP/6 460	MANKIND PHARM LTD	TATA UGANDA LIMITED	NUROKIND-OD	MECOBALAMIN	1500MCG/ML	MANKIND PHARMA LTD.VILLAGE KISHANPURA, POAMTA SAHI DISTRICT SIRMOUR HIMACHAL PRADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X4.0X1.0 ML AMPOULE	27/03/2019

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3084	NDA/MAL/HDP/6 462	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	AMOXYN-500	AMOXICILLIN TRIHYDRATE	500MG	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	26/09/2018
3085	NDA/MAL/HDP/6 465	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	NEUROGAB 75	PREGABALIN	75MG	MACLEODS PHARMACEUTICALS LIMITED BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH – 174101 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2017
3086	NDA/MAL/HDP/6 468	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CIROLAZINE	HYDRALAZINE HYDROCHLORIDE	20MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE,1.0X5.0X 1.0 ML AMPOULE	30/05/2018

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3087	NDA/MAL/HDP/6 472	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MOXICLAV 375	AMOXICILLIN TRIHYDRATE + CLAVULINIC ACID	250MG + 125MG	MEDOCHEMIE LTD – FACTORY B-PLOT 48, IAPETOU STREET, AGIOS ATHANASSIOS INDUSTRIAL; AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X10.0 CAPSULE STRIP	29/01/2019
3088	NDA/MAL/HDP/6 476	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIZOLONE- DEPOT	METHYLPREDNIS OLONE	80MG/2ML	EGYPTIAN INT.PHARMACEUTIC AL INDUSTRIES CO. E.I.P.C.O --10TH OF RAMADAN CITY – INDUSTRIAL AREA B1. P.O BOX: 149 TENTH EGYPT	EGYPT	PARENTERAL RETARD VIALS	1.0X1.0X2.0 ML VIAL	25/07/2018
3089	NDA/MAL/HDP/6 477	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MEDOFULVIN	GRISEOFULVIN	500 MG	MEDOCHEMIE (FACTORY AZ).-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	27/03/2019

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3090	NDA/MAL/HDP/6 482	MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	EUTHROX 75MCG	LEVOTHYROXINE SODIUM	75 MCG	MERCK KGAA- PHARMA PRODUCTION DARMSTADT FRANKFURTER STRABE 250, D- 64293, DARMSTADT	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X2.0X25.0 TABLET BLISTER	27/03/2019
3091	NDA/MAL/HDP/6 491	INTAS PHARMACEUTICAL S LIMITED	NORVIK ENTERPRISES LIMITED	PREGATAS ME 75	PREGABALIN +MECOBALAMIN	75MG+750MCG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI- 248197,DEHRADUN UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	28/03/2018
3092	NDA/MAL/HDP/6 495	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	MACROLYN® 500 MG FILM COATED TABLETS	AZITHROMYCIN DIHYDRATE	500MG	DEVA HOLDING A. S.ÇERKEZKÖY ORGANIZE SANAYI BOLGESI. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKİRDAĞ/ TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	29/11/2017

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3093	NDA/MAL/HDP/6 498	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	AMOXICILLIN DISPERSIBLE TABLETS 250 MG	AMOXICILLIN TRIHYDRATE	250MG	MICRO LABS LIMITED PLOT NO. 16, VEERASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BANGALORE – 560 100. KARNATAKA, INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET STRIP	25/07/2018
3094	NDA/MAL/HDP/6 499	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	TACROZ FORTE	TACROLIMUS USP	0.1%W/W	GLENMARK PHARMACEUTICALS LTD .PLOT E-37, 39, D ROAD, MIDC, SATPUR, NASHIK 422007, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X10.0 G TUBE	28/05/2019
3095	NDA/MAL/HDP/6 500	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICAL S LTD	DERIVA C GEL	ADAPLENE BP + CLINDAMYCIN PHOSPHATE USP EQUIVALENT TO CLINDAMYCIN	1MG + 10MG	GLENMARK PHARMACEUTICALS LTD .PLOT E-37, 39, D ROAD, MIDC, SATPUR, NASHIK 422007, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X15.0 G TUBE	28/05/2019

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3096	NDA/MAL/HDP/6 501	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICAL S LIMITED	AARTROGYL 200 TABLET	METRONIDAZOLE	200MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/11/2017
3097	NDA/MAL/HDP/6 506	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	ACTITOP	ETOPOSIDE	50MG	KHANDELWAL LABORATORIES PVT. LTDB-1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1X8 CAPSULE BOTTLE	29/05/2019
3098	NDA/MAL/HDP/6 507	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	ZITRAM P	ACETAMINOPHEN + TRAMADOL HYDROCHLORIDE	325MG + 37.5MG	IPCA LABORATORIES LTD PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017

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3099	NDA/MAL/HDP/6 508	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	XALIPAT-100	OXALIPLATIN	100 MG/ 50ML (2MG/ML)	KHANDELWAL LABORATORIES PVT. LTDB-1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	PARENTERAL ORDINARY VIALS	1X1X50 ML VIAL	29/05/2019
3100	NDA/MAL/HDP/6 510	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	TACROZ	TACROLIMUS USP	0.03%W/W	GLENMARK PHARMACEUTICALS LTD .PLOT E-37, 39, D ROAD, MIDC, SATPUR, NASHIK 422007, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X10.0 G TUBE	28/05/2019
3101	NDA/MAL/HDP/6 512	AXA PARENTERALS LTD	VITACARE LIMITED	AXACIP	CIPROFLOXACIN	200MG/100ML	AXA PARENTERAL LIMITEDPLOT NO.936,937&939, VILL. KISHANPUR, JAMALPUR,ROORKEE 247667, DISTT. HARIDWAR (UTTARAKHAND) INDIA.	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	31/01/2018

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3102	NDA/MAL/HDP/6 513	MACARTHYS LABORATORIES	LABOREX UGANDA LIMITED	GLYCOPYRRONIUM BROMIDE 200 MICROGRAMS PER ML SOLUTION FOR INJECTION	GLYCOPYRRONIUM BROMIDE	200MCG/ML	MACARTHYS LABORATORIES LIMITED T/A MARTINDALE PHARMABAMPTON ROAD, ROMFORD, ESSEX RM3 8UG,	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0 ML AMPOULE	28/05/2019
3103	NDA/MAL/HDP/6 514	EXPHAR SA.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	FEBRILEX	PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + CHLORPHENAMINE MALEATE	500MG + 5M + 2MG	MILAN LABORATORIES (INDIA) PVT LTD,63,67,87,35,36, 64, 65 JAWAHAR CO- OP INDUSTRIAL ESTATE KAMOTHE, PANVEL NAVI MUMBAI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET STRIP	28/05/2019
3104	NDA/MAL/HDP/6 515	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

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3105	NDA/MAL/HDP/6 516	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	WOMASTIN	CARBOPLATIN	150MG/15ML	KHANDELWAL LABORATORIES PVT. LTDB-1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1X45 ML VIAL	29/05/2019
3106	NDA/MAL/HDP/6 520	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	VOMIKIND-MD 8	ONDASENTRON	8MG	MANKIND PHARMA LTD-UNIT II VILLAGE KISHANPURA P.O JAMNIWALA TEHSIL PAONTA SAHIB DISTRICT SIRMOUR 173 025 HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017
3107	NDA/MAL/HDP/6 521	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	KIPEL 4	MONTELUKAST	4MG	MSN LABORATORIES LTD. PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, ZIP CODE - 502 325, ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/03/2019

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3108	NDA/MAL/HDP/6 522	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EPNONE 25	EPLERENONE	25MG	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	27/03/2019
3109	NDA/MAL/HDP/6 523	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	FLEXDOL	IBUPROFEN+MET HOCARBAMOL	200MG+500MG	GRACURE PHARMACEUTICAL LTDE-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017
3110	NDA/MAL/HDP/6 524	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S LIMITED	RAMGIC	TRAMADOL HYDROCHLORIDE	50MG/ML	MSN LABORATORIES LTD. PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, ZIP CODE - 502 325, ANDHRA PRADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X2.0 ML AMPOULE	27/03/2019

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3111	NDA/MAL/HDP/6 525	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S LIMITED	DAPOXEM 30	DAPOXETINE	30MG	MSN LABORATORIES LTD. PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, ZIP CODE - 502 325, ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/03/2019
3112	NDA/MAL/HDP/6 526	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S LIMITED	DAPOXEM 60	DAPOXETINE	60MG	MSN LABORATORIES LTD. PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, ZIP CODE - 502 325, ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/03/2019
3113	NDA/MAL/HDP/6 527	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PULMOFIRST 62.5	BOSENTAN MONOHYDRATE	62.5MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISION PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	27/03/2019

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3114	NDA/MAL/HDP/6 528	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PULMOFIRST 125	BOSENTAN MONOHYDRATE	125MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISION PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	27/03/2019
3115	NDA/MAL/HDP/6 532	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	BUNASE 200	BUDESONIDE	200MCG / ACTUATION	OXALIS LABS- VILLAGE THEDA, P.O. LODHIM AJRA, TEHSIL BADDI, DIST. SOLAN (HIMACHAL PRADESH) - 174101 INDIA	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X1.0 CANNISTER CARTON	28/03/2018
3116	NDA/MAL/HDP/6 536	PHARMATHEN INVESTMENTS GROUP LTD	GOODMAN INTERNATIONAL LTD	OZAPEX 5MG	OLANZAPINE	5MG	PHARMATHEN S.A6, DERVENAKION STR. 15351 PALLINI ATHENS	GREECE	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X4.0X7.0 TABLET BLISTER	28/03/2019

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3117	NDA/MAL/HDP/6 537	EXPHAR LTD.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	CARBOSOL	CARMELLOSE SODIUM	0.5%W/V	AHLCONPARENTERA LS (INDIA) LIMITEDSP-918, PHASE-III, BHIWADI- 301019, RAJASTHAN (INDIA) TEL: +91-1493- 305300 (30 LINES) FAX: +91-1493- 221045, 305345	INDIA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE	31/01/2018
3118	NDA/MAL/HDP/6 538	PHARMATHEN INVESTMENTS GROUP LTD	GOODMAN INTERNATIONAL LTD	OZAPEX 10MG	OLANZAPINE	10MG	PHARMATHEN S.A6, DERVENAKION STR. 15351 PALLINI ATHENS	GREECE	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X4.0X7.0 TABLET BLISTER	28/03/2019
3119	NDA/MAL/HDP/6 545	RAPTAKOS, BRETT & CO. LTD.	EUROPA HEALTHCARE (U) LTD	ZYTEE RB	CHOLINE SALICYLATE + BENZALKONIUM CHLORIDE	9%W/W + 0.02% W/V	RAPTAKOS BRETT & CO.LTD1ST POKHRAN ROAD,THANE 400 606	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X10.0 ML TUBE	27/03/2019

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3120	NDA/MAL/HDP/6 546	RAPTAKOS, BRETT & CO. LTD.	EUROPA HEALTHCARE (U) LTD	NEOPEPTINE	ALPHA AMYLASE + PAPAIN	100MG + 50MG /5ML	RAPTAKOS BRETT & CO.LTD1ST POKHRAN ROAD,THANE 400 606	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X60.0 ML BOTTLE	27/03/2019
3121	NDA/MAL/HDP/6 549	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	PIRAV-75	PREGABALIN	75MG	RAVIAN LIFE SCIENCE PVT LTD PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1X10X10 CAPSULE BLISTER	28/03/2019
3122	NDA/MAL/HDP/6 550	REDDYS PHARMA LIMITED	REDDYS PHARMA LIMITED	REDCEPHIN	CEFTRIAZONE	1 G	INJECT CARE PARENTERALS PVT LTD PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	27/03/2019

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3123	NDA/MAL/HDP/6 551	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICAL S LIMITED	NUROFEN FOR CHILDREN SUGAR FREE	IBUPROFEN	100MG/5ML	RECKITT BENCKISER HEALTHCARE - DAMSON LANE,HULL, HUB HU8 7DS	UNITED KINGDOM	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	27/03/2019
3124	NDA/MAL/HDP/6 552	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICAL S LIMITED	NUROFEN	IBUPROFEN + LYSINE	342MG	RECKITT BENCKISER HEALTHCARE - DAMSON LANE,HULL, HUB HU8 7DS	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X12.0 TABLET BLISTER	27/03/2019
3125	NDA/MAL/HDP/6 553	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENSOL SOLUTION	CHLORHEXIDINE GLUCONATE + ISOPROPYL ALCOHOL	0.5% W/W + 70% W/W	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X5.0 L CONTAINER	27/03/2019

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3126	NDA/MAL/HDP/6 554	SEGURA PHARMA PRIVATE LTD	ABACUS PHARMA (AFRICA) LIMITED	RESPIQUIN-750	LEVOFLOXACIN	750MG	SAI MIRRA INNOPHARM PVT LIMITED 288&299, SIDCO ESTATE AMBTTUR, CHENNAI 600098	INDIA	ORAL SOLID ORDINARY TABLETS	2.0X1.0X1.0X10.0 TABLET BLISTER	27/03/2019
3127	NDA/MAL/HDP/6 556	SAVA HEALTHCARE LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	BECLOGEN CREAM	CLOTRIMAZOLE USP, BECLOMETASONE DIPROPIONATE BP, GENTAMICIN SULPHATE BP	1%W/W, 0.025%W/W, 0.1%W/W	SAVA HEALTHCARE LIMITED.PLOT NO 507B -512, G.I.D.C. ESTATE, WADHWANCITY-363 035 SURENDRANAGAR, GUJARAT, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	27/03/2019
3128	NDA/MAL/HDP/6 562	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	ATROPINE EYE DROP BP 1 %W/V	ATROPINE SULPHATE	1%W/V	SWISS PARENTERALS PVT LTD ..809, KERALA INDUSTRIAL ESTAE, GIDC NEAR BAVLA, AHMEDABAD 382220, GUJARAT	INDIA	OPHTHALMIC LIQUIDS	1X1X10 ML VIAL	28/03/2019

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3129	NDA/MAL/HDP/6 563	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
3130	NDA/MAL/HDP/6 565	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	IBUPROFEN	IBUPROFEN	200MG	TRIVENI FORMULATIONS LTD PLOT NO. 52,53,54,63,62,64 ALEAP INDUSTRIAL ESTATE SARAMPALLI VIJAYWADA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	28/03/2019
3131	NDA/MAL/HDP/6 568	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICAL S LIMITED	PINNADIP 50 TABLET	DICLOFENAC	50MG	PINNACLE LIFE SCIENCE PVT LTD KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017

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3132	NDA/MAL/HDP/6569	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	MARDAGRA 50	SILDENAFIL CITRATE	50MG	ZIM LABORATORIES LIMITED B-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
3133	NDA/MAL/HDP/6572	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
3134	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

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3135	NDA/MAL/HDP/6 577	UNOSOURCE PHARMA LTD	MEDVIN PHARMA LIMITED	CEFIWEL-200	CEFIXIME	200MG	MALIK LIFESCENCES PRIVATE LIMITED PLOT NO. 16, NH 58, VARDHMAN INDUTRIAL ESTATE, VILLAGE BAHADARPUR SAINI HARIDWAR, UTTARAKHAND- 247667	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	21/11/2019
3136	NDA/MAL/HDP/6 578	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ACINET DRY SYRUP 228.5MG/5ML	AMOXYCILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	200MG + 28.5MG PER 5ML	INDCHEMIE HEALTH SPECIALITIES PVT. LTD VILLAGE-THANA, BADDI, DIST. SOLAN, HIMACHAL PRADESH- 173 205.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	27/08/2019
3137	NDA/MAL/HDP/6 579	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	PLENCOXIB 200	CELECOXIB	200 MG	AKUMS DRUGS AND PHARMACEUTICALS 19,20,21, SEC.6-A, IIE, SIDCUL, RANIPUR,HARIDWAR 249403, UTTARAKHAND, INDIAINDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X6.0X10.0 CAPSULE BLISTER,10.0X10.0 CAPSULE BLISTER	27/08/2019

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3138	NDA/MAL/HDP/6 589	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICAL S LIMITED	VANBACT	VANCOMYCIN HYDROCHLORIDE	500MG	NABIQASIM INDUSTRIES (PVT) LTD .17/24 KORANGI INDUSTRIAL AREA KORANGI KARACHI	PAKISTAN	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	28/05/2019
3139	NDA/MAL/HDP/6 590	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICAL S LIMITED	LOPROT	OMEPRAZOLE SODIUM	40MG	NABIQASIM INDUSTRIES (PVT) LTD .17/24 KORANGI INDUSTRIAL AREA KORANGI KARACHI	PAKISTAN	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	28/05/2019
3140	NDA/MAL/HDP/6 593	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICAL S LIMITED	TRANSIC	TRANEXAMIC ACID	500MG	SURGE LABS (PVT) LTD10TH KM FAISALABAD ROAD, BIKHI DISTRICT SHEIKHUPURA	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0 ML AMPOULE	28/05/2019

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3141	NDA/MAL/HDP/6 598	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S LIMITED	BREATHEZY-L (10/5)	MONTELUKAST SODIUM + LEVOCETIRIZINE DIHYDROCHLORID E	10MG + 5MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/01/2019
3142	NDA/MAL/HDP/6 600	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	PROSTALEN	ALFUZOSIN HYDROCHLORIDE	10MG	GRACURE PHARMACEUTICAL LTDE-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/03/2019
3143	NDA/MAL/HDP/6 602	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	CARDIURINE	CAPTOPRIL + HYDROCHLOROT HIAZIDE	50MG + 25MG	GRACURE PHARMACEUTICAL LTDE-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/03/2019

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3144	NDA/MAL/HDP/6 608	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CIPROCIN 0.3%	CIPROFLOXACIN HYDROCHLORIDE	0.3%W/W	ORCHIDIA10TH RAMADHAN CITY INDUSTRIAL AREA- B1 , P. O. BOX 149 TENTH, EGYPT	EGYPT	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE	28/05/2019
3145	NDA/MAL/HDP/6 610	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	VOMIKIND	ONDANSETRON HYDROCHLORIDE	2MG/ML	MANKIND PHARMA LTD-UNIT II VILLAGE KISHANPURA P.O JAMNIWALA TEHSIL PAONTA SAHIB DISTRICT SIRMOUR 173 025 HIMACHAL PRADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X4.0X2.0 ML AMPOULE,1.0X4.0X 4.0 ML AMPOULE	01/07/2014
3146	NDA/MAL/HDP/6 611	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	MARDAGRA 100	SILDENAFIL CITRATE	100MG	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA PSA CHEMICALS & PHARMACEUTICALS PRIVATE LIMITED - 3, SEZ-II, PITHAMPUR, DISTT. DHAR, MADHYA PRADESH - 454 774, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	29/05/2019

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3147	NDA/MAL/HDP/6 612	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	APRAZOLE PLUS- 20	OMEPRAZOLE + SODIUM BICARBONATE	20MG/6G + 1680MG/6G	AJANTA PHARMA LIMITED PAITHANMANUFACT URING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY POWDERS	1.0X20.0X6.0 G SACHET	01/07/2008
3148	NDA/MAL/HDP/6 613	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	OLMAT-40	OLMESARTAN MEDOXOMIL	40MG	MICRO LABS LTD 92 SIPCOT 92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3149	NDA/MAL/HDP/6 614	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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3150	NDA/MAL/HDP/6 616	SHIN POONG PHARMACEUTICAL S CO.LTD	AAFIYA (A) LIMITED	PYRAMAX	PYRONARIDINE TETRAPHOSPHAT E + ARTESUNATE	180MG + 60MG	SHIN POONG PHARM. CO., LTD70, SANDAN-RO, 19 BEON-GIL, DANWON- GU, ANSAN-SI, GYEONGGI-DO, REPUBLIC OF KOREA	SOUTH KOREA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X9.0 TABLET BLISTER	01/07/2016
3151	NDA/MAL/HDP/6 617	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	APFLU	CHLOROPHENERA MINE + PARACETAMOL + VITAMIN C	0.5MG + 120MG + 50MG	AJANTA PHARMA LIMITED31-0 MIDC INDUSTRIAL AREA CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA STATE	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2009
3152	NDA/MAL/HDP/6 619	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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3153	NDA/MAL/HDP/6 620	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICAL S (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
3154	NDA/MAL/HDP/6 621	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	BAROLE 20	RABEPRAZOLE	20MG	INVENTIA HEALTHCARE LIMITEDF-1 - F-1/1 - F75/1, ADDITIONAL AMBERNATH MIDC, AMBERNATH EAST 421506, DIST. THANE, MAHARASHTRA - INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2011
3155	NDA/MAL/HDP/6 622	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	CEFIWEL-100 DT	CEFIXIME TRIHYDRATE	100MG	MALIK LIFESCIENCES PRIVATE LIMITEDPLOT NO. 16, NH 58, VARDHMAN INDUTRIAL ESTATE, VILLAGE BAHADARPUR SAINI HARIDWAR, UTTARAKHAND- 247667	INDIA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016

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3156	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
3157	NDA/MAL/HDP/6625	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILET PLUS 5/12.5	NEBIVOLOL HYDROCHLORIDE + HYDROCHLOROT HIAZIDE	5MG + 12.5MG	BERLIN-CHEMIE AG/MENARINI,GLIENICKER WEG 125, D-12489 BERLIN GERMANY BERLIN-CHEMIE AG, SITE BRITZ (BULK PRODUCTION,) BERLIN-CHEMIE AG, SITE BRITZ (BULK PRODUCTION, BATCH CONTROL) TEMPELHOFFER WEG 83 D-12347 BERLIN	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER,1.0X1.0X4.0 TABLET BLISTER (FREE MEDICAL SAMPLE)	01/07/2016
3158	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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3159	NDA/MAL/HDP/628	RECKITT BENCKISER HEALTHCARE INTERNATIONAL	GITTOES PHARMACEUTICALS LIMITED	STREPSILS ORIGINAL	MULTI-INGREDIENT	MULTI-INGREDIENT	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITEDRECKITT BENCKISER HEALTHCARE INTERNATIONAL-65 MOO 12,LARD KRABANG-BANGPLEE ROAD, BANGPLEE SAMUTPRAKARAN 10 540, THALAND	THAILAND	ORAL SOLID ORDINARY LOZENGES	1.0X24.0 LOZENGE PACK,1.0X70.0 LOZENGE PACK,100.0X2.0 LOZENGE BLISTER,2.0X12.0 LOZENGE BLISTER	01/07/1997
3160	NDA/MAL/HDP/629	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILET PLUS 5/25	NEBIVOLOL+HYDR OCHLOROTHIAZIDE	5MG+25MG	BERLIN-CHEMIE AG/MENARINIGLIENICKER WEG 125, D-12489 BERLIN GERMANY(BATCH RELEASE) BERLIN-CHEMIE AG, SITE BRITZ (BULK PRODUCTION)TEMP ELHOFER WEG 83 D-12347 BERLIN GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER,1.0X1.0X4.0 TABLET BLISTER	01/07/2016
3161	NDA/MAL/HDP/630	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TOPRAZ 20	PANTOPRAZOLE	20MG	AUROBINDO PHARMA LIMITED (SEZ, UNIT " VII), SURVEY NO.411, 425, 434, 435 & 458, APIIC, PLOT NO. SI GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHERLA MANDAL, MAHABOOB NAGAR DISTRICT, HYDERABAD, ANDHRA PRADESH 500090, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016

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3162	NDA/MAL/HDP/6 631	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOBURN	SILVER SULFADIAZINE	1%W/W	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X500.0 G JAR	01/07/2016
3163	NDA/MAL/HDP/6 633	SHELYS PHARMACEUTICAL S LTD	BETA HEALTHCARE UGANDA LIMITED	COLDRIIL	PARACETAMOL + CHLORPHENIRAM INE MALEATE + PSEUDOEPHEDRI NE HCL	500MG + 30MG + 2MG	BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X12.0X1 .0X2.0X10.0 CAPSULE BLISTER	01/07/2017
3164	NDA/MAL/HDP/6 636	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S LIMITED	COSAMIDE 100	LACOSAMIDE	100MG	MSN LABORATORIES LTD PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISION PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325-	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016

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3165	NDA/MAL/HDP/6 638	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S 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
3166	NDA/MAL/HDP/6 640	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SAFETELMI H (40/ 12.5)	TELMISARTAN + HYDROCHLOROT HIAZIDE	40MG + 12.5MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3167	NDA/MAL/HDP/6 641	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	CEFTRISONE- S 1.5G	CEFTRIAZONE SODIUM + SULBACTAM SODIUM	1.0G + 0.5G	AKUMS DRUGS & PHARMACEUTICALS LTD. -PLANT III,PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL,RANIPUR, 249 403	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.5 G VIAL + 10ML WFI AMPOULE	01/07/2016

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3168	NDA/MAL/HDP/6 645	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SAFETELMI H (80/ 12.5)	TELMISARTAN + HYDROCHLOROT HIAZIDE	80MG + 12.5MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3169	NDA/MAL/HDP/6 650	INDUS LIFE SCIENCES PVT LIMITED	NORVIK ENTERPRISES LIMITED	INTRIAX-S-1	CEFTRIAZONE SODIUM+SULBAC TAM SODIUM	1G+0.5G	INJECT CARE PARENTERALS PVT LTD PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	01/07/2016
3170	NDA/MAL/HDP/6 653	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	METSAFE 500 ER	METFORMIN HYDROCHLORIDE	500MG	MSN LABORATORIES PVT. LIMITED PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID RETARD TABLETS	1X3X10 TABLET BLISTER	01/07/2017

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3171	NDA/MAL/HDP/6 654	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
3172	NDA/MAL/HDP/6 658	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	NEBIEM 10	NEBIVOLOL	10MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3173	NDA/MAL/HDP/6 662	SAKAR HEALTHCARE PVT LTD	ROYAL PHARMA 2011 LIMITED	DIAPAM	DIAZEPAM	5MG/ML	SAKAR HEALTHCARE PVT LIMITEDPLOT 10/13 SARKHEJ- BAVLA ROAD, AHMEDABAD, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X2.0 ML AMPOULE	01/07/2013

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3174	NDA/MAL/HDP/663	PANACEA BIOTEC PHARMA LTD	VITACARE LIMITED	SITCOM	EUPHORBIA PROSTATA DRY EXTRACT	10MG/G	PANACEA BIOTEC PHARMA LIMITEDMALPURI BADDI, DISTRICT SOLAN, HIMACHAL PRADESH-173205 - INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	01/07/2013
3175	NDA/MAL/HDP/664	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMOX 125 KID	AMOXICILLIN TRIHYDRATE	125MG	SPARSH BIO-TECH PVT. LIMITEDPLOT NO. 1;SURVEY NO. 242/243/244,LAKHA BAVAD,JAMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
3176	NDA/MAL/HDP/665	REGAL PHARMACEUCIALS LTD	REGAL PHARMA (U) LTD	SALBUMOL SYRUP	SALBUTAMOL	2MG/5ML	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997

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3177	NDA/MAL/HDP/666	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
3178	NDA/MAL/HDP/667	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMOX 250 DT	AMOXICILLIN TRIHYDRATE	250MG	SPARSH BIO-TECH PVT. LIMITED PLOT NO. 1; SURVEY NO. 242/243/244, LAKHA BAVAD, JAMNAGAR- 361 006, INDIA.	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2016
3179	NDA/MAL/HDP/669	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	SUPER WELGRA - 100	SILDENAFIL CITRATE + DAPOXETINE HYDROCHLORIDE	100MG + 60MG	AKUMS DRUGS AND PHARMACEUTICALS LTD PLANT-1 PLOT NO.19, 20&21 SECTOR-6A, 11E, SIDCUL, RAHIPUR DISTT; HARIDWAR, 249403, (UTTRAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0 TABLET BLISTER	01/07/2016

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3180	NDA/MAL/HDP/670	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
3181	NDA/MAL/HDP/675	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	UNOSEMIDE -10	FUROSEMIDE	10MG/ML	AKUMS DRUGS & PHARMACEUTICALS LTD. -PLANT III, PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL, RANIPUR, 249 403	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2016
3182	NDA/MAL/HDP/679	BLUE CROSS LABORATORIES LIMITED	STAR PHARMACEUTICALS LTD	WOMIBAN TABLETS	ALBENDAZOLE	400MG	BLUE CROSS LABORATORIES LTD-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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3183	NDA/MAL/HDP/6 681	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	WELQUINE	LEVOFLOXACIN	0.5%W/V	AKUMS DRUGS & PHARMACEUTICALS LTD. PLANT III, PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL, RANIPUR, HARIDWAR, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2016
3184	NDA/MAL/HDP/6 685	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	EVACEF	CEFOTAXIME	1 G	NEON LABORATORIES LTD PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2014
3185	NDA/MAL/HDP/6 686	DAWA LIMITED	SUPER MEDIC LTD	DAWASOLONE	PREDNISOLONE	5MG	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/2010

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3186	NDA/MAL/HDP/6 689	DAWA LIMITED	SUPER MEDIC LTD	EFLARON	METRONIDAZOLE	200MG	MEDICO REMEDIES PVT LTD.,8 & 9 DEWAN AND SONS, UDYOG NAGAR, PALGHAR, DIST. THANE-401404, MAHARSHITRA DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10. 0X10.0 TABLET BLISTER	01/07/1997
3187	NDA/MAL/HDP/6 693	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	CERTICAN1	EVEROLIMUS	1MG	NOVARTIS PHARMA STEIN AG.SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X6.0X10.0 TABLET BLISTER	01/07/2016
3188	NDA/MAL/HDP/6 694	NOVARTIS PHARMA SERVICES INC.	SURGIPHARM (U) LIMITED	CERTICAN 0.5	EVEROLIMUS	0.5MG	NOVARTIS PHARMA STEIN AG.SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X6.0X10.0 TABLET BLISTER	01/07/2016

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3189	NDA/MAL/HDP/6 695	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ORAV-OZ	OFLOXACIN + ORNIDAZOLE	200MG + 500MG	RAVIAN LIFE SCIENCE PVT LTD PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1X1X10 TABLET BLISTER	29/05/2019
3190	NDA/MAL/HDP/6 699	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ATVIN-20	ATORVASTATIN	20MG	RAVIAN LIFE SCIENCE PVT LTD PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	28/05/2019
3191	NDA/MAL/HDP/6 713	CACHET PHARMACEUTICAL S PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	CAMET	METOCLOPRAMI DE HYDROCHLORIDE	10MG	CACHET PHARMACEUTICALS PVT LTD THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009

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3192	NDA/MAL/HDP/6 715	CACHET PHARMACEUTICAL S PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	CAZITHRO	AZITHROMYCIN	200MG/5ML	CACHET PHARMACEUTICALS PVT LTD THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X15.0 ML BOTTLE	01/07/2009
3193	NDA/MAL/HDP/6 717	CACHET PHARMACEUTICAL S PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	CAZITHRO	AZITHROMYCIN	500MG	CACHET PHARMACEUTICALS PVT LTD THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER	01/07/2011
3194	NDA/MAL/HDP/6 722	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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3195	NDA/MAL/HDP/6 724	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
3196	NDA/MAL/HDP/6 728	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CIPROCOS-500 TABLETS	CIPROFLOXACIN	500MG	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,10.0X10.0 TABLET BLISTER	01/07/2000
3197	NDA/MAL/HDP/6 729	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSCOF 'C' LINCTUS	MULTI- INGREDIENT	MULTI- INGREDIENT	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2010

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3198	NDA/MAL/HDP/6 732	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSCOF EXPECTORANT ORIGINAL	MULTI- INGREDIENT	MULTI- INGREDIENT	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2010
3199	NDA/MAL/HDP/6 734	CACHET PHARMACEUTICAL S PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	EASCOF	BROMHEXINE HCL + SALBUTAMOL SULPHATE + GUAIPHENESIN + MENTHOL	(4MG + 2MG + 100MG + 1MG)/10ML	CACHET PHARMACEUTICALS PVT LTD THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2009
3200	NDA/MAL/HDP/6 736	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	SANDOSTATIN	OCTREOTIDE ACETATE	0.05MG	NOVARTIS PHARMA STEIN AG.SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	PARENTERAL ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE	01/07/2016

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3201	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
3202	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
3203	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) .KOZHIPANNAI PUDUMUND P.O DR. BASAVIAH NAGAR UDHAGAMANDALA M PIN: 643007 TAMIL NADU	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X2.5 I.U VIAL 1*0.5ML DILUENT(0.9%W/V SODIUM CHLORIDE INJ. B.P) - 1 DOSE VIAL	01/07/2016

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3204	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
3205	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
3206	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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3207	NDA/MAL/HDP/6 764	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	IZRA 40	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40MG	UNICHEM LABORATORIES LTDUNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0 TABLET STRIP	01/07/2006
3208	NDA/MAL/HDP/6 767	ADCOCK INGRAM LIMITED	SURGIPHARM (U) LIMITED	MEDI-KEEL A	BENZOCAINE+CET YLPYRIDINIUM CHLORIDE	12MG+1.5MG	UNIQUE PHARMACEUTICALS LABORATORIESSURV EY NO. 101/2 AND 102/1, DAMAN INDUSTRIAL ESTATE, AIRPORT ROAD, KADAIYA, DAMAN – 396 210 INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X2.0X8.0 LOZENGE BLISTER	01/07/2016
3209	NDA/MAL/HDP/6 769	ADCOCK INGRAM LIMITED	SURGIPHARM (U) LIMITED	MEDI-KEEL A HONEY & LEMON	BENZOCAINE+CET YLPYRIDINIUM CHLORIDE	12MG+1.5MG	UNIQUE PHARMACEUTICALS LABORATORIESSURV EY NO. 101/2 AND 102/1, DAMAN INDUSTRIAL ESTATE, AIRPORT ROAD, KADAIYA, DAMAN – 396 210 INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X2.0X8.0 LOZENGE BLISTER	01/07/2016

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3210	NDA/MAL/HDP/6 771	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DIFLUVID	FLUCONAZOLE	150MG	HOVID BERHAD,LOT 56442, 7 1/2 MILES JALAN IPOH/CHEMOR 31200, CHEMOR PERAK	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0 CAPSULE BLISTER	01/07/2016
3211	NDA/MAL/HDP/6 772	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	PIOSAFE 30	PIOGLITAZONE HCL	30MG	ARISTO PHARMACEUTICALS PVT LTD PLOT NO 208 NEW INDUSTRIAL GREEN NO2 MANDIDEED 462046	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2007
3212	NDA/MAL/HDP/6 776	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICAL S LIMITED	M-FORLIN 500	METFORMIN	500MG	LINCOLN PHARMACEUTICAL LIMITEDTRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010

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3213	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
3214	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
3215	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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3216	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
3217	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
3218	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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3219	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
3220	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
3221	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, MAHABOONAGAR (DISTRICT). PIN 509301	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/2017

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3222	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
3223	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
3224	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-O-DESACYL-4'MONOPHOSPHORYL LIPID A(MPL)	GLAXOSMITHKLINE BOIOLOGICALS.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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3225	NDA/MAL/HDP/6 812	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
3226	NDA/MAL/HDP/6 815	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABCROM EYE DROPS	SODIUM CROMOGLYCATE	2%W/V	ABACUS PARENTERAL DRUGS LTD. PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE, 1.0X5.0 ML BOTTLE	01/07/2016
3227	NDA/MAL/HDP/6 817	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	LETROZOLE DENK 2.5	LETROZOLE	2.5MG	HAUPT PHARMA MÜNSTER GMBH SCHLEEBRÜG GENKAMP 15 48159 MÜNSTER GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016

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3228	NDA/MAL/HDP/6 818	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
3229	NDA/MAL/HDP/6 820	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABBORI EAR DROPS	BORIC ACID	1.83%W/V	ABACUS PARENTERAL DRUGS LIMITEDBLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	OTIC DROPS	1.0X10.0 ML BOTTLE	01/07/2017
3230	NDA/MAL/HDP/6 821	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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3231	NDA/MAL/HDP/6 823	LABOREX UGANDA LIMITED	LABOREX UGANDA LIMITED	EPHEDRINE HYDROCHLORIDE	EPHEDRINE HYDROCHLORIDE	30MG/ML	MARTINDALE PHARMACEUTICALS .ROMFORD ESSEX RM3 8UG UK	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE	01/07/2016
3232	NDA/MAL/HDP/6 833	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	ON.SENTRON- DENK 8MG ODT	ONDANSETRON	8MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X6.0 TABLET BLISTER	01/07/2016
3233	NDA/MAL/HDP/6 837	ZEE PHARMACEUTICAL S LTD	ZEE PHARMACEUTICAL S LIMITED	ZEEL KIT	CLARITHROMYCIN + METRONIDAZOLE + PANTOPRAZOLE SODIUM SESQUIHYDRATE	250MG + 400MG +40MG	THE MADRAS PHARMACEUTICALS 137-B,OLD MAHABALI PURAM ROAD,KARAPAKKAM ,CHENNAL INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET STRIP	01/07/2016

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3234	NDA/MAL/HDP/6 843	CADILA PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S LTD.	FYTOBACT	CEFOPERAZONE + SULBACTAM	0.5 G + 0.5 G	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2009
3235	NDA/MAL/HDP/6 845	CADILA PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S LTD.	FYTOBACT 2G	SULBACTAM SODIUM + CEFOPERAZONE SODIUM	1G + 1G	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X2.0 G VIAL	01/07/2017
3236	NDA/MAL/HDP/6 857	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BRUCIPRO TABLETS	CIPROFLOXACIN	500MG	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	10.0X10.0 TABLET BLISTER	29/11/2017

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3237	NDA/MAL/HDP/6 859	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BRUVEL-500 TABLETS	LEVOFLOXACIN HEMIHYDRATE	500MG	BRAWN LABORATORIES LTD..13,NEW INDUSTRIAL TOWNSHIP, FARIDABAD-121 001,HARYANA - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	26/09/2018
3238	NDA/MAL/HDP/6 862	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	DITS GEL	DICLOFENAC DIETHYLAMINE	1%W/W	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X15.0 G TUBE,1.0X30.0 G TUBE	01/07/2017
3239	NDA/MAL/HDP/6 865	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	DITS INJECTION	DICLOFENAC SODIUM	25MG/ML	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X3.0 ML AMPOULE	29/11/2017

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3240	NDA/MAL/HDP/6 870	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	HYDROSONE 100MG	HYDROCORTISON E SODIUM SUCCINATE	100MG	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON (1*100MG GLASS VIAL + 1*2ML AMP WFI),1.0X50.0 VIAL CARTON	29/11/2017
3241	NDA/MAL/HDP/6 871	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	VIVAX 100	SILDENAFIL	100MG	BRAWN LABORATORIES LTD..13,NEW INDUSTRIAL TOWNSHIP, FARIDABAD-121 001,HARYANA - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	26/09/2018
3242	NDA/MAL/HDP/6 872	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	NETRACORTIL EYE/EAR SUSPENSION	OXYTETRACYCLIN E HYDROCHLORIDE +HYDROCORTISO NE ACETATE+POLYM YXIN B SULPHATE	10MG+5MG+1000 OI.U	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML BOTTLE	01/07/2017

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3243	NDA/MAL/HDP/6 873	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	ROXITHIN TABLETS	ROXITHROMYCIN	150MG	BRAWN LABORATORIES LTD..13,NEW INDUSTRIAL TOWNSHIP, FARIDABAD-121 001,HARYANA - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	26/09/2018
3244	NDA/MAL/HDP/6 874	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	CITRAX TABLETS	CETIRIZINE HYDROCHLORIDE	10MG	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017
3245	NDA/MAL/HDP/6 875	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BRUMOX-250 CAPSULES	AMOXICILLIN TRIHYDRATE	250MG	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER	29/11/2017

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3246	NDA/MAL/HDP/6 879	RAVIAN LIFE SCIENCE PVT. LTD	ROYAL PHARMA 2011 LIMITED	ORAV-200	OFLOXACIN	200MG	RAVIAN LIFE SCIENCE PVT LTD PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/05/2019
3247	NDA/MAL/HDP/6 882	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	VORM-400	ALBENDAZOLE	400MG	RAVIAN LIFE SCIENCE PVT LTD PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0X1.0 TABLET BLISTER	28/05/2019
3248	NDA/MAL/HDP/6 887	RAVIAN LIFE SCIENCE PVT. LTD	ROYAL PHARMA 2011 LIMITED	WELBEEN-L	LEVOCETIRIZINE DIHYDROCHLORID E	5MG	RAVIAN LIFE SCIENCE PVT LTD PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1X10X10 TABLET BLISTER	29/05/2019

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3249	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
3250	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
3251	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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3252	NDA/MAL/HDP/6905	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICALS LIMITED	NUROFEN	IBUPROFEN	400MG	ASTRA ZENECA 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
3253	NDA/MAL/HDP/6907	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICALS LIMITED	NUROFEN EXPRESS	IBUPROFEN	400MG	ASTRA ZENECA 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
3254	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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3255	NDA/MAL/HDP/6 919	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	MACSUNATE AQ JUNIOR	ARTESUNATE + AMODIAQUINE	50MG + 135MG	MACLEODS PHARMACEUTICALS LTD.PLOT NO. 25-27 SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN (UT) - 396210, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0 TABLET BLISTER,1.0X25.0X3 .0 TABLET BLISTER	27/03/2019
3256	NDA/MAL/HDP/6 921	B & O PHARM ZAC	TRIDEM PHARMA UGANDA LIMITED	DUFENAC	DICLOFENAC SODIUM	75MG	GUILIN PHARMACEUTICAL CO LTD-NO. 43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	ORAL SOLID ORDINARY ENTERIC-COATED CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/2017
3257	NDA/MAL/HDP/6 922	EXPHAR S.A. ZONING INDUSTRIEL DE NIVELLES SUD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	FLUCAZOL	FLUCONAZOLE	50 MG / 5 ML	GRACURE PHARMACEUTICALS LIMITED E- 1105, RIICO INDUSTRIAL AREA, PHASE-III BHIWADI, PIN- 301019 DIST. ALWAR, RAJASTHAN, INDI	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE	27/11/2018

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3258	NDA/MAL/HDP/6 923	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	MACSUNATE AQ KID	ARTESUNATE + AMODIAQUINE	25MG + 67.5MG	MACLEODS PHARMACEUTICALS LTD ,.PHASE I & II, PLOT NO. 25-27 SURVEY NO. 366, PREMIERE INDUSTRIAL ESTATE, KACHIGAN, DAMAN- 396210	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER,1.0X25.0X3 .0 TABLET BLISTER	27/03/2019
3259	NDA/MAL/HDP/6 924	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	NAC MR	DICLOFENAC POTASSIUM+PAR ACETAMOL+CHLO RZOAZONE	50MG+325MG+25 0MG	CORONA REMEDIES PVT LIMITEDVILLAGE JATOLI, POST OFFICE - OACHGHAT, TEHSIL SOLAN, DIST. SOLAN HIMACHAL PRADESH – 173223. INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	31/01/2018
3260	NDA/MAL/HDP/6 926	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	ERYTHROKANT-ES	ERYTHROMYCIN ETHYL SUCCINATE	125MG/5ML	S KANT HEALTHCARE LTD PLOT NO. 1805, G.I.D.C PHASE III, VAPI 396195, GUJARAT	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	29/05/2019

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3261	NDA/MAL/HDP/6 927	SEGURA PHARMA PRIVATE LTD	ABACUS PHARMA (AFRICA) LIMITED	GOPAYN MR	ACECLOFENAC BP+TIZANIDINE HYDROCHLORIDE USP+PARACETAM OL BP	100MG+2MG+500 MG	SAI MIRRA INNOPHARM PVT LIMITED 288&299, SIDCO ESTATE AMBTTUR, CHENNAI 600098	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	28/05/2019
3262	NDA/MAL/HDP/6 928	SAVA HEALTHCARE LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	MOMENAP NS 0.05	MOMETASONE FUROATE	0.05%W/V	SAVA HEALTHCARE LIMITED.PLOT NO 507B -512, G.I.D.C. ESTATE, WADHWANCITY-363 035 SURENDRANAGAR, GUJARAT, INDIA	INDIA	NASAL SYSTEMIC UNIT DOSE AEROSOLS	1.0X1.0X12.0 ML CANNISTER	28/05/2019
3263	NDA/MAL/HDP/6 929	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	RANCV1000	RANOLAZINE	1000MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/03/2019

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3264	NDA/MAL/HDP/6 930	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICAL S LIMITED	TAPAL 50	TAPENTADOL	50MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	27/03/2019
3265	NDA/MAL/HDP/6 931	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AMORIV	AMBROXOL HYDROCHLORIDE	15MG/5ML	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	27/08/2019
3266	NDA/MAL/HDP/6 932	PSYCHOTROPICS INDIA LTD	ABACUS PHARMA (AFRICA) LIMITED	VALATE-200	SODIUM VALPROATE	200 MG	PSYCHOTROPICS INDIA LTD PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	25/07/2018

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3267	NDA/MAL/HDP/6 933	PSYCHOTROPICS INDIA LTD	ABACUS PHARMA (AFRICA) LIMITED	VALATE 500	SODIUM VALPROATE BP	500MG	PSYCHOTROPICS INDIA LTD PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	25/07/2018
3268	NDA/MAL/HDP/6 936	SAVA HEALTHCARE LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	RANKOF	PARACETAMOL+C AFFEINE, PHENYLEPHRINE + CHLORPHENAMINE MALEATE	500MG+30MG+10 MG+2MG	SAVA HEALTHCARE LIMITED.PLOT NO 507B -512, G.I.D.C. ESTATE, WADHWANCITY-363 035 SURENDRANAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	28/05/2019
3269	NDA/MAL/HDP/6 939	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	TAPAL 100	TAPENTADOL	100MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISION PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	27/03/2019

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3270	NDA/MAL/HDP/6 941	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TOLVAT 30	TOLVAPTAN	30MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	07/11/2018
3271	NDA/MAL/HDP/6 942	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TOLVAT 15	TOLVAPTAN	15MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	07/11/2018
3272	NDA/MAL/HDP/6 946	PHARMACTIV FZCO	JEET PHARMACEUTICAL S LIMITED	FEVERAL	PARACETAMOL	10MG/ML	SURGE LABORATORIES (PVT) LTD.,,10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN.	PAKISTAN	PARENTERAL ORDINARY I V VIALS	1.0X1.0X100.0 ML VIAL	28/05/2019

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3273	NDA/MAL/HDP/6 948	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	D3 MUST 60 K	CHOLECALCIFERO L	60000IU	MANKIND PHARMA LTD-UNIT II VILLAGE KISHANPURA P.O JAMNIWALA TEHSIL PAONTA SAHIB DISTRICT SIRMOUR 173 025 HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	01/07/2017
3274	NDA/MAL/HDP/6 949	PHARMACTIV FZCO	JEET PHARMACEUTICAL S LIMITED	MEGA FER	IRON SUCROSE	100MG/5ML	SURGE LABORATORIES (PVT) LTD.,,10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN.	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X5.0 ML AMPOULE	28/05/2019
3275	NDA/MAL/HDP/6 953	SYNOKEM PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MISOFREE	MISOPROSTOL	200MCG	SYNOKEM PHARMACEUTICALS LIMITEDSYNOKEM PHARMACEUTICALS LIMITED, PLOT NO. 35-36, SECTOR-6A, IIE, (SIDCUL), RANIPUR (BHEL), HARIDWAR, 249403, (UTTARAKHAND) - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	28/05/2019

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3276	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
3277	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
3278	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

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3279	NDA/MAL/HDP/6 962	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROXONE- S	CEFTRIAZONE SODIUM + SULBACTAM SODIUM	1G+0.5G	ZEISS PHARMACEUTICALS PVT LTD - PLOT 72, EPIP, PHASE 1, JHARMAJRI BADDI, 173205, DIST: SOLAN HIMACHAL PRADESH, INDIA INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL	28/05/2019
3280	NDA/MAL/HDP/6 963	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	LANAC	LANSOPRAZOLE	30MG	ZIM LABS LTD.B 21/22, MIDC AREA, KALMESHWAR 441501, DIST- NAGPUR	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	28/05/2019
3281	NDA/MAL/HDP/6 964	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	TOXXET 200	CEFPODOXIME PROXETIL	200MG	ZIM LABORATORIES LTDB-21/22 MIDC, KALMESHWAR 441501	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	29/05/2019

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3282	NDA/MAL/HDP/6 967	EVA PHARMA FOR PHARMACEUTICALS & 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
3283	NDA/MAL/HDP/6 970	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	VOMIKIND ORAL SOLUTION	ONDANSETRON	4MG/5ML	MANKIND PHARMA LTD-UNIT II VILLAGE KISHANPURA P.O JAMNIWALA TEHSIL PAONTA SAHIB DISTRICT SIRMOUR 173 025 HIMACHAL PRADESH	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X50.0 ML BOTTLE	01/07/2017
3284	NDA/MAL/HDP/6 971	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	MONTIRIV-10	MONTELUKAST SODIUM	10 MG	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1X3X10 TABLET BLISTER	28/08/2019

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3285	NDA/MAL/HDP/6 973	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIFED DM SYRUP 120ML	TRIPROLDINE HYDROCHLORIDE + PSEUDOEPHEDRI NE HYDROCHLORIDE + DEXTROMETHOR PHAN	1.25MG + 30MG + 10MG/5ML	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	21/11/2019
3286	NDA/MAL/HDP/6 974	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	VOMIKIND-MD 4	ONDANSETRON	4MG	MANKIND PHARMA LIMITED, UNIT-II. VILLAGE KISHANPURA, P.O JAMNIWALA, PAONTA SAHIB IN H.P.	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017
3287	NDA/MAL/HDP/6 976	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	KETORIV SOAP	KETOCONAZOLE	2.0%W/V	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN “ 248011 (U.K), INDIA	INDIA	TOPICAL EXTERNAL SOLID SOAPS/BARS	1.0X75.0 G SACHET	28/08/2019

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3288	NDA/MAL/HDP/6 977	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CLINDARIV	CLINDAMYCIN PHOSPHATE	1.0%W/W	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN “ 248011 (U.K), INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	28/08/2019
3289	NDA/MAL/HDP/6 978	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	DEXARIV	DEXAMETHASON E SODIUM PHOSPHATE	4 MG/ML	EAST AFRICAN (INDIA) OVERSEASPLOT 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
3290	NDA/MAL/HDP/6 979	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	TERBIRIV	TERBINAFINE HYDROCHLORIDE	1.0%W/W	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	28/08/2019

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3291	NDA/MAL/HDP/6 980	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	KETORIV	KETOCONAZOLE	2.0%W/W	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	NASAL TOPICAL CREAMS	1.0X1.0X15.0 G TUBE	28/08/2019
3292	NDA/MAL/HDP/6 982	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	DEXARIV	DEXAMETHASON E SODIUM PHOSPHATE	0.5 MG	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	27/08/2019
3293	NDA/MAL/HDP/6 983	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	FASICON	FLUCONAZOLE	200 MG	EAST AFRICAN (INDIA) OVERSEASPLOT 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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3294	NDA/MAL/HDP/6 984	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	VIREXIM-400	CEFIXIME TRIHYDRATE	400 MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X5.0 CAPSULE BLISTER,1.0X10.0X1 0.0 CAPSULE BLISTER	27/08/2019
3295	NDA/MAL/HDP/6 985	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	COLDRID SYRUP	CETIRIZINE DIHYDROCHLORID E + PHENYLEPHRINE HCL + PARACETAMOL	2.5MG + 5MG + 125MG	MEDLEY PHARMACEUTICALS, LTD PLOT 18/19 ZORIC CORSE WAY ROAD KACHIGAM DAMAN	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2017
3296	NDA/MAL/HDP/6 986	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	REPRAZ 20 TABLETS	RABEPRAZOLE SODIUM	20MG	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017

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3297	NDA/MAL/HDP/6 989	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIFED EXPECTORANT SYRUP 120ML	TRIPROLIDINE HYDROCHLORIDE + PSEUDOEPHEDRI NE HYDROCHLORIDE + GUAIFENESIN	1.25MG+30MG+10 0MG/5ML	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	21/11/2019
3298	NDA/MAL/HDP/6 990	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ESORIV-40	ESOMEPRAZOLE MAGNESIUM	40MG	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	28/05/2019
3299	NDA/MAL/HDP/6 991	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ESORIV-20	ESOMEPRAZOLE MAGNESIUM	20MG	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	28/05/2019

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3300	NDA/MAL/HDP/6 992	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AZIRIV-200	AZITHROMYCIN	200MG	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X15.0 ML BOTTLE	28/05/2019
3301	NDA/MAL/HDP/6 993	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AZIRIV-500	AZITHROMYCIN (AS DIHYDRATE)	500MG	EAST AFRICAN (INDIA) OVERSEASPLOT 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
3302	NDA/MAL/HDP/6 999	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	NYSTATIN ORAL SUSPENSION	NYSTATIN	100000 UNITS/5ML	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119, N-113 MIDC TARAPUR BOISAR DIST. THANE 401506 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1X30 ML BOTTLE	31/01/2018

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3303	NDA/MAL/HDP/7003	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
3304	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
3305	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 INDUSTIRAL ESTATE, VERNA SALCETTE-GOIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	27/08/2019

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3306	NDA/MAL/HDP/7 006	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	PREDNIMAX	PREDNISOLONE	5MG	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILSHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	27/08/2019
3307	NDA/MAL/HDP/7 007	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EPNONE 50	EPLERENONE	50MG	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/11/2018
3308	NDA/MAL/HDP/7 009	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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3309	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
3310	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
3311	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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3312	NDA/MAL/HDP/7013	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	AZITHRAA 500	AZITHROMYCIN	500MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	29/11/2017
3313	NDA/MAL/HDP/7014	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	ACEAAR 100 TABLET	ACECLOFENAC	100MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	29/11/2017
3314	NDA/MAL/HDP/7015	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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3315	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/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	27/08/2019
3316	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
3317	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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3318	NDA/MAL/HDP/7 021	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICAL S LIMITED	PINNOFEC PLUS	ACECLOFENAC+P ARACETAMOL	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
3319	NDA/MAL/HDP/7 022	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICAL S LIMITED	PINNAFLAM PLUS	DICLOFENAC SODIUM+PARACE TAMOL	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
3320	NDA/MAL/HDP/7 023	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	VERZOL ORAL SUSPENSION	ALBENDAZOLE	200 MG / 5 ML	GRACURE PHARMACEUTICAL LTDE-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X10.0 ML BOTTLE,1.0X20.0X1 0.0 ML BOTTLE	28/03/2018

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3321	NDA/MAL/HDP/7 024	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	MICOZAL	KETOCONAZOLE	2%W/W	GRACURE PHARMACEUTICAL LTDE-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	29/11/2017
3322	NDA/MAL/HDP/7 027	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
3323	NDA/MAL/HDP/7 028	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	DEXAFLOX	OFLOXACIN + DEXAMETHASON E	3MG + 1MG PER ML	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	OPHTHALMIC LIQUIDS	1.0X5.0 ML BOTTLE	02/09/2019

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3324	NDA/MAL/HDP/7 029	ZIM LABORATORIES LTD	REDDYS PHARMA LIMITED	LIPIZAR 20	ATORVASTATIN CALCIUM (TRIHYDRATE)	20MG	ZIM LABORATORIES LTDB-21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X3X10 TABLET BLISTER	28/03/2018
3325	NDA/MAL/HDP/7 037	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	O2	OFLOXACIN + ORNIDAZOLE	50MG + 125MG	MEDLEY PHARMACEUTICALS LTDLANE 03, PHASE 1, SIDCO INDUSTRIAL COMPLEX, BARI BRAHMANA JAMMU 181133	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X30.0 ML BOTTLE	27/08/2019
3326	NDA/MAL/HDP/7 039	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	O2	OFLOXACIN + ORNIDAZOLE	200MG + 500MG	MEDLEY PHARMACEUTICALS LTDLANE 03, PHASE 1, SIDCO INDUSTRIAL COMPLEX, BARI BRAHMANA JAMMU 181133	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	27/08/2019

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3327	NDA/MAL/HDP/7 053	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	KETOVID CREAM	KETOCONAZOLE	2%W/W	HOVID BHD 121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2017
3328	NDA/MAL/HDP/7 057	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	VIREST CREAM 5%	ACICLOVIR	5%W/W	HOVID BHD 121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE	01/07/2017
3329	NDA/MAL/HDP/7 058	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	NEURAN 300 MG CAPSULE	GABAPENTIN	300MG	HOVID BERHAD,LOT 56442, 7 1/2 MILES JALAN IPOH/CHEMOR 31200, CHEMOR PERAK	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1X10X10 CAPSULE BLISTER	28/08/2019

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3330	NDA/MAL/HDP/7 063	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	GRISEOFULVIN 500MG FILM- COATED TABLET	GRISEOFULVIN	500MG	HOVID BHDLOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	31/01/2018
3331	NDA/MAL/HDP/7 064	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLIMICRON 80MG TABLET	GLICLAZIDE	80MG	HOVID BHDLOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2018
3332	NDA/MAL/HDP/7 065	JAMJOOM PHARMACEUTICAL S 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

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3333	NDA/MAL/HDP/7 066	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MABRON SR	TRAMADOL HYDROCHLORIDE	100MG	MEDOCHEMIE (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
3334	NDA/MAL/HDP/7 067	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
3335	NDA/MAL/HDP/7 070	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DIABETMIN 1000 MG FILM-COATED TABLET	METFORMIN HYDROCHLORIDE	1000MG	HOVID BERHAD (CHEMOR SITE)-LOT 56442, 71/2, JALAN IPOH/CHEMOR 31200, PERAK. MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	31/01/2018

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3336	NDA/MAL/HDP/7 075	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
3337	NDA/MAL/HDP/7 080	HETERO DRUGS LTD	AIVEEN (U) LIMITED	Q-TAB-100	QUETIAPINE FUMARATE	100MG	HETERO LABS LIMITED (UNIT V)SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/08/2019
3338	NDA/MAL/HDP/7 083	HETERO DRUGS LTD	AIVEEN (U) LIMITED	ETROBAX 90	ETORICOXIB	90MG	HETERO LABS PRIVATE LIMITED UNIT IISURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) JEEDIMETLA, HYDERABAD-500 055, TELANGANA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1X3X10 TABLET BLISTER	28/08/2019

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3339	NDA/MAL/HDP/7 084	PHARMACTIV FZCO	JEET PHARMACEUTICAL S LIMITED	GABA 300	GABAPENTIN	300MG	NABIQASIM INDUSTRIES (PVT) LTD.17/24, KORANGI INDUSTRIAL AREA, KORANGI,KARACHI - PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	28/08/2019
3340	NDA/MAL/HDP/7 085	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICAL S LIMITED	DYSEN SUSPENSION	SECNIDAZOLE	750MG	NABIQASIM INDUSTRIES (PVT) LTD.17/24, KORANGI INDUSTRIAL AREA, KORANGI,KARACHI - PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X30.0 ML BOTTLE	27/08/2019
3341	NDA/MAL/HDP/7 088	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICAL S LIMITED	PINNOX 200	OFLOXACIN	200MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	30/05/2018

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3342	NDA/MAL/HDP/7089	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	ES-LOPROT	ESOMEPRAZOLE SODIUM	40MG	NABIQASIM INDUSTRIES (PVT) LTD.17/24, KORANGI INDUSTRIAL AREA, KORANGI,KARACHI - PAKISTAN	PAKISTAN	PARENTERAL ORDINARY DRY VIALS	1.0X40.0 MG VIAL (+ 1*10ML AMPOULE OF 0.9% NAACL)	27/08/2019
3343	NDA/MAL/HDP/7091	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	AARLEFLOX 500 TABLETS	LEVOFLOXACIN HEMIHYDRATE	500MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/11/2017
3344	NDA/MAL/HDP/7092	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	PATMAC	PANTOPRAZOLE SODIUM	40MG	NABIQASIM INDUSTRIES (PVT) LTD.17/24, KORANGI INDUSTRIAL AREA, KORANGI,KARACHI - PAKISTAN	PAKISTAN	PARENTERAL ORDINARY DRY VIALS	1.0X40.0 MG VIAL (+ 1*10ML AMPOULE OF 0.9% NAACL)	27/08/2019

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3345	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
3346	NDA/MAL/HDP/7096	GAMA PHARMACEUTICALS (U) LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DEXAPHEN SYRUP	DEXAMETHASON E + 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
3347	NDA/MAL/HDP/7098	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	ACEFORCE SP	ACECLOFENAC+PARACETAMOL+SERRATIOPEPTIDASE	100MG+325MG+15MG	AKUMS DRUGS AND PHARMACEUTICALS LTDPLANT-1 PLOT NO.19, 20&21 SECTOR-6A, 11E, SIDCUL, RAHIPUR DISTT; HARIDWAR, 249403, (UTTRAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER	31/01/2018

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3348	NDA/MAL/HDP/7099	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	MYGESTY	MEDROXYPROGESTERONE ACETATE	150MG/ML	MYLAN LABORATORIES LIMITED-PLOT NO. 20 & 21, PHARMEZ, SARKHEJ - BAVLA, NATIONAL HIGHWAY NO. 8 - A, NEAR VILLAGE - MATODA, TAL - SANAND, DIST., AHMEDABAD - 382213	INDIA	PARENTERAL ORDINARY VIALS	1.0X12.0X1.0 ML VIAL,1.0X25.0X1.0 ML VIAL	27/11/2019
3349	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
3350	NDA/MAL/HDP/7102	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REPRAZINE	CHLORPROMAZINE HYDROCHLORIDE	100MG	RENE INDUSTRIES LIMITEDPLOT 680 KAMULI- KIREKA	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016

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3351	NDA/MAL/HDP/7 103	MACARTHYS LABORATORIES LTD	LABOREX UGANDA LIMITED	CAFFEINE CITRATE 10MG/ ML SOLUTION FOR INJECTION	CAFFEINE CITRATE	10MG/ML	MACARTHYS LABORATORIES LIMITED T/A MARTINDALE PHARMABAMPTON ROAD, ROMFORD, ESSEX RM3 8UG,	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	21/11/2019
3352	NDA/MAL/HDP/7 104	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPISOPT	DOROZOLAMIDE + TIMOLOL	20MG/1ML + 5MG/1ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B EGYPT	EGYPT	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	30/05/2018
3353	NDA/MAL/HDP/7 105	CACHET PHARMACEUTICAL S PVT LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TRAMACETAL TABLETS	ACETAMINOPHEN +TRAMADOL HYDROCHLORIDE	325MG+37.5MG	CACHET PHARMACEUTICALS PVT LTDVILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	29/01/2019

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3354	NDA/MAL/HDP/7 106	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REVIVE	GLUCOSE ANHYDROUS + TRISODIUM CITRATE DIHYDRATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE	13.5G + 2.9G + 2.6G + 1.5G	RENE INDUSTRIES LIMITED PLOT 680 KAMULI- KIREKA	UGANDA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X1.0 SACHET CARTON	01/07/2016
3355	NDA/MAL/HDP/7 107	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	FEBUMAC 40	FEBUXOSTAT	40 MG	MACLEODS PHARMACEUTICALS LIMITED BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH – 174101 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER, 1.0X3.0X10 .0 TABLET BLISTER, 1.0X10.0X1 0.0 TABLET BLISTER	27/03/2019
3356	NDA/MAL/HDP/7 109	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	BRUTAFLAM-60	ETORICOXIB	60MG	MANKIND PHARMA LTD, UNIT II ,VILLAGE KISHANPURA, PAONTA SAHIB, DIST. SIRMOUR, HP	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019

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3357	NDA/MAL/HDP/7 110	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIFED EXTRA SYRUP 120ML	TRIPROLIDINE HYDROCHLORIDE + PSEUDOEPHEDRI NE HYDROCHLORIDE + DEXTROMETHOR PHAN + GUAIFENESIN	1.25MG + 10MG + 7.5MG + 50MG/5ML	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	21/11/2019
3358	NDA/MAL/HDP/7 112	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
3359	NDA/MAL/HDP/7 115	INTAS, PHARMACEUTICAL S LTD	STAR BIOTECH UGANDA LTD	SARTEL 40H	TELMISARTAN +HYDROCHLOROT HIAZIDE	(40+12.5)MG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI- 248197,DEHRADUN UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	07/11/2018

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3360	NDA/MAL/HDP/7 116	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIFED SYRUP 120ML	TRIPROLIDINE HYDROCHLORIDE + PSEUDOEPHEDRI NE HYDROCHLORIDE	1.25MG + 30MG/5ML	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	21/11/2019
3361	NDA/MAL/HDP/7 117	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIFED TABLETS	TRIPROLIDINE HYDROCHLORIDE + PSEUDOEPHEDRI NE HYDROCHLORIDE	2.5MG+60MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	21/11/2019
3362	NDA/MAL/HDP/7 118	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	BRUTAFLAM-90	ETORICOXIB	90MG	MANKIND PHARMA LTD, UNIT II ,VILLAGE KISHANPURA, PAONTA SAHIB, DIST. SIRMOUR, HP	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019

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3363	NDA/MAL/HDP/7 119	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	OLMAT-40 H	OLMESARTAN MEDOXOMIL + HYDROCHLOROT HIAZIDE	40MG + 12.5MG	MICRO LABS LIMITED .92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
3364	NDA/MAL/HDP/7 120	BESINS HEALTHCARE BENELUX SA	SURGIPHARM (U) LIMITED	ANDROGEL	TESTOSTERONE	16.2MG/G	BESINS MANUFACTURING BELGIUM (BMB)GROOT BIJGAARDENSTRAAT, 128. 1620	BELGIUM	TOPICAL EXTERNAL EMULSION GELS	1.0X88.0 G CANNISTER	21/11/2019
3365	NDA/MAL/HDP/7 122	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	ATERISE-50	ATENOLOL	50MG	SUNRISE INTERNATIONAL LABS LTD PLOT NO. 100, LANE-5, SECTOR-II, PHASE-II, IDA, CHERLAPALLY INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/08/2019

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3366	NDA/MAL/HDP/7 123	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	MARTINEZ 10	MONTELUKAST SODIUM	10MG	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	1.0X1.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	28/03/2018
3367	NDA/MAL/HDP/7 124	PHARCO PHARMACEUTICAL S	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VITAMIN E 400 MG.	VITAMIN E	400 MG	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT, P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X12.0 CAPSULE BLISTER	01/07/2017
3368	NDA/MAL/HDP/7 125	SYNOKEM PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	I-FREE 72	LEVONORGESTRE L	1.5MG	SYNOKEM PHARMACEUTICALS LTD-PLOT NO. - 35- 36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X1.0 TABLET BLISTER	29/01/2019

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3369	NDA/MAL/HDP/7 127	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	CASPOGIN 50	CASPOFUNGIN ACETATE	50MG	CIPLA LTD UNIT 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
3370	NDA/MAL/HDP/7 128	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	COTRIKANT-960	TRIMETHOPRIM+ SULFAMETHOXAZ OLE	800MG+160MG	S KANT HEALTHCARE LTD PLOT NO. 1802- 1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	26/09/2018
3371	NDA/MAL/HDP/7 131	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPOTCLAV OS	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	125MG + 31.25MG/5ML	SPARSH BIO-TECH PVT. LTD.-PLOT NO. 1, SURVEY NO. 242/243/244, VILLAGE LAKHABAVAD POST KHODIYAR COLONY DISTRICT, JAMNAGAR – 361006 GUJARAT INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	26/09/2018

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3372	NDA/MAL/HDP/7132	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	CASPOGIN 70	CASPOFUNGIN ACETATE	70MG	CIPLA LTD UNIT 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
3373	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 HYDROCHLORIDE +	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
3374	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

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3375	NDA/MAL/HDP/7 136	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	AMIKACIN 100 MG / 2ML	AMIKACIN SULPHATE	100MG/2ML	EGYPTIAN INT.PHARMACEUTIC AL INDUSTRIES CO. E.I.P.C.O --10TH OF RAMADAN CITY – INDUSTRIAL AREA B1 P.O BOX: 149 TENTH EGYPT	EGYPT	PARENTERAL ORDINARY VIALS	1.0X1.0X2.0 ML VIAL	25/07/2018
3376	NDA/MAL/HDP/7 145	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LEVOTOP 0.5%	LEVOFLOXACIN	0.5%W/V	CIRON DRUGS AND PHARMACEUTICALS PVT LTD .N-118, 118/1, 119, 119/1, 119/2, 113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, MAHARASHTRA STATE	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	28/03/2019
3377	NDA/MAL/HDP/7 147	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BIMAT	BIMATOPROST	0.03% W/V	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X3.0 ML VIAL	30/05/2018

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3378	NDA/MAL/HDP/7 148	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	OMEPSUN	OMEPRAZOLE	20 MG	SUNRISE INTERNATIONAL LABS LTD.PLOT NO. 100, LANE 5, SECTOR II, PHASE II IDA CHERLAPALLY, HYDERABAD-500 051	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X10.0X1 0.0 TABLET STRIP	25/07/2018
3379	NDA/MAL/HDP/7 149	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	OLOPAT OD	OLOPATADINE HYDROCHLORIDE	0.2% W/V	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	OPHTHALMIC DROPS	1.0X1.0X3.0 ML VIAL	30/05/2018
3380	NDA/MAL/HDP/7 150	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

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3381	NDA/MAL/HDP/7 151	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	APDROPS DX	MOXIFLOXACIN HYDROCHLORIDE + DEXAMETHASON E SODIUM PHOSPHATE	5MG+1MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML VIAL	30/05/2018
3382	NDA/MAL/HDP/7 152	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	MINOXIN PLUS	MINOXIDIL	50MG/ML	BROOKES PHARMA (PRIVATE) LIMITED58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	TOPICAL EXTERNAL LIQUIDS	1.0X1.0X6.0 ML BOTTLE WITH A DERMA ROLLER ADMINISTRATION DEVICE	29/01/2019
3383	NDA/MAL/HDP/7 154	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CIPROFLOXACIN HYDROCHLORIDE	CIPROFLOXACIN HYDROCHLORIDE	2MG/ML	ABARIS HEALTHCARE PVT LTD - SURVEY NO. 1407-11, VILLAGE RAJPUR, TALUKA KADI DIST. MEHSANA, GUJARAT- 382740	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	29/11/2017

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3384	NDA/MAL/HDP/7 162	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	TEXAVIR	TENOFOVIR DISOPROXIL FUMARATE	300MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED PLOT 1-7, LUZIRA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2017
3385	NDA/MAL/HDP/7 163	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	STODIL	LOPERAMIDE HYDROCHLORIDE	2MG	TRIVENI FORMULATIONS LTD PLOT NO. 52,53,54,63,62,64 ALEAP INDUSTRIAL ESTATE SARAMPALLI VIJAYWADA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	27/08/2019
3386	NDA/MAL/HDP/7 167	SPARSH BIO-TECH PVT.LTD.	ABACUS PHARMA (AFRICA) LIMITED	SPOTCLAV DS	AMOXICILLIN TRIHYDRATE + CLAVULANATE	200MG + 28.5MG PER 5ML	SPARSH BIO-TECH PRIVATE LIMITED, PLOT NO.1, SURVEY NO. 242/243/244, VILLAGE LAKHABVAD, JAMNAGAR 361006	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	27/08/2019

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3387	NDA/MAL/HDP/7 172	WOCKHARD LTD	ROYAL PHARMA 2011 LIMITED	MERIMIX	MEROPENEM TRIHYDRATE + SULBACTAM SODIUM	1G + 0.5G	ZEISS PHARMACEUTICALS PVT LTD - PLOT 72, EPIP, PHASE 1, JHARMAJRI BADDI, 173205, DIST: SOLAN HIMACHAL PRADESH, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1X1 VIAL CARTON	29/08/2019
3388	NDA/MAL/HDP/7 175	PSYCHOTROPICS INDIA LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	TELPRESS-AM 40/5	TELMISARTAN + AMLODIPINE BESYLATE	40MG + 5MG	PSYCHOTROPICS INDIA LTD PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	25/07/2018
3389	NDA/MAL/HDP/7 179	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	AVONZA	TENOFOVIR DISOPROXIL FUMARATE+LAMI VUDINE+EFAVIRE NZ	300MG+300MG+4 00MG	MYLAN LABORATORIES LIMITEDD ,PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE-II, SECTOR-III, PITHAMPUR-454775 DIST. DHAR, MADHYA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER,1.0X90. 0 TABLET CONTAINER	07/11/2018

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3390	NDA/MAL/HDP/7 180	SQUARE PHARMACEUTICAL S LTD	GAMA PHARMACEUTICAL S (U) LIMITED	IVENTI	MOXIFLOXACIN HYDROCHLORIDE	0.5%W/V	SQUARE PHARMACEUTICALS LIMITED - DHAKA UNITKALIAKOIR GAZIPUR	BANGLADESH	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	29/08/2019
3391	NDA/MAL/HDP/7 181	PHARMACTIV FZCO	JEET PHARMACEUTICAL S LIMITED	SURGIBION	VITAMIN B1 + VITAMIN B6 + VITAMIN B12	100MG, + 100MG + 1000MCG	SURGE LABORATORIES (PVT) LTD.,,10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN.	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X5.0X5.0X3.0 ML AMPOULE	27/08/2019
3392	NDA/MAL/HDP/7 182	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	SUNFLAM	MELOXICAM	7.5G	SUNRISE INTERNATIONAL LABS LTD PLOT NO. 100, LANE-5, SECTOR-II, PHASE-II, IDA, CHERLAPALLY INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/08/2019

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3393	NDA/MAL/HDP/7 183	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	LEVOSUN-500	LEVOFLOXACIN HEMIHYDRATE	500MG	SUNRISE INTERNATIONAL LABS LTD PLOT NO. 100, LANE-5, SECTOR-II, PHASE-II, IDA, CHERLAPALLY INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X10.0 TABLET BLISTER	27/08/2019
3394	NDA/MAL/HDP/7 187	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	ZITHROSUN-500	AZITHROMYCIN DEHYDRATE	500MG	SUNRISE INTERNATIONAL LABS LTD PLOT NO. 100, LANE-5, SECTOR-II, PHASE-II, IDA, CHERLAPALLY INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X3X10 TABLET BLISTER	29/08/2019
3395	NDA/MAL/HDP/7 191	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROSOL	HYPROMELLOSE	0.7%W/V	AUROLAB .NO. 1, SIVAGANGAI MAIN ROAD, VEERAPANJANI, MADURAI 1 - 625 020	INDIA	OPHTHALMIC LIQUIDS	1.0X1.0X10.0 ML VIAL	29/01/2019

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3396	NDA/MAL/HDP/7 192	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TINAZOL	TINIDAZOLE	500 MG	GRACURE PHARMACEUTICAL LTDE-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	28/05/2019
3397	NDA/MAL/HDP/7 193	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (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
3398	NDA/MAL/HDP/7 194	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENSCRUB SOLUTION	LINEZOLID ,CHLORHEXIDINE GLUCONATE	200 MG/100 ML ,4%W/V	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X500.0 ML BOTTLE	29/01/2019

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3399	NDA/MAL/HDP/7 197	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
3400	NDA/MAL/HDP/7 198	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICAL S LTD)	PLANET PHARMACEUTICAL S UGANDA LTD	SILBECOR	SILVER SULFADIAZINE	1%W/W	UNIQUE PHARMACEUTICAL LABS LIMITED. .215- 216, 216-219, 304- 308, GIDC PANOLI 394116-GUJARAT	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X50.0 G TUBE	29/08/2019
3401	NDA/MAL/HDP/7 201	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,1.0X50.0X 1.0 DOSE VIAL + 1ML DILUENT	27/08/2019

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3402	NDA/MAL/HDP/7 206	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	LOS ANGIO	LOSARTAN POTASSIUM	50MG	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA PSA CHEMICALS & PHARMACEUTICALS PRIVATE LIMITED - 3, SEZ-II, PITHAMPUR, DISTT. DHAR, MADHYA PRADESH - 454 774, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER	29/08/2019
3403	NDA/MAL/HDP/7 207	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	TOXXET 50	CEFPODOXIME PROXETIL	50MG	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X30.0 ML BOTTLE	29/08/2019
3404	NDA/MAL/HDP/7 211	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	PYODINE GEL	POVIDONE- IODINE	5GM/100GM	BROOKES PHARMA (PRIVATE) LIMITED58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	TOPICAL EXTERNAL GELS AND SOLS	1.0X1.0X20.0 G TUBE	27/03/2019

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3405	NDA/MAL/HDP/7 215	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
3406	NDA/MAL/HDP/7 216	SHIN POONG PHARMACEUTICAL S CO.LTD	AAFIYA (A) LIMITED	PYRAMAX	PYRONARIDINE TETRAPHOSPHAT E + ARTESUNATE	60MG + 20MG	SHIN POONG PHARM. CO., LTD70, SANDAN-RO, 19 BEON-GIL, DANWON- GU, ANSAN-SI, GYEONGGI-DO, REPUBLIC OF KOREA	SOUTH KOREA	ORAL LIQUID ORDINARY OTHER POWDERS/GRANU LES	1.0X90.0 SACHET CARTON	27/08/2019
3407	NDA/MAL/HDP/7 217	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICAL S LIMITED	AARPANTO 40	PANTOPRAZOLE	40MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	25/07/2018

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3408	NDA/MAL/HDP/7 218	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICAL S LIMITED	AARTMIN 500	METFORMIN	500MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/11/2017
3409	NDA/MAL/HDP/7 219	THEON PHARMACEUTICAL S LTD	AIVEEN (U) LIMITED	THEOXONE -1 G	CEFTRIAZONE	1G	THEON PHARMACEUTICALS LTD.VILLAGE SAINI MAJRA, TEHSIL NALAGARH DIST, SOLAN- 174101,	INDIA	PARENTERAL ORDINARY DRY VIALS	1X1 G VIAL	29/11/2017
3410	NDA/MAL/HDP/7 220	RAINBOW LIFE SCIENCES PVT.LTD.	EUROPA HEALTHCARE (U) LTD	NAPRIN	NAPROXEN	500MG	GLOBELA PHARMA PVT.LTD.357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/08/2019

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3411	NDA/MAL/HDP/7 222	I-CARE PHARMA LTD	AIVEEN (U) LIMITED	SAMSUNATE	ARTESUNATE	60MG	SAMRUDH PHARMACEUTICALS PVT LTDJ-174, J-168 & J-168/1, MIDC, TARAPUL, BOISAR, DIST THANE-401506	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL OF ARTESUNATE +(1*1ML AMPOULE OF SODIUM BICARBONATE BP 5%W/V)+(1*5ML SODIUM CHLORIDE BP 0.9%W/V)	21/11/2019
3412	NDA/MAL/HDP/7 223	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	DOLUTEGRAVIR	DOLUTEGRAVIR	50MG	LAURUS LABS LTD (UNIT 2)PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE	21/11/2019
3413	NDA/MAL/HDP/7 225	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	LUMITER 80/480	ARTEMETHER + LUMEFANTRINE	80MG + 480MG	OXALIS LABVILLAGE THEDA, P.O. LODHIMAJRA, TEHSIL BADDI, DIST. SOLAN (HP) PIN CODE 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X6.0 TABLET BLISTER	21/11/2019

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3414	NDA/MAL/HDP/7 226	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	ELICA-M	MOMETASONE FUROATE + MICONAZOLE NITRATE	0.1%W/W + 2%W/W	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	27/11/2019
3415	NDA/MAL/HDP/7 229	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICAL S LIMITED	AARCIFLOX 500	CIPROFLOXACIN	500MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/11/2017
3416	NDA/MAL/HDP/7 234	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	LEVOFLOXACIN INTRAVENOUS INFUSION	LEVOFLOXACIN HEMIHYDRATE + GLUCOSE ANHYDROUS	500MG + 5W/V%	ABARIS HEALTHCARE PVT. LTDSURVEY NO. 1407/11, VILLAGE RAJPUR, TAL KADI DIST. MEHSANA, GUJARAT-382740	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	27/08/2019

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3417	NDA/MAL/HDP/7 235	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	OPTIDEX-T	DEXAMETHASON E + TOBRAMYCIN	0.1W/V + 0.3%W/V	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML BOTTLE	27/11/2019
3418	NDA/MAL/HDP/7 237	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	CONTUS PAEDIATRIC	CHLORPHENAMIN E MALEATE + PHENYLEPHRINE HYDROCHLORIDE	1MG + 2.5MG	STEDMAN PHARMACEUTICALS PVT. LTD.C-4, SIDCO PHARMACEUTICALS COMPLEX, ALATHUR, THIRUPORUR- 603 110, TAMIL NADU INDIA	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X15.0 ML BOTTLE	21/11/2019
3419	NDA/MAL/HDP/7 238	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (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

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3420	NDA/MAL/HDP/7 239	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICAL S 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
3421	NDA/MAL/HDP/7 240	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED	GITTOES PHARMACEUTICAL S LIMITED	GAVISCON DOUBLE ACTION	SODIUM AGINATE + SODIUM BICARBONATE + CALCIUM CARBONATE	250MG + 106.5MG + 187.5MG	RECKITT BENCKISER HEALTHCARE - DAMSON LANE,HULL, HUB HU8 7DS	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X4.0X8.0 TABLET BLISTER	28/05/2019
3422	NDA/MAL/HDP/7 241	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	GENTASOL	GENTAMICIN SULFATE	0.3%W/V	AHLCON PARENTERAL (I) LTD.- SP-918,BHLWADI (RAJ) INDIA M.LIC.: RAJ 2002	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	29/11/2017

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3423	NDA/MAL/HDP/7 242	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	AMINORICH	MULTIVITAMINS, MINERALS	NA	STEDMAN PHARMACEUTICALS PVT. LTD.C-4, SIDCO PHARMACEUTICALS COMPLEX, ALATHUR, THIRUPORUR- 603 110, TAMIL NADU INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X15.0 CAPSULE BLISTER,1.0X1.0X2. 0 CAPSULE BLISTER	21/11/2019
3424	NDA/MAL/HDP/7 245	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	CEFAKIND-500	CEFUROXIME AXETIL	500MG	COPMED PHARMACEUTICALS PVT LTDUNIT-II, PLOT NO. 50, GONDPUR INDUSTRIAL AREA, TEHSIL-PAONTA SAHIB, DISTT. SIRMOUR,HIMACHAL PRADESH-173025, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	29/01/2019
3425	NDA/MAL/HDP/7 246	EVA PHARMA FOR PHARMACEUTICAL S & MEDICAL APPLIANCES	GAMA PHARMACEUTICAL S (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

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3426	NDA/MAL/HDP/7 247	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	VITAFIL-Z	MULTIVITAMINS, MINERALS	NA	STEDMAN PHARMACEUTICALS PVT. LTD.C-4, SIDCO PHARMACEUTICALS COMPLEX, ALATHUR, THIRUPORUR- 603 110, TAMIL NADU INDIA	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X15.0 ML BOTTLE,1.0X30.0 ML BOTTLE	21/11/2019
3427	NDA/MAL/HDP/7 248	EVA PHARMA FOR PHARMACEUTICAL S & MEDICAL APPLIANCES	GAMA PHARMACEUTICAL S (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
3428	NDA/MAL/HDP/7 249	EVA PHARMA FOR PHARMACEUTICAL S & MEDICAL APPLIANCES	GAMA PHARMACEUTICAL S (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

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3429	NDA/MAL/HDP/7 250	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	DOLUTEGRAVIR SODIUM, LAMIVUDINE AND TENOFVIR DISOPROXIL FUMARATE	DOLUTEGRAVIR SODIUM +LAMIVUDINE +TENOFVIR DISOPROXIL FUMARATE	50MG + 300MG + 300MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED (CIPLAQCIL)PLOT 1- 7, 1ST RING ROAD, LUZIRA INDUSTRIAL PARK	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE	21/11/2019
3430	NDA/MAL/HDP/7 251	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	HYDROXYUREA	HYDROXYCARBA MIDE	500MG	HAUPT PHARMA AMAREG GMBHDONAUSTAUF ER STRASSE 378, 93055 REGENSBURG	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	21/11/2019
3431	NDA/MAL/HDP/7 253	MANKIND PHARM LTD	TATA UGANDA LIMITED	MONTICOPE	MONTELUKAST SODIUM + LEVOCETIRIZINE DIHYDROCHLORID E	10MG + 5MG	MANKIND PHARMA LTD, UNIT II ,VILLAGE KISHANPURA, PAONTA SAHIB, DIST. SIRMOUR, HP	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019

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3432	NDA/MAL/HDP/7 257	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICAL S LIMITED	PAARPIN TABLET	PARACETAMOL	650 MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017
3433	NDA/MAL/HDP/7 258	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	DESCOVY 200MG/10MG	EMTRICITABINE + TENOFIVIR ALAFENAMIDE	200MG/10MG	PATHEON INC.-- TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9	CANADA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	31/01/2018
3434	NDA/MAL/HDP/7 259	FERRER INTERNATIONAL, S.A.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	ENEAS 10/20	ENALAPRIL + NITRENDIPINE	10MG + 20MG	FERRER INTERNATIONAL S.A ..JOAN BUSCALLA, 1 - 9, 08173 SANT CUGAT DEL VALLES, BARCELONA	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019

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3435	NDA/MAL/HDP/7 260	MICRO LABS LTD	LABOREX UGANDA LIMITED	ESOFAG-40	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40MG	MICRO LABS LIMITED .92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
3436	NDA/MAL/HDP/7 264	PHARCO PHARMACEUTICAL S	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MIOPAN PLUS SUSPENSION	MAGALDRATE+SI METHICONE	540MG + 40MG/5ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT, P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2017
3437	NDA/MAL/HDP/7 267	MICRO LABS LTD	LABOREX UGANDA LIMITED	ESOFAG-20	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	20MG	MICRO LABS LIMITED .92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019

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3438	NDA/MAL/HDP/7 269	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	FEBRILEX SYRUP	PARACETAMOL+D EXTROMETORPH AN HYDROBROMIDE+ CHLORPHENAMIN E MALEATE	125MG+5MG+1M G/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
3439	NDA/MAL/HDP/7 271	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (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
3440	NDA/MAL/HDP/7 272	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	MONTIGET	MONTELUKAST SODIUM	10MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	25/11/2021

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3441	NDA/MAL/HDP/7 275	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TILYPTIN 20	TENELIGLIPTIN HYDROBROMIDE HYDRATE	20MG	MICRO LABS LIMITED .,92, SIPCOT, HOSUR 635126	INDIA	TOPICAL EXTERNAL TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
3442	NDA/MAL/HDP/7 284	İLKO İLAÇ SANAYI VE TİCARET A. Ş.	CORE ACCESS LTD	LIVERCOL 10	ROSUVASTATIN CALCIUM	10MG	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
3443	NDA/MAL/HDP/7 286	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TOBRIN OPHTHALMIC OINTMENT	TOBRAMYCIN	3MG/G	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B EGYPT	EGYPT	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE	01/07/2017

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3444	NDA/MAL/HDP/7 287	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPISTIGMIN 0.05%	NEOSTIGMINE METHYLSULPHAT E	0.05%W/V	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B1,EGYPT	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE	01/07/2017
3445	NDA/MAL/HDP/7 288	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICAL S (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
3446	NDA/MAL/HDP/7 292	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	IBUPLUS SUSPENSION	IBUPROFEN+.PAR ACETAMOL	100MG + 125MG / 5ML	LEBEN LABORATORIES PVT LTD .L-14 PHASE III MIDC AKOLA 444 104	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	21/11/2019

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3447	NDA/MAL/HDP/7 293	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
3448	NDA/MAL/HDP/7 295	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	LAMIFEN	TERBINAFINE HYDROCHLORIDE	1%W/W	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	27/11/2019
3449	NDA/MAL/HDP/7 296	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MEDAXONUM 2G	CEFTRIAZONE SODIUM	2G	MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X2.0 G VIAL	29/01/2019

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3450	NDA/MAL/HDP/7 298	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (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
3451	NDA/MAL/HDP/7 301	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
3452	NDA/MAL/HDP/7 302	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	ACRETIN 0.025%	TRETINOIN	0.025%W/W	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	27/11/2019

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3453	NDA/MAL/HDP/7 304	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	GABAZURE	GABAPENTIN	300 MG	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER,1.0X3.0X10 .0 CAPSULE BLISTER	26/09/2018
3454	NDA/MAL/HDP/7 305	HETERO LABS LTD	AIVEEN (U) LIMITED	PACLITERO 30	PACLITAXEL	6 MG/ML	HETERO LABS LIMITED UNIT-VI APIIC FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOB NAGAR (DISTRICT) ANDHRA PRADESH-509301, , INDIA	INDIA	PARENTERAL ORDINARY VIALS	1X1X5 ML VIAL	26/09/2018
3455	NDA/MAL/HDP/7 306	HETERO LABS LTD	AIVEEN (U) LIMITED	PACLITERO 100	PACLITAXEL	100 MG/16.7 ML	HETERO LABS LIMITED UNIT-VI APIIC FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOB NAGAR (DISTRICT) ANDHRA PRADESH-509301, , INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X16.7 ML VIAL	26/09/2018

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3456	NDA/MAL/HDP/7 307	EXPHAR SA.	PHILLIPS PHARMACEUTICAL S (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
3457	NDA/MAL/HDP/7 310	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
3458	NDA/MAL/HDP/7 311	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	FLUCA OPHTHALMIC SUSPENSION	FLUOROMETHOL ON + SODIUM CROMOGLICATE	1%W/V + 2%W/V	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML BOTTLE	27/11/2019

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3459	NDA/MAL/HDP/7 312	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	BETADINE OINTMENT 5%W/W	POVIDONE IODINE	5%W/W	G.S PHAMBUTOR PVT LTD .B-172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE,1.0X125.0 G TUBE,1.0X250.0 G JAR	01/07/2017
3460	NDA/MAL/HDP/7 317	CACHET PHARMACEUTICAL S PVT LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EMITINO TABLETS 8MG	ONDANSETRON	8MG	CACHET PHARMACEUTICAL PVT LTD. VILLAGE- THANA, NEAR BADDI, TEHSIL_NALAGARH, DIST. SOLAN, HIMACHAL PRADESH - 173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	21/11/2019
3461	NDA/MAL/HDP/7 318	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

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3462	NDA/MAL/HDP/7 319	DROGSAN İLAÇLARI SAN. VE TIC. A.Ş.	BUFFALO HEALTH CARE LTD	SIPROSAN 500	CIPROFLOXACIN HYDROCHLORIDE	500MG	DROGSAN İLAÇLARI SAN. VE TIC. A.Ş.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
3463	NDA/MAL/HDP/7 321	GLENMARK PHARMACEUTICAL S LTD	ABACUS PHARMA (AFRICA) LIMITED	ASCORIL-D	DEXTROMETHOR PHAN HYDROBROMIDE + TRIPROLIDINE HYDROCHLORIDE + PSEUDOEPHEDRI NE HYDROCHLORIDE + MENTHOL	10MG + 1.25MG + 30MG + 1.5MG / 5ML	GLENMARK PHARMACEUTICALS LTD .PLOT E-37, 39, D ROAD, MIDC, SATPUR, NASHIK 422007, MAHARASHTRA STATE	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	27/11/2019
3464	NDA/MAL/HDP/7 325	DROGSAN İLAÇLARI SAN. VE TIC. A.Ş.	BUFFALO HEALTH CARE LTD	DALMAN AQ NASAL SPRAY	FLUTICASONE PROPRIONATE	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

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3465	NDA/MAL/HDP/7 329	DAWA LIMITED	SUPER MEDIC LTD	ACEPAR- MR	PARACETAMOL +ACECLOFENAC+ CHLORZOXAZONE	500 MG+100 MG +375 MG	DAWA LTD PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	28/03/2018
3466	NDA/MAL/HDP/7 330	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	FAMY-POP	LEVONORGESTRE L	0.03MG	MYLAN LABORATORIES LIMITEDPLOT 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
3467	NDA/MAL/HDP/7 335	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	BETADINE 5%	POVIDONE IODINE	5%W/V	G.S PHAMBUTOR PVT LTD .B-172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X100.0 ML BOTTLE,1.0X500.0 ML BOTTLE,1.0X50.0 ML BOTTLE	01/07/2017

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3468	NDA/MAL/HDP/7 336	MODI NUNDIPHARMA PVT LTD	SURGIPHARM (U) LIMITED	BETADINE GERMICIDE GARGLE 2% MINT	POVIDONE IODINE	2%W/V	G.S PHAMBUTOR PVT LTDG.S PHAMBUTOR PVT LTD B-172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA	INDIA	ORAL TOPICAL LIQUIDS	1.0X50.0 ML BOTTLE,1.0X100.0 ML BOTTLE	31/01/2018
3469	NDA/MAL/HDP/7 337	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	PREZISTA 150	DARUNAVIR	150MG	JANSSEN ORTHO LLC.-STATE ROAD 933 KM 0.1 MARNEY WARD GURABO PUERTO RICO 00778	UNITED STATES	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X240.0 TABLET BOTTLE	01/07/2017
3470	NDA/MAL/HDP/7 338	LEBEN LABORATORIES PVT.LTD	MALIX PHARMA (U) LIMITED	IBUPLUS	IBUPROFEN + PARACETAMOL	400MG + 325MG	LEBEN LABORATORIES PVT. LTD PLOT NO. L-4, PHASE-III, MIDC, AKOLA- 444 104 (MS).	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X15.0X2.0X20.0 TABLET BLISTER	27/08/2019

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3471	NDA/MAL/HDP/7 339	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ADERAN 16	CANDESARTAN CILEXETIL	16 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	30/05/2018
3472	NDA/MAL/HDP/7 340	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	HIFEN -200	IBUPROFEN	200MG	PINNACLE LIFE SCIENCE PVT LTD- KHASRA NO. 1328 - 1330, VILLAGE MANPURA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH - 174101 KESAR PHARMA PVT LTD- PLOT SURVEY NO. 50/2. VILLAGE BILSHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	21/11/2019
3473	NDA/MAL/HDP/7 341	M/S.MAXHEAL PHARMACEUTICAL S(INDIA)	ABACUS PHARMA (AFRICA) LIMITED	ZITHROHEAL 500	AZITHROMYCIN	500MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328 - 1330, VILLAGE MANPURA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH - 174101 MAXHEAL PHARMACEUTICALS INDIA LIMITEDJ-7, MIDC, TERAPUR INDUSTRIAL AREA, BOISAR 401506 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER	28/11/2019

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3474	NDA/MAL/HDP/7 342	CADILA PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICAL S LTD.	ZEALARGY	RUPATADINE FUMERATE	10 MG	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3475	NDA/MAL/HDP/7 345	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	DELTACEF	CEFEPIME	1G	MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	21/11/2019
3476	NDA/MAL/HDP/7 346	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REZN TABLETS	ZINC SULFATE MONOHYDRATE	20MG	RENE INDUSTRIES LIMITEDPLOT 680 KAMULI- KIREKA	UGANDA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/11/2017

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3477	NDA/MAL/HDP/7 350	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	SULCEF	CEFOPERAZONE+ SULBACTUM	1G+1G	MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X1.0 ML VIAL	27/03/2019
3478	NDA/MAL/HDP/7 351	TWENTY FIRST CENTURY PHARMACEUTICAL S PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYFIX CV DS	CEFIXIME+CLAVU LANIC ACID	50MG+31.25MG	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD-ROORKEE DISTT HARIDWAR	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
3479	NDA/MAL/HDP/7 353	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE XR 500MG	METFORMIN HYDROCHLORIDE	500MG	MERCK SANTÉ S.A.S.2 RUE DU PRESOIR VERT 45400 SEMOY FRANCE MERCK KGAA-PHARMA PRODUCTION DARMSTADT FRANKFURTER STRABE 250, D- 64293, DARMSTADT	GERMANY FRANCE	ORAL SOLID RETARD TABLETS	1.0X6.0X15.0 TABLET BLISTER	28/03/2018

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3480	NDA/MAL/HDP/7 355	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN SUSPENSION	ARTEMETHER+LU MEFANTRINE	180MG+1080MG	AJANTA PHARMA LIMITED.B-41516, MIDC INDUSTRIAL AREA, PAITHAN, AURANGABAD-431 148 DIST: AURANGABAD MAHARASHTRA,INDI A	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE	31/01/2018
3481	NDA/MAL/HDP/7 357	CACHET PHARMACEUTICAL S PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	PAMAGIN-C SYRUP	CETIRIZINE HYDROCHLORIDE +DEXTROMETHO RPHAN HYDROBROMIDE+ ACETAMINOPHEN +PHENYLEPHRINE HYDROCHLORIDE +ZINC GLUCONATE+ME NTHOL	2.5MG+7.5MG+12 5MG+5MG+7.5MG +2.5MG/5ML	CACHET PHARMACEUTICALS PVT LTD THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	31/01/2018
3482	NDA/MAL/HDP/7 359	INDCHEMIE HEALTH SPECIALITIES PVT. LTD.	NUMED STORES SMC LIMITED	INDCLAV 625	AMOXICILLIN+CLA VULANATE POTASSIUM	500MG+125MG	INDCHEMIE HEALTH SPECIALITIES PVT LTDVILLAGE THANA TEHSIL BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X2.0X7. 0 TABLET BLISTER	01/07/2017

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3483	NDA/MAL/HDP/7 360	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICAL S LIMITED	GAVISCON DOUBLE ACTION LIQUID	SODIUM ALGINATE + SODIUM BICARBONATE + CALCIUM CARBONATE	500MG + 213MG + 325MG/10ML	RECKITT BENCKISER HEALTHCARE - DAMSON LANE,HULL, HUB HU8 7DS	UNITED KINGDOM	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X150.0 ML BOTTLE,1.0X300.0 ML BOTTLE,1.0X12.0X1 0.0 ML SACHET	21/11/2019
3484	NDA/MAL/HDP/7 361	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	DOLUTEGRAVIR	DOLUTEGRAVIR SODIUM	50MG	MYLAN LABORATORIES LTD PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR - 454775; DIST; DHAR; MADHYA PRADESH;	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X30.0 TABLET BOTTLE	21/11/2019
3485	NDA/MAL/HDP/7 363	INDCHEMIE HEALTH SPECIALITIES PVT. LTD.	NUMED STORES SMC LIMITED	INDCLAV 228	AMOXICILLIN+CLA VULANATE POTASSIUM	200MG+28MG/5M L	INDCHEMIE HEALTH SPECIALITIES PVT. LTD.VILLAGE & P.O – THANA, TEHSIL – BADDI, DIST- SOLAN, HIMACHAL	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017

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3486	NDA/MAL/HDP/7 364	İLKO İLAÇ SANAYI VE TICARET A. Ş.	CORE ACCESS LIMITED	MOKSEFEN 400 MG	MOXIFLOXACIN HYDROCHLORIDE	400MG	İLKO İLAÇ SANAYI VE TICARET A. Ş3. ORGANIZE SANAYI BÖLGESİ KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X7.0 TABLET BLISTER	01/07/2017
3487	NDA/MAL/HDP/7 365	OCHOA LABORATORIES LIMITED -	SUPER MEDIC LTD	DOLOACT MR	PARACETAMOL+ DICLOFENAC POTASSIUM+CHL ORZOAZONE	500 MG+50 MG+250 MG	AUROCHEM PHARMACEUTICALS INDIA PRIVATE LIMITED58, PALGHAR TALUKA INDUSTRIAL CO - OPERATIVE ESTATE LIMITED PALGHAR, DISTRICT - PALGHAR, 401 404	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/01/2019
3488	NDA/MAL/HDP/7 366	TWENTY FIRST CENTURY PHARMACEUTICAL S PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYFIX	CEFIXIME	200MG	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD-ROORKEE DISTT HARIDWAR	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET STRIP	01/07/2017

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3489	NDA/MAL/HDP/7 367	TWENTY FIRST CENTURY PHARMACEUTICAL S PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYFIX 100 DS	CEFIXIME	100MG/5ML	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD-ROORKEE DISTT HARIDWAR	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
3490	NDA/MAL/HDP/7 369	TWENTY FIRST CENTURY PHARMACEUTICAL S PVT.LTD	SWASTIK PHARMACEUTICAL LTD	XOMOX CV DS	AMOXICILLIN TRIHYDRATE+POT ASSIUM CLAVULANATE	200MG+28.5MG/5 ML	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTDUNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
3491	NDA/MAL/HDP/7 370	TWENTY FIRST CENTURY PHARMACEUTICAL S PVT.LTD	SWASTIK PHARMACEUTICAL LTD	XOMOX CV 625	AMOXICILLIN TRIHYDRATE+POT ASSIUM 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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3492	NDA/MAL/HDP/7 375	INTAS PHARMACEUTICAL S 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
3493	NDA/MAL/HDP/7 381	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	BETADINE ANTISEPTIC CREAM 5%	POVIDONE- IODINE	5%W/W	G.S PHAMBUTOR PVT LTD .B-172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE,1.0X20.0 G TUBE	01/07/2017
3494	NDA/MAL/HDP/7 384	YURIA-PHARM LTD	PHARMA VILLE LIMITED	TIVORTIN	ARGININE HYDROCHLORIDE	42MG/ML	YURIA-PHARM LLC MANUFACTURING SITE NO. 1108, KOBZARSKA STREET, CHERKASY, 18030	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	28/03/2018

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3495	NDA/MAL/HDP/7 386	TWENTY FIRST CENTURY PHARMACEUTICAL S PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYLEXIN 125 DS	CEFALEXIN MONOHYDRATE	125MG/5ML	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD-ROORKEE DISTT HARIDWAR	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
3496	NDA/MAL/HDP/7 388	TWENTY FIRST CENTURY PHARMACEUTICAL S PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYFIX CV 200	CEFIXIME+CLAVU LANIC ACID	200MG+125MG	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD-ROORKEE DISTT HARIDWAR	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET STRIP	01/07/2017
3497	NDA/MAL/HDP/7 389	EVA PHARMA FOR PHARMACEUTICAL S & MEDICAL APPLIANCES -	GAMA PHARMACEUTICAL S (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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3498	NDA/MAL/HDP/7 391	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	TAVIN-EM	TENOFOVIR DISOPROXIL FUMARATE + EMTRICITABINE	300MG + 200MG	EMCURE PHARMACEUTICALS LTD .PLOT NO. P-2 IT- BT PARK PHASE II MIDC HINJWADI PUNE 411057	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	27/11/2018
3499	NDA/MAL/HDP/7 407	HETERO LABS LTD	AIVEEN (U) LIMITED	MONAST 5	MONTELUKAST SODIUM	5MG	HETERO LABS LIMITED (UNIT V)SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301 HETERO DRUGS LTD. VILLAGE KALYANPUR, CHAKKAN ROAD, BADDI, TEHSIL	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
3500	NDA/MAL/HDP/7 408	ZIM LABORATORIES LTD	ROYAL PHARMA 2011 LIMITED	ZIFLAM 100	ACECLOFENAC	100MG	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019

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3501	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
3502	NDA/MAL/HDP/7410	MEDOPHARM, INDIA	PLANET PHARMACEUTICALS UGANDA LTD	COTRIMOXAZOLE TABLETS BP 960 MG	TRIMETHOPRIM +SULPHAMETHOXAZOLE	960MG	WATERLAND LABORATORIES 34 B, INDUSTRIAL AREA, MALUR - 563160, KARNATAKA, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X50.0X10.0 TABLET BLISTER, 1.0X100.0X10.0 TABLET BLISTER, 1.0X1000.0 TABLET CONTAINER	26/09/2018
3503	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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3504	NDA/MAL/HDP/7413	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
3505	NDA/MAL/HDP/7414	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
3506	NDA/MAL/HDP/7415	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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3507	NDA/MAL/HDP/7 417	INTAS PHARMACUITICALS LTD	STAR BIOTECH UGANDA LTD	SARTEL-40	TELMISARTAN	40MG	INTAS PHARMACEUTICALS LTD ...,CAMP ROAD, SELAQUI, DEHRADUN- 248197, UTTARKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
3508	NDA/MAL/HDP/7 418	INTAS PHARMACEUTICAL S LTD	AIVEEN (U) LIMITED	FOLISURGE 1200	FOLLITROPIN ALFA	1200 IU/1.92ML	INTAS PHARMACEUTICALS LTD (BIOPHARMA DIVISION)PLOT NO. 423/P/A, SARKHEJ- BAVLA HIGHWAY, MORAIYA, TALUKA SANAND, AHMEDABAD- 382213, GUJARAT	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.92 ML VIAL	28/11/2019
3509	NDA/MAL/HDP/7 419	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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3510	NDA/MAL/HDP/7 421	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICAL S 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
3511	NDA/MAL/HDP/7 424	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	ZINC SULFATE TABLETS USP 20MG	ZINC SULFATE MONOHYDRATE	20MG	MACLEODS PHARMACEUTICALS LTD - VILLAGE THEDA P.O LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH INDIA 174101	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017
3512	NDA/MAL/HDP/7 425	OCHOA LABORATORIES LIMITED -	AIVEEN (U) LIMITED	DOLOACT PLUS	ACECLOFENAC + PARACETAMOL	100MG + 500MG	AUROCHEM PHARMACEUTICALS (I)PLOT NO. 58, PTICE LTD PALGHAR 401404, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X1.0X10 .0 TABLET BLISTER	21/11/2019

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3513	NDA/MAL/HDP/7 426	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MEDOFED	GUAIFENESIN + DEXTROMETHOR PHAN HYDROBROMIDE + PSEUDOEPHEDRI NE HYDROCHLORIDE AND + TRIPROLIDINE HYDROCHLORIDE	100MG + 15MG + 20MG + 1.25MG/5ML	MEDOCHEMIE ACTORY).....1-10 CONSTANTINOUPOL EOS STREET, 3011, LIMASSOL	CYPRUS	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE	21/11/2019
3514	NDA/MAL/HDP/7 431	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	MOVICOL	MACROGOL 3350 (POLYETHYLENE GLYCOL)+SODIUM CHLORIDE+SODIU M BICARBONATE+ POTASSIUM CHLORIDE	13.125G+350.7MG +178.5MG+46.6M G	WIN-MEDICARE PVT. LTDMODIPURAM- 250 110, UTTAR PRADESH,INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X10.0X13.81 G SACHET	26/09/2018
3515	NDA/MAL/HDP/7 432	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

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3516	NDA/MAL/HDP/7 435	SQUARE FORMULATIONS LTD	GAMA PHARMACEUTICAL S (U) LIMITED	ZIMAX	AZITHROMYCIN DIHYDRATE	200MG/5ML	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X30.0 ML BOTTLE	28/11/2019
3517	NDA/MAL/HDP/7 436	SQUARE PHARMACEUTICAL S LTD	GAMA PHARMACEUTICAL S (U) LIMITED	CEFOTIL PLUS 500	CEFUROXIME AXETIL + CLAVULANATE	500MG + 125MG	SQUARE CEPALOSPORINS LTD..KALIAKOIR GAZIPUR	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X6.0 TABLET BLISTER	28/11/2019
3518	NDA/MAL/HDP/7 439	DAWA PHARMACEUTICAL S LIMITED	SUPER MEDIC LTD	LORVIC	LORATADINE	5MG/5ML	DAWA LIMITED16633- 00620, RUARAKA, BABA DOGO ROAD, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	21/11/2019

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3519	NDA/MAL/HDP/7 440	MANKIND	TATA UGANDA LIMITED	TOTACEF-1000	CEFEPIME	1000MG	MANKIND PHARMA LTD.VILLAGE KISHANPURA, POAMTA SAHI DISTRICT SIRMOUR HIMACHAL PRADESH	INDIA	PARENTERAL RETARD DRY VIALS	1.0X1000.0 MG VIAL	28/11/2019
3520	NDA/MAL/HDP/7 441	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	HYORTH XL	SODIUM HYALURONATE	8MG/ML	VIRCHOW BIOTECH PVT LTDSURVEY NO. 172, PART GAGILLAPUR(P) QUTHBULLAPUR(MA NDAL), R.R, DISTRICT, TELANGANA STATE, 500043.INDIA	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X6.0 ML PRE- FILLED SYRINGE	29/11/2017
3521	NDA/MAL/HDP/7 442	DAWA LIMITED-	SUPER MEDIC LTD	NERVILIN NT	PREGABALIN + NORTRIPTYLINE HYDROCHLORIDE	75MG + 10MG	DAWA LIMITED16633- 00620, RUARAKA, BABA DOGO ROAD, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019

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3522	NDA/MAL/HDP/7 447	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	LORADIN 10	LORATADINE	10MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	21/11/2019
3523	NDA/MAL/HDP/7 448	OCHOA LABORATORIES LIMITED -	SUPER MEDIC LTD	SORID OINTMENT	CALCIPOTRIOL MONOHYDRATE + BETAMETHASONE DIPROPIONATE	50MCG +0.5MG	AUROCHEM LABORATORIES (I) PVT LTD8, PALGHAR TALUKA INDUSTRIAL CO - OPERATIVE ESTATE LIMITED PALGHAR, DISTRICT - PALGHAR, 401404	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE	29/11/2017
3524	NDA/MAL/HDP/7 450	OCHOA LABORATORIES	SUPER MEDIC LTD	DOLOACT GEL	KETOPROFEN + CAPSICUM OLEORESIN	2.50%W/W + 0.25%W/W	AUROCHEM LABORATORIES (I) PVT LTD-8 PALGHAR TALUKA INDUSTRIAL CO-OP ESTATE LTD PALGHAR 401 404 DIST THANE	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	29/11/2017

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3525	NDA/MAL/HDP/7 454	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
3526	NDA/MAL/HDP/7 456	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	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	21/11/2019
3527	NDA/MAL/HDP/7 460	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

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3528	NDA/MAL/HDP/7 461	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICAL S 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
3529	NDA/MAL/HDP/7 463	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	ACURON	ATRACURIUM BESYLATE	10MG/ML	BROOKES PHARMA (PRIVATE) LIMITED58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X5.0X5.0 ML AMPOULE	27/08/2019
3530	NDA/MAL/HDP/7 464	INVENTIA HEALTHCARE PVT LTD	EUROPA HEALTHCARE (U) LTD	SEGABIN M 75	PREGABALIN + METHYCOBALAMI N	75MG + 1500MCG	INVENTIA HEALTHCARE PVT LTD F1-F1/1 ADDITIONAL MIDC AMBERNATH (E) DIST. THANE	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019

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3531	NDA/MAL/HDP/7 465	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	P-ALAXIN TS	DIHYDROARTEMI SININ + PIPERAQUINE PHOSPHATE	120MG + 960MG	M/S BLISS GVS PHARMA LIMITED PLOT 10, SURVEY NO. 38/1, DEWAN UDYOG NAGAR, ALIYALI VILLAGE PALGHAR, DIST. THANE - 401404	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X3.0 TABLET BLISTER	21/11/2019
3532	NDA/MAL/HDP/7 467	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	TEZOLE CREAM	KETOCONAZOLE	20 MG	BROOKES PHARMA (PRIVATE) LIMITED58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE	27/08/2019
3533	NDA/MAL/HDP/7 468	AKRITI PHARMACEUTICAL S PVT LTD	PHARMA VILLE LIMITED	GYNO PLUS	METRONIDAZOLE + MICONAZOLE NITRATE	100MG + 100MG	AKRITI PHARMACEUTICALS PVT LTD PLOT NO. D- 10 & 11, MIDC, JEJURI, TAL. PURANDAR, DIST. PUNE (MAHARASHTRA) INDIA	INDIA	VAGINAL TABLETS	1.0X1.0X10.0 TABLET BLISTER	28/11/2019

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3534	NDA/MAL/HDP/7 469	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	ECZEMUS 0.03% OINTMENT	TACROLIMUS MONOHYDRATE	0.03%W/W	BROOKES PHARMA (PRIVATE) LIMITED58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X10.0 G TUBE	25/07/2018
3535	NDA/MAL/HDP/7 470	AKRITI PHARMACEUTICAL S PVT LTD	PHARMA VILLE LIMITED	AKSONE	CEFTRIAZONE SODIUM	1G	AKRITI PHARMACEUTICALS PVT LTD PLOT NO. D- 10 & 11, MIDC, JEJURI, TAL. PURANDAR, DIST. PUNE (MAHARASHTRA) INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	21/11/2019
3536	NDA/MAL/HDP/7 473	INVENTIA HEALTHCARE PVT LTD	EUROPA HEALTHCARE (U) LTD	AFLODOR 16	ACECLOFENAC + THIOPOLCHICOSI DE	200MG + 16MG	INVENTIA HEALTHCARE PVT LTD F1-F1/1 ADDITIONAL MIDC AMBERNATH (E) DIST. THANE	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X6.0X5.0 CAPSULE BLISTER	21/11/2019

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3537	NDA/MAL/HDP/7 474	INVENTIA HEALTHCARE PVT LTD	EUROPA HEALTHCARE (U) LTD	AFLODOR 8	ACECLOFENAC + THIOLCHOLCHICOSI DE	200 MG + 8 MG	INVENTIA HEALTHCARE PVT LTD F1-F1/1 ADDITIONAL MIDC AMBERNATH (E) DIST. THANE	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X6.0X5.0 CAPSULE BLISTER	21/11/2019
3538	NDA/MAL/HDP/7 475	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	UMOCLOX 500	AMPICILLIN TRIHYDRATE+CLO XACILLIN SODIUM	250MG+250MG	UNI MEDICOLABS. 21-22 PHARMACITY SELAQUI DEHRADUN 248197	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2015
3539	NDA/MAL/HDP/7 477	CHEPLAPHARM ARZNEIMITTEL GMBH	LABOREX UGANDA LIMITED	ROHYPNOL	FLUNITRAZEPAM	1 MG	CENEXI S.A.S52, RUE MARCEL ET JACQUES GAUCHER 94120 FONTENAY-SOUS- BOIS- FRANCE	FRANCE	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/03/2019

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3540	NDA/MAL/HDP/7 480	DEVA HOLDING A.S	SHREEJI PHARMACEUTICAL S LIMITED	AMOKLAVIN BID	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	200MG + 28.5MG/5ML	DEVA HOLDING A.SCERKEZKOY ORGANIZE SANAYI BOLGESI, KARAAGAC MAH., ATATURK CAD., NO.: 32 KAPAKLI TEKIRDAG	TURKEY	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X70.0 ML BOTTLE	21/11/2019
3541	NDA/MAL/HDP/7 481	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	INTAGRA 100	SILDENAFIL CIRATE	100MG	INTAS PHARMACEUTICALS LTD .PLOT NOS. 457, 458 & 191/218P SARKHEJ-BAVLA HIGHWAY MATODA SANAND AHMEDABAD GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0 TABLET BLISTER	01/07/2017
3542	NDA/MAL/HDP/7 483	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APISOPT PLUS	DORZOLAMIDE HYDROCHLORIDE + TIMOLOL MALEATE	2%W/V + 0.5%W/V	AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	JORDAN	OPHTHALMIC LIQUIDS	1.0X5.0 ML VIAL	21/11/2019

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3543	NDA/MAL/HDP/7 487	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	BETASALIC	BETAMETHASONE DIPROPIONATE + SALICYLIC ACID	0.05%W/W + 3%W/W	ATCO LABS LTD,B- 18, S.I.T.E, KARACHI	PAKISTAN	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	21/11/2019
3544	NDA/MAL/HDP/7 488	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	FINTAS 5	FINASTERIDE	5MG	INTAS PHARMACEUTICALS LTD .PLOT NOS. 457, 458 & 191/218P SARKHEJ-BAVLA HIGHWAY MATODA SANAND AHMEDABAD GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2017
3545	NDA/MAL/HDP/7 489	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	DOLUTEGRAVIR, LAMIVUDINE AND TENOFIVIR DISOPROXIL FUMARATE	DOLUTEGRAVIR + LAMIVUDINE + TENOFIVIR DISOPROXIL FUMARATE	50MG + 300MG + 300MG	OXALIS LABS LIMITEDVILLAGE 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	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

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3546	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
3547	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
3548	NDA/MAL/HDP/7492	LINCOLN PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	CYPRODINE	CYPROHEPTADINE HYDROCHLORIDE	2MG/5ML	LINCOLN PHARMACEUTICAL LIMITED..LINCOLN PHARMACEUTICALS LIMITED, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	27/08/2019

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3549	NDA/MAL/HDP/7 493	ZIM LABORATORIES LTD	REDDYS PHARMA LIMITED	CEFRAZ 200	CEFIXIME TRIHYDRATE	200 MG	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X1X10 TABLET BLISTER	27/11/2019
3550	NDA/MAL/HDP/7 503	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	DUTABIT 0.5	DUTASTERIDE	0.5 MG	AUROBINDO PHARMA LTD-UNIT VII ,/SY. NO'S 411, 425, 434, 435 & 458, PLOT NO. S1 (PART), SPECIAL ECONOMIC ZONE (PHARMA), APIIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE JEDEHERLA MANDAL, MAHABOOB NAGAR DISTRICT-509302, ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	27/11/2019
3551	NDA/MAL/HDP/7 504	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	IMATINATE 400	IMATINIB MESYLATE	400MG	KHANDELWAL LABORATORIES PVT. LTDB-1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1X1X10 CAPSULE BLISTER	26/09/2018

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3552	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
3553	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
3554	NDA/MAL/HDP/7514	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	ILFLOX 500	LEVOFLOXACIN HEMIHYDRATE	500 MG	ILKO İLAC SANAYİ VE TİCARET A.Ş.ORGANIZE SANAYİ BOLGESİ, BUYUK KAYACIK MAH. KUDDISI CAD.23 SOKAKNO. 1 42050 SELCUKLU, KONYA	TURKEY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X7.0 TABLET BLISTER	21/11/2019

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3555	NDA/MAL/HDP/7 515	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	HEPBEST	PREGABALIN + NORTRIPTYLINE (AS HYDROCHLORIDE)	75MG + 10MG	MYLAN LABORATORIES LTD PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR - 454775; DIST; DHAR; MADHYA PRADESH;	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	21/11/2019
3556	NDA/MAL/HDP/7 516	İLKO İLAÇ SANAYI VE TİCARET A. Ş.	CORE ACCESS LIMITED	İLFLX 750	LEVOFLOXACIN HEMIHYDRATE	750 MG	İLKO İLAC SANAYI VE TİCARET A.Ş.ORGANIZE SANAYI BOLGESI, BUYUK KAYACIK MAH. KUDDISI CAD.23 SOKAKNO. 1 42050 SELCUKLU, KONYA	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X7.0 TABLET BLISTER	21/11/2019
3557	NDA/MAL/HDP/7 517	RESONANT PHARMACEUTICAL S PVT LTD	SHREEJI PHARMACEUTICAL S LIMITED	LEVOCET-M	LEVOCETIRIZINE DIHYDROCHLORID E + MONTELUKAST SODIUM	5MG + 10MG	RESONANT PHARMACEUTICALS PRIVATE LIMITED - PLOT NO – 430-1-A NEAR SAFFRO MELLOW COLOUR FACTORY, VILLAGE, NAVAGAM, DISTRICT KHEDA, GUJARAT - 387540, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019

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3558	NDA/MAL/HDP/7 518	RESONANT PHARMACEUTICAL S	SHREEJI PHARMACEUTICAL S LIMITED	LEVOCET-M SUSPENSION	LEVOCETIRIZINE DIHYDROCHLORID E + MONTELUKAST SODIUM	2.5MG / 5ML + 4MG / 5ML	CENTURION LABORATORIES PVT LTD PLOT NO 2, BIO- TECH PARK, MANJUSAR, TAL- SAVLI VADODARA, GUJARAT INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	21/11/2019
3559	NDA/MAL/HDP/7 519	MACLEODS PHARMACEUTICAL S LTDS LTD	VITACARE LIMITED	LEVOFLOXACIN	LEVOFLOXACIN HEMIHYDRATE	250 MG	MACLEODS PHARMACEUTICALS LTD BLOCK N2, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X5.0 TABLET BLISTER	27/11/2019
3560	NDA/MAL/HDP/7 520	DAWA LIMITED	SUPER MEDIC LTD	LEVOXCIN	LEVOFLOXACIN HEMIHYDRATE	750 MG	DAWA LIMITED 16633-00620, RUARAKA, BABA DOGO ROAD, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	21/11/2019

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3561	NDA/MAL/HDP/7 523	DENK PHARMA GMB H & CO. KG	BENLE CONSULT LIMITED	LEVOFLOX-DENK 5 MG/ML	LEVOFLOXACIN HEMIHYDRATE	5MG/ML	SOLUPHARM PHARMAZEUTISCHE ERZEUGNISSE GMBH- INDUSTRIESTR. 3 34212 MELSUNGEN GERMANY	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML VIAL	01/07/2017
3562	NDA/MAL/HDP/7 524	AMMAN PHARMACEUTICAL S LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LOPROSTAN	LATANOPROST + TIMOLOL MALEATE	0.005% W/V + 0.5%W/V	AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	JORDAN	OPHTHALMIC LIQUIDS	1.0X2.5 ML VIAL	21/11/2019
3563	NDA/MAL/HDP/7 525	DAWA LIMITED	SUPER MEDIC LTD	LORVIC	LORATADINE	10 MG	DAWA LIMITED16633- 00620, RUARAKA, BABA DOGO ROAD, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019

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3564	NDA/MAL/HDP/7 526	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
3565	NDA/MAL/HDP/7 529	FDC LTD	AIVEEN (U) LIMITED	MOSI EYE DROPS	MOXIFLOXACIN HYDROCHLORIDE	5 MG/ML	FDC LIMITED, WALUJ .PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD	INDIA	OPHTHALMIC LIQUIDS	1.0X1.0X5.0 ML VIAL	21/11/2019
3566	NDA/MAL/HDP/7 530	HETERO LABS LTD	AIVEEN (U) LIMITED	DOLUTEGRAVIR TABLETS 50MG	DOLUTEGRAVIR	50MG	HETERO LABS LTD UNIT III22-110 IDA JEEDIMETIA HYDERABAD ANDHRA PRADESH , HETERO LABS LIMITED (UNIT V)SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	07/11/2018

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3567	NDA/MAL/HDP/7 535	ACME FORMULATION PVT. LTD.	MARIE STOPES UGANDA LIMITED	MARIPRIST	MIFEPRISTONE + MISOPROSTOL	200MG + 200MCG	ACME FORMULATION PVT. LTDROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X1.0X4.0 TABLET BLISTER	27/08/2019
3568	NDA/MAL/HDP/7 536	PLANET PHARMACEUTICAL S UGANDA LTD	PLANET PHARMACEUTICAL S UGANDA LTD	SPINESIA-D	BUPIVACAINE HYDROCHLORIDE + DEXTROSE	5MG + 80MG /ML	UNIQUE PHARMACEUTICAL LABORATORIESPLOT NO.4, PHASE IV, GIDC, INDUSTRIAL AREA, PANOLI- 394 116, DIST: BHARUCH, INDIA SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X10.0X4.0 ML AMPOULE,1.0X10.0 X4.0 ML AMPOULE,1.0X1.0X 5.0X5.0X4.0 ML AMPOULE,1.0X5.0X 4.0 ML AMPOULE	01/07/2017
3569	NDA/MAL/HDP/7 539	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICAL S LIMITED	COUGH LINCTUS	CHLORPHENIRAM INE	2MG/5ML	SEV PHARMACEUTICALS LIMITEDPLOT 100 NALUKOLONGO	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X1000.0 ML JERRYCAN,1.0X200. 0 ML BOTTLE	01/07/2011

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3570	NDA/MAL/HDP/7 541	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICAL S LIMITED	CHLORHEXIDINE SCRUB	CHLORHEXIDINE GLUCONATE	4%W/V	SEV PHARMACEUTICALS LIMITEDPLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X1000.0 ML JERRYCAN	01/07/2012
3571	NDA/MAL/HDP/7 544	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICAL S LIMITED	GLYCERIN OF BORAX	GLYCERINE+BORA X	12%W/V	SEV PHARMACEUTICALS LIMITEDPLOT 100 NALUKOLONGO	UGANDA	ORAL LIQUID ORDINARY LIQUIDS	1.0X22.0 ML BOTTLE	01/07/2013
3572	NDA/MAL/HDP/7 546	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICAL S LIMITED	HYDROGEN PEROXIDE	HYDROGEN PEROXIDE	6%W/V	SEV PHARMACEUTICALS LIMITEDPLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X200.0 ML BOTTLE,1.0X1.0 L JERRYCAN	01/07/2012

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3573	NDA/MAL/HDP/7 548	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICAL S LIMITED	IODINE TINCTURE	IODINE + POTASSIUM IODIDE	2.5%W/V+2.5%W/ V	SEV PHARMACEUTICALS LIMITEDPLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X22.0 ML BOTTLE	01/07/2013
3574	NDA/MAL/HDP/7 552	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICAL S LIMITED	MAGNESIUM TRISILICATE MIXTURE	MAGNESIUM TRISILICATE + LIGHT MAGNESIUM CARBONATE + SODIUM BICARBONATE	250MG + 250MG + 250MG/5ML	SEV PHARMACEUTICALS LIMITEDPLOT 100 NALUKOLONGO	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	01/07/2010
3575	NDA/MAL/HDP/7 554	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICAL S LIMITED	POVIDONE IODINE BP	POVIDONE IODINE	10%W/V	SEV PHARMACEUTICALS LIMITEDPLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X200.0 ML BOTTLE,1.0X1000.0 ML JERRYCAN	01/07/2013

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3576	NDA/MAL/HDP/7 556	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICAL S LIMITED	SEVASTAT	CETRIMIDE + CHLORHEXIDINE	3%W/V+0.3%W/V	SEV PHARMACEUTICALS LIMITEDPLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X1.0 L BOTTLE	01/07/2012
3577	NDA/MAL/HDP/7 559	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICAL S LIMITED	SURGICAL SPIRIT	METHYL SALICYLATE	0.5%V/V	SEV PHARMACEUTICALS LIMITEDPLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL SPIRITS	1.0X100.0 ML BOTTLE	01/07/2011
3578	NDA/MAL/HDP/7 560	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICAL S LIMITED	VIOLGENT	CRYSTAL VIOLET	0.5%W/V	SEV PHARMACEUTICALS LIMITEDPLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X25.0 ML BOTTLE	01/07/2014

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3579	NDA/MAL/HDP/7571	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	NEUROVIT FILM-COATED TABLET	THIAMINE MONONITRATE + PYRIDOXINE HCL + CYANOCOBALAMINE	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
3580	NDA/MAL/HDP/7586	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
3581	NDA/MAL/HDP/7587	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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3582	NDA/MAL/HDP/7 588	OCHOA LABORATORIES LIMITED -	SUPER MEDIC LTD	EXEVATE-MF OINTMENT	BETAMETHASONE DIPROPIONATE + SALICYLIC ACID + UREA + LACTIC ACID + SODIUM LACTATE SOLUTION	0.05 % W/W + 3.0 % W/W + 10.0 % W/W + 3.0 % W/W + 2.0 % W/W	AUROCHEM LABORATORIES (I) PVT LTD8, PALGHAR TALUKA INDUSTRIAL CO - OPERATIVE ESTATE LIMITED PALGHAR, DISTRICT - PALGHAR, 401404	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE	29/11/2017
3583	NDA/MAL/HDP/7 589	OCHOA LABORATORIES	SUPER MEDIC LTD	LACX SYRUP	LACTULOSE	10G/15ML	AUROCHEM LABORATORIES (I) PVT LTD-8 PALGHAR TALUKA INDUSTRIAL CO-OP ESTATE LTD PALGHAR 401 404 DIST THANE	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE,1.0X100.0 ML BOTTLE	29/11/2017
3584	NDA/MAL/HDP/7 590	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	MONTIGET	MONTELUKAST SODIUM	5MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	25/11/2021

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3585	NDA/MAL/HDP/7 595	AMMAN PHARMACEUTICAL S LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LOPROST	LATANOPROST	0.005% W/V	AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	JORDAN	OPHTHALMIC VIALS	1.0X2.5 ML VIAL	21/11/2019
3586	NDA/MAL/HDP/7 598	STEDMAN PHARMACEUTICAL S PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	RABEFLUX-DSR	RABEPRAZOLE SODIUM + DOMPERIDONE	20MG + 30MG	STEDMAN PHARMACEUTICALS PVT. LTD.C-4, SIDCO PHARMACEUTICALS COMPLEX, ALATHUR, THIRUPORUR- 603 110, TAMIL NADU INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X3.0X10 .0 CAPSULE BLISTER	21/11/2019
3587	NDA/MAL/HDP/7 605	GUFIC BIOSCIENCES LTD	EUROPA HEALTHCARE (U) LTD	STRIPOLE	PANTOPRAZOLE SODIUM SESQUIHYDRATE	40 MG	GUFIC BIOSCIENCES LIMITED (UNIT 2)SURVEY NO. 171, NATIONAL HIGHWAY NO. 8, NEAR GRID, AT & PO: KABILPORE, NAVSARI - 396424, GUJARAT - INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	27/11/2019

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3588	NDA/MAL/HDP/7 607	FDC LTD	AIVEEN (U) LIMITED	TEARMAX EYE DROPS	CARMELLOSE SODIUM	5MG/ML	FDC LIMITED, WALUJ .PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD	INDIA	OPHTHALMIC LIQUIDS	1.0X1.0X10.0 ML VIAL	21/11/2019
3589	NDA/MAL/HDP/7 610	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	TERBIDERM FORTE	TERBINAFINE HYDROCHLORIDE	250 MG	ATCO LABS LTD,B- 18, S.I.T.E, KARACHI	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	21/11/2019
3590	NDA/MAL/HDP/7 611	FERRING GMBH	MACNAUGHTON LIMITED	PABAL	CARBETOCIN	100MCG/ML	FERRING GMBH.11, WITTLAND	GERMANY	PARENTERAL ORDINARY VIALS	1.0X5.0X1.0 ML VIAL	01/07/2017

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3591	NDA/MAL/HDP/7 614	PLANET PHARMACEUTICAL S UGANDA LTD	PLANET PHARMACEUTICAL S 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
3592	NDA/MAL/HDP/7 615	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
3593	NDA/MAL/HDP/7 622	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	MONTELAIR 5	MONTELUKAST SODIUM	5MG	HOVID BHDLOT 56442,71/2 MILES JALAN IPOH,PERAK,MALAY SIA	MALAYSIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2018

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3594	NDA/MAL/HDP/7 652	MSD (PTY) LTD	SURGIPHARM (U) LIMITED	JANUVIA 100	SITAGLIPTIN	100MG	MSD PTY LTD117 16TH ROAD, HALFWAY HOUSE 1685	SOUTH AFRICA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2017
3595	NDA/MAL/HDP/7 653	MSD (PTY) LTD	SURGIPHARM (U) LIMITED	JANUVIA 50	SITAGLIPTIN	50MG	MSD PTY LTD117 16TH ROAD, HALFWAY HOUSE 1685	SOUTH AFRICA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2017
3596	NDA/MAL/HDP/7 656	A.MENARINI INDUSTRIE FARMACEUTICHE RIUNITE	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	SPASMOMEN	OTILONIUM BROMIDE	40MG	A.MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.LVIA CAMPO DI PILE, L'AQUILA (AQ), ITALY	ITALY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER,1.0X1.0X10 .0 TABLET BLISTER (FREE PHYSICIAN'S SAMPLE, NOT FOR SALE)	01/07/2017

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3597	NDA/MAL/HDP/7 674	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
3598	NDA/MAL/HDP/7 681	ZEE PHARMACEUTICAL S LTD	ZEE PHARMACEUTICAL S LIMITED	ZEECEL 200	CELECOXIB	200MG	THE MADRAS PHARMACEUTICALS. .NO. 137B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI 600096	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2017
3599	NDA/MAL/HDP/7 683	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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3600	NDA/MAL/HDP/7 686	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OPTIGENT EYE/EAR DROPS	GENTAMICIN SULPHATE	0.3W/V	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2017
3601	NDA/MAL/HDP/7 687	ABACUS PHARMA (AFRICA) LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DI - QUIN	DIHYDROARTEMI SININ+PIPERAQUI NE PHOSPHATE	40MG + 320MG	SKANT HEALTH CARE LTD 1802-1805 GIDC PHASE III VAPI GUJARAT	CHINA	ORAL SOLID ORDINARY TABLETS	1X9 TABLET BLISTER,	09/07/2017
3602	NDA/MAL/HDP/7 688	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE 850MG TABLET	METFORMIN HYDROCHLORIDE	850MG	NKUNZI PHARMACEUTICALS 259 DAVIDSON ROAD, WADEVILLEGERMIST ON, 1428 SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X300.0 TABLET CONTAINER,1.0X60. 0 TABLET CONTAINER,1.0X4.0 X15.0 TABLET BLISTER	01/07/2017

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3603	NDA/MAL/HDP/7 695	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	CORTUM 500	CEFUROXIME AXETIL	500MG	MALIK LIFESCENCES PRIVATE LIMITED PLOT NO. 16, NH 58, VARDHMAN INDUTRIAL ESTATE, VILLAGE BAHADARPUR SAINI HARIDWAR, UTTARAKHAND- 247667	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017
3604	NDA/MAL/HDP/7 706	CACHET PHARMACEUTICAL S PVT LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CACEF 200	CEFPODOXIME PROXETIL	200MG	INNOVA CAPTAB PVT. LTD1281/1, 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	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	01/07/2017
3605	NDA/MAL/HDP/7 714	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROXONE 1GM	CEFTRIAZONE SODIUM	1 G	ZEISS PHARMACEUTICALS PVT LTD - PLOT 72, EPIP, PHASE 1, JHARMAJRI BADDI, 173205, DIST: SOLAN HIMACHAL PRADESH, INDIA M/S SCOTT-EDIL ADVANCE RESEARCH LABORATORIES AND EDUCATION LIMITEDHILL-TOP, INDUSTRIAL AREA, BHATOLI KALAN,	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	07/11/2018

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3606	NDA/MAL/HDP/7 715	JANSSEN-CILAG INTERNATIONAL NV	LABOREX UGANDA LIMITED	SIRTURO	BEDAQUILINE FUMARATE	100MG	RECIPHARM PHARMACEUTICALS PVT LTD34TH KM, TUMKUR ROAD, T- BEGUR, NELAMANGALA TALUK BENGALURU, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X188.0 TABLET BOTTLE	29/11/2017
3607	NDA/MAL/HDP/7 716	CORE ACCESS LIMITED	CORE ACCESS LTD	ALRINAST 2.5 MG / 5 ML SYRUP	DESLOTRATIDINE	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
3608	NDA/MAL/HDP/7 726	NTICALS LTD.	VITACARE LIMITED	LOPINAVIR + RITONAVIR	LOPINAVIR + RITONAVIR	100MG + 25MG	MACLEODS PHARMACEUTICALS LTD(BLOCK N2)VILLAGE THEDA,P.O LODHI MAJRA,TEHSIL BADDI,HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2017

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3609	NDA/MAL/HDP/7 735	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	IBUMOL 400	PARACETAMOL + IBUPROFEN	325MG + 400MG	AJANTA PHARMA LIMITED PAITHANMANUFACT URING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3610	NDA/MAL/HDP/7 745	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	TAZOGARD	PIPERACILLIN +TAZOBACTAM	4G + 0.5G	AKUMS DRUGS & PHARMACEUTICALS LTD.2, 3, 4, & 5, SEC- 6B, I.I.E., SIDCUL, RANIPUR, HARIDWAR-249403 (INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X4.5 G VIAL ,2X10ML LDPE AMPOULES OF WFI	01/07/2017
3611	NDA/MAL/HDP/7 747	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	THERMODOL	PARACETAMOL	1.0%W/V	AKUMS DRUGS & PHARMACEUTICALS LTD.2, 3, 4, & 5, SEC- 6B, I.I.E., SIDCUL, RANIPUR, HARIDWAR-249403 (INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2017

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3612	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 II PLOT NO.22, SECTOR 6-A, IIE, SIDCUL, RANIPUR, DISTRICT: HARIDWAR 249 403, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2017
3613	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
3614	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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3615	NDA/MAL/HDP/7 903	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (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
3616	NDA/MAL/HDP/7 905	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICAL S LIMITED	ACEFYL	ACEFYLINE PIPERAZINE + DIPHENHYDRAMINE HYDROCHLORIDE	45MG +8MG	NABIQASIM INDUSTRIES (PVT) LIMITED17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2016
3617	NDA/MAL/HDP/7 907	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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3618	NDA/MAL/HDP/8 015	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	D-FEN	DICLOFENAC SODIUM	25MG/ML	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X3.0 ML AMPOULE,1.0X10.0 X1.0X10.0X3.0 ML AMPOULE	01/07/2011
3619	NDA/MAL/HDP/8 023	DENK PHARMA GMB H &CO. KG	BENLE CONSULT LIMITED	AMOXICLAV- DENK 500/62.5	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500 MG + 62.5 MG	PENCEF PHARMA GMBHBREITENBACHS TRASSE 13 D-13509 BERLIN	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X8.0 TABLET BLISTER	01/07/2011
3620	NDA/MAL/HDP/8 043	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	RABEZOL	RABEPRAZOLE SODIUM	20MG	BİLİM PHARMACEUTICALS GOSB 41480 GEBZE- KOCAELİ/TURKE	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X14.0 TABLET BLISTER	01/07/2017

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3621	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
3622	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
3623	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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3624	NDA/MAL/HDP/8 091	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEGEL SUSPENSION	ALUMINIUM HYDROXIDE+MAG NESIUM TRISILICATE	120MG+250MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2001
3625	NDA/MAL/HDP/8 092	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	KEMOXYL 250MG	AMOXYCILLIN	250MG	LABORATORY & ALLIED LTD PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER, 1.0X10. 0X10.0 CAPSULE BLISTER	01/07/1997
3626	NDA/MAL/HDP/8 095	DENK PHARMA GMB H & CO. KG	BENLE CONSULT LIMITED	COLOSAR-DENK 100/12.5	LOSARTAN POTASSIUM + HYDROCHLOROT HIAZIDE	100MG + 12.5MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2016

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3627	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, 1.0X100.0 X2.4 VIAL CARTON, 1.0X10.0X2.4 VIAL CARTON	01/07/2011
3628	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
3629	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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3630	NDA/MAL/HDP/8 104	ABACUS PHARMA (AFRICA) LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TELPRESS 40	TELMISARTAN	40MG	PSYCHOTROPICS INDIA LTD PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3631	NDA/MAL/HDP/8 105	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	XERIN	LEVOCETIRIZINE HYDROCHLORIDE + MONTELUKAST SODIUM	5MG + 10MG	AKUMS DRUGS AND PHARMACEUTICALS LTD PLANT-1 PLOT NO.19, 20&21 SECTOR-6A, 11E, SIDCUL, RAHIPUR DISTT; HARIDWAR, 249403, (UTTRAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X1.0X10 .0 TABLET BLISTER	01/07/2017
3632	NDA/MAL/HDP/8 107	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	WELRAB 20	RABEPRAZOLE SODIUM	20MG	AKUMS DRUGS & PHARMACEUTICALS LTD -19,20,21, SECTOR 6A, I.I.E, SIDCUL, RANIPUR, HARIDWAR 249403 DISTRICT: UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017

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3633	NDA/MAL/HDP/8 108	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	ORS	GLUCOSE ANHYDROUS+TRI SODIUM CITRATE+SODIUM CHLORIDE+POTAS SIUM CHLORIDE	6.75G + 1.45G + 1.3G + 0.75G	MEDIPHARM INDUSTRIES LTD PLOT 65, KAKAJJO ROAD, BWEYOGERERE POSTAL ADDRESS : P.O.BOX 5917, KAMPALA.	UGANDA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X10.0X25.0 G SACHET	01/07/2017
3634	NDA/MAL/HDP/8 109	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	IRON FOLATE	FERROUS SULPHATE + FOLIC ACI	200MG + 0.4MG	MEDICAMEN BIOTECH LTDSP- 1192, A & B, PHASE -IV, INDUSTRIAL AREA BHIWADI -301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET JAR	01/07/2017
3635	NDA/MAL/HDP/8 110	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	R.B.TONE SYRUP	MULTI- INGREDIENT	N/A	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X200.0 ML BOTTLE,1.0X1.0X10 0.0 ML BOTTLE	01/07/2017

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3636	NDA/MAL/HDP/8 112	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
3637	NDA/MAL/HDP/8 113	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
3638	NDA/MAL/HDP/8 114	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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3639	NDA/MAL/HDP/8115	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
3640	NDA/MAL/HDP/8118	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	LOPINAVIR + RITONAVIR	LOPINAVIR + RITONAVIR	200MG + 50MG	MACLEODS PHARMACEUTICALS LTD .PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAM DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET BOTTLE	01/07/2013
3641	NDA/MAL/HDP/8119	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICALS LIMITED	HALOPERIDOL DECANOATE	HALOPERIDOL DECANOATE	50MG/ML	SWISS PARENTERALS LTD809 KERALA INDUSTRIAL ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE,1.0X10.0 X1.0 ML AMPOULE	01/07/2017

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3642	NDA/MAL/HDP/8 121	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	SWISSQUINE	QUININE	300MG/ML	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2011
3643	NDA/MAL/HDP/8 125	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO. LTD	GAMA PHARMACEUTICAL S (U) LIMITED	MATADOR	LEVOFLOXACIN	500MG	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO. LTD, NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET, AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X7.0 TABLET BLISTER	01/07/2009
3644	NDA/MAL/HDP/8 127	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE	2% W/V	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X30.0 ML VIAL	01/07/2016

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3645	NDA/MAL/HDP/8 130	DEVA HOLDING A.S	SHREEJI PHARMACEUTICAL S LIMITED	DEGRA 100	SILDENAFIL CITRATE	100MG	DEVA HOLDING A. S.ÇERKEZKÖY ORGANIZE SANAYI BOLGESI. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKİRDAĞ/ TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	30/05/2018
3646	NDA/MAL/HDP/8 131	DEVA HOLDING A.S	SHREEJI PHARMACEUTICAL S LIMITED	DEGRA	SILDENAFIL CITRATE	50MG	DEVA HOLDING A. S.ÇERKEZKÖY ORGANIZE SANAYI BOLGESI. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKİRDAĞ/ TURKEY	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	01/07/2017
3647	NDA/MAL/HDP/8 133	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	MYHEP	SOFOBUVIR	400MG	MYLAN LABORATORIES LIMITEDD ,F-4 & F- 12,MIDC, MALEGAON,SIRRRRA R, NASHIK -422113 MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X28.0 TABLET BOTTLE	01/07/2017

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3648	NDA/MAL/HDP/8 142	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	XARELTO	RIVAROXABAN	2.5MG	BAYER PHARMA AG 51368 LEVERKUSENBAYER PHARMA AG 51368 LEVERKUSEN	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X14.0 TABLET BLISTER,1.0X2.0X14 .0 TABLET BLISTER	01/07/2017
3649	NDA/MAL/HDP/8 143	NAARI LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	LYDIA POSTPIL	LEVONORGESTRE L	1.5MG	NAARI PHARMA PRIVATE LIMITEDPLOT NO. 14- 16, 55-57, SECTOR-5, IIE, PANT NAGAR RUDRAPUR-263153 DIST-U.S. NAGAR UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0 TABLET BLISTER	01/07/2013
3650	NDA/MAL/HDP/8 144	NAARI LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	MA KARE	MIFEPRISTONE + MISOPROSTOL	200MG+ 200MCG	NAARI PHARMA PRIVATE LIMITEDPLOT NO. 14- 16, 55-57, SECTOR-5, IIE, PANT NAGAR RUDRAPUR-263153 DIST-U.S. NAGAR UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0 TABLET BLISTER	01/07/2017

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3651	NDA/MAL/HDP/8 145	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DENK- AIR 10	MONTELUKAST SODIUM	10MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2017
3652	NDA/MAL/HDP/8 146	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DENK- AIR JUNIOR 4	MONTELUKAST SODIUM	4MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2017
3653	NDA/MAL/HDP/8 147	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DENK- AIR JUNIOR 5	MONTELUKAST SODIUM	5 MG	DENK PHARMA GMBH & CO. KG GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2017

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3654	NDA/MAL/HDP/8 148	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	FLUCLOXACILLIN	FLUCLOXACILLIN	500MG	SPARSH BIO-TECH PVT. LTD.-PLOT NO. 1, SURVEY NO. 242/243/244, VILLAGE LAKHABAVAD POST KHODIYAR COLONY DISTRICT, JAMNAGAR – 361006 GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2017
3655	NDA/MAL/HDP/8 150	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	JAKAVI	RUXOLITINIB	20MG	NOVARTIS PHARMA STEIN AGCH. 4002 STEIN, SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER	01/07/2017
3656	NDA/MAL/HDP/8 151	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGO-C	VITAMIN C	100MG	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE 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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3657	NDA/MAL/HDP/8 152	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	JAKAVI	RUXOLITINIB	15MG	NOVARTIS PHARMA STEIN AG.SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER	01/07/2017
3658	NDA/MAL/HDP/8 154	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOGCORT	HYDROCORTISON E ACETATE	1%W/W	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2013
3659	NDA/MAL/HDP/8 155	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	JAKAVI	RUXOLITINIB	5MG	NOVARTIS PHARMA STEIN AG.SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER	01/07/2017

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3660	NDA/MAL/HDP/8 156	TATA UGANDA LIMITED	GITTOES PHARMACEUTICAL S LIMITED	DIPHThERIA + TETANUS + PERTUSSIS + HEPATITIS B + HAEMOPHILUS TYPE B CONJUGATE VACCINE	DIPHThERIA + TETANUS + PERTUSSIS + HEPATITIS B + HAEMOPHILUS TYPE B CONJUGATE VACCINE	25 LF (≥ 30 IU)+5.5 LF (≥ 40 IU)+16 IOU (≥ 4.0 IU)+12.5MCG+11M CG	BIOLOGICAL E LTD PLOT NO.1, S.P BIOTECHNOLOGY PARK, PHASE II KOLThER (V), SHAMEERPET(M), RANGA REDDY(DIST), ANDHRA PRADESH, INDIA 500078	INDIA	PARENTERAL ORDINARY I M VIALS	1.0X48.0X0.5 ML VIAL (1 DOSE VIAL),1.0X24.0X5.0 ML VIAL (10 DOSE VIAL)	01/07/2014
3661	NDA/MAL/HDP/8 157	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICAL S LIMITED	D LYTE- PLAIN	ANHYDROUS GLUCOSE + SODIUM CHLORIDE + TRISODIUM CITRATE + POTASSIUM CHLORIDE	13.50G + 2.60G + 2.90G +1.50G/ 1L	AGOG PHARMA LTD PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X20.5 G SACHET	01/07/2016
3662	NDA/MAL/HDP/8 159	AUROBINDO PHARMA LIMITED	GITTOES PHARMACEUTICAL S LIMITED	LOPINAVIR + RITONAVIR	LOPINAVIR + RITONAVIR	100MG + 25MG	AUROBINDO PHARMA LIMITED, UNIT IIISURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELENGANA (STATE)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2017

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3663	NDA/MAL/HDP/8 160	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	ULGICID (CHERRY FLAVOUR)	ALGINIC ACID+ MAGNESIUM HYDROXIDE+ ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE +SIMETICONE	200MG+250MG+2 50MG+250MG+12 5MG/15ML	STEDMAN PHARMACEUTICALS PVT LTD...C-4, SIDCO PHARMACEUTICAL COMPLEX ALATHUR, THIRUPORUR	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	01/07/2017
3664	NDA/MAL/HDP/8 162	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	HUMOG 75 HP	HIGHLY PURIFIED MENOTROPHIN [CORRESPONDING TO FOLLICLE STIMULATING HORMONE ACTIVITY (FSH) 75 IU + LUTEINISING HORMONE ACTIVITY (LH) 75 IU] /150 I.U	75 IU + 75 IU/ 150 I.U VIAL	BHARAT SERUMS AND VACCINES LTD PLOT NO. K-27 ADDITIONAL MIDC AMBERNATH (E) 412 501	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1*1 ML AMPOULE OF 0.9%W/V NAACL	01/07/2017
3665	NDA/MAL/HDP/8 163	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	BETADINE SURGICAL SCRUB	POVIDONE- IODINE	7.5%W/W	G,S PHARMBUTOR PVT LTD B-172 INDUSTRIAL AREA BEHROR 301701 RAJASTHAN	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X1.0X50.0 ML BOTTLE,1.0X500.0 ML BOTTLE	26/09/2018

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3666	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
3667	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+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
3668	NDA/MAL/HDP/8177	MEGA LIFSCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	CILZEC PLUS	TELMISARTAN + HYDROCHLOROT HIAZIDE	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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3669	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
3670	NDA/MAL/HDP/8185	AFRICURE PHARMACEUTICALS (INDIA) LTD	AFRICURE PHARMACEUTICALS U LIMITED	INDOSIM	INDOMETHACIN	25MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/1997
3671	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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3672	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
3673	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
3674	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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3675	NDA/MAL/HDP/8 199	MEDLEY PHARMACEUTICAL S LTD	EUROPA HEALTHCARE (U) LTD	XYMEX SYRUP	MULTI- INGREDIENT	MULTI- INGREDIENT	MEDLEY PHARMACEUTICALS LTD PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2000
3676	NDA/MAL/HDP/8 200	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	ORS ORANGE	GLUCOSE ANHYDROUS + TRISODIUM CITRATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE	6.75G + 1.45G + 1.3G + 0.75G / SACHET	MEDIPHARM INDUSTRIES(EA) LTD PLOT 65 KAKAJJO ROAD BWEYOGERERE P.O.BOX 6218,KAMPALA,UGA NDA	UGANDA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X10.4 G SACHET	01/07/2017
3677	NDA/MAL/HDP/8 201	CIRON DRUGS AND PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	CENTROZINE	CETIRIZINE HYDROCHLORIDE	5MG/5ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, 119 MIDC TARAPUR BOISAR DIST THANE 4011 506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2017

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3678	NDA/MAL/HDP/8 202	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	ISONIAZID	ISONIAZID	300MG	OXALIS LABS- VILLAGE THEDA,P.O.LODHIM AJRA ,TEHSIL BADDI,DIST .SOLAN (HIMACHAL PRADESH) - 174101 INDIA MACLEODS PHARMACEUTICALS LTD.PLOT NO. 25-27 SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN (UT) -	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X28.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER,1.0X24.0X2 8.0 TABLET BLISTER	01/07/2017
3679	NDA/MAL/HDP/8 206	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BRULEXIN	CEFALEXIN MONOHYDRATE	125MG/5ML	BRAWN LABORATORIES LTD.13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2018
3680	NDA/MAL/HDP/8 207	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	ZOMETA	ZOLEDRONIC ACID	4MG/5ML	NOVARTIS PHARMA STEIN AG ;SCHAFFHAUSERSTR ASSE CH 4332 STEIN- SWITZERLAND	SWITZERLAND	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X5.0 ML VIAL	01/07/2017

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3681	NDA/MAL/HDP/8 210	CIRON DRUGS & PHARMACEUTICAL S PVT LTD	RENE PHARMACY LTD	HYDROCORTISON E SODIUM SUCCINATE FOR INJECTION BP	HYDROCORTISON E	100MG	CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, 119 MIDC TARAPUR BOISAR DIST THANE 4011 506	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X100.0 MG VIAL	01/07/2007
3682	NDA/MAL/HDP/8 211	SHELYS PHARMACEUTICAL S LTD	BETA HEALTHCARE UGANDA LIMITED	MUCO-ASTHALIN SYRUP	SALBUTAMOL + BROMHEXINE	2MG/5ML + 4MG/5ML	BETA HEALTHCARE INTERNATIONAL LTD - PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2010
3683	NDA/MAL/HDP/8 212	FDC LIMITED -	AIVEEN (U) LIMITED	BACTIGEN EYE/EAR DROPS	GENTAMICIN	0.3%W/V	FDC LIMITED B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.☐	INDIA	OPHTHALMIC VIALS	1.0X5.0 ML VIAL,1.0X10.0 ML VIAL	01/07/1998

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3684	NDA/MAL/HDP/8 213	FDC LTD	AIVEEN (U) LIMITED	ZOCON 200	FLUCONAZOLE	200MG	FDC LTD.L-56/L-57,PHASE II-D, VERNA INDUSTRIAL ESTATE,VERNA-403722, SALCETE,GOA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X2.0 TABLET BLISTER	01/07/2001
3685	NDA/MAL/HDP/8 216	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
3686	NDA/MAL/HDP/8 221	NATIONAL HEALTHCARE PVT LTD	VITACARE LTD	NEMADOL	TRAMADOL HYDROCHLORIDE	50MG/ML	NATIONAL HEALTHCARE PVT LTD-CHHATAPIPRA 3 BARA	NEPAL	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE	01/07/2017

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3687	NDA/MAL/HDP/8 224	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OPTIGENT OINTMENT	GENTAMICIN SULFATE	0.3%W/W	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B EGYPT	EGYPT	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE	01/07/2017
3688	NDA/MAL/HDP/8 226	DEVA HOLDING A.S	SHREEJI PHARMACEUTICAL S LIMITED	SALRES	SALBUTAMOL SULPHATE	120.5MCG/SPRAY	DEVA HOLDING A. S.ÇERKEZKÖY ORGANIZE SANAYI BOLGESI. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKİRDAĞ/ TURKEY	TURKEY	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER	01/07/2017
3689	NDA/MAL/HDP/8 228	AFRICURE PHARMACEUTICAL S (INDIA) LTD	AFRICURE PHARMACEUTICAL S U LIMITED	VITAMIN B- COMPLEX (BEEKO)	VITAMINS B1 + B2 + B6 + NIACINAMIDE	1MG +1MG +1MG +15MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9- 12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017

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3690	NDA/MAL/HDP/8 232	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICAL S LTD	MOMATE	MOMETASONE FUROATE MONOHYDRATE	50MCG/ SPRAY	GLENMARK PHARMACEUTICALS LTDVILLAGE, KISHANPURA, BADDI, NALAGARH ROAD, INDIA GLENMARK PHARMACEUTICALS LTDVILLAGE: KISHANPURA, BADDI NALAGARH DISTRICT SOLAN - 174101, INDIA	INDIA	NASAL SYSTEMIC METERED-DOSE LIQUIDS	1.0X120.0 METERED DOSE BOTTLE	01/07/2017
3691	NDA/MAL/HDP/8 235	DAWA LIMITED-	SUPER MEDIC LTD	ACEPAR	ACECLOFENAC + SERRATIOPEPTID ASE + PARACETAMOL	100MG + 15MG + 500MG	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017
3692	NDA/MAL/HDP/8 243	OCHOA LABORATORIES LIMITED -	SUPER MEDIC LTD	TX-MF	TRANEXAMIC ACID + MEFENAMIC ACID	500MG + 250MG	AUROCHEM PHARMACEUTICALS INDIA PRIVATE LIMITED58, PALGHAR TALUKA INDUSTRIAL CO - OPERATIVE ESTATE LIMITED PALGHAR, DISTRICT - PALGHAR, 401 404	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017

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3693	NDA/MAL/HDP/8 252	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED	SURGIPHARM (U) LIMITED	PARACETAMOL FRESENIUS	PARACETAMOL	10MG/ML	FRESENIUS KABI DEUTSCHLAND GMBHFRESENIUSSTR ASSE 1, D-61169, FRIEDBERG	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X10.0X50.0 ML VIAL,1.0X10.0X100. 0 ML VIAL	01/07/2017
3694	NDA/MAL/HDP/8 253	REYOUNG PHARMACEUTICAL CO LTD	ROYAL PHARMA 2011 LIMITED	DICLOFENAC SODIUM	DICLOFENAC SODIUM	25MG/ML	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	10X10X3 ML AMPOULE	01/07/2017
3695	NDA/MAL/HDP/8 254	MICRO LABS LTD	LABOREX UGANDA LIMITED	GRAMOCEF-CV	CEFIXIME TRIHYDRATE + CLAVULANIC ACID	200MG + 125MG	MICRO LABS LIMITED, BOMMASANDRA PLOT NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET STRIP	01/07/2017

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3696	NDA/MAL/HDP/8 264	CACHET PHARMA PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	EMITINO ORAL SOLUTION	ONDANSETRON	2MG/5ML	CACHET PHARMACEUTICALS PVT LTD THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X30.0 ML BOTTLE	01/07/2017
3697	NDA/MAL/HDP/8 274	HETERO LABS LTD	AIVEEN (U) LIMITED	BICATERO 50	BICALUTAMIDE	50MG	HETERO LABS LTD (UNIT-VI)"SY.NO. 439, 440 & 458,APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR DISTRICT ANDHRA PRADESH-509301 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2013
3698	NDA/MAL/HDP/8 275	HETERO LABS LTD	AIVEEN (U) LIMITED	LETERO	LETROZOLE	2.5MG	HETERO LABS LTD (UNIT-VI)"SY.NO. 439, 440 & 458,APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR DISTRICT ANDHRA PRADESH-509301 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2013

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3699	NDA/MAL/HDP/8 276	HETERO LABS LTD	AIVEEN (U) LIMITED	GEMTERO 1G	GEMCITABINE	1G	HETERO LABS (UNIT VI), INDIAAPIIC, FORMULATION SEZ, POLEPALLY (V),JEDCHERLA(M) MAHABOBNAGER DISTRICT ANDHRA PRADESH-509301, INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 G VIAL	01/07/2013
3700	NDA/MAL/HDP/8 277	HETERO LABS LTD	AIVEEN (U) LIMITED	GEMTERO 200MG	GEMCITABINE	200MG	HETERO LABS (UNIT VI), INDIAAPIIC, FORMULATION SEZ, POLEPALLY (V),JEDCHERLA(M) MAHABOBNAGER DISTRICT ANDHRA PRADESH-509301, INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X200.0 MG VIAL	01/07/2013
3701	NDA/MAL/HDP/8 278	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

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3702	NDA/MAL/HDP/8 299	AFRICURE PHARMACEUTICAL S (INDIA) PRIVATELIMITED	AFRICURE PHARMACEUTICAL S U LIMITED	DICLOFENAC TABLETS BP	DICLOFENAC SODIUM	50MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9- 12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007
3703	NDA/MAL/HDP/8 300	AFRICURE PHARMACEUTICAL S (INDIA) PRIVATELIMITED	AFRICURE PHARMACEUTICAL S U LIMITED	CIPRONE-500	CIPROFLOXACIN HYDROCHLORIDE	500MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9- 12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007
3704	NDA/MAL/HDP/8 307	NAME AFRICURE PHARMACEUTICAL S (INDIA) PRIVATELIMITED	AFRICURE PHARMACEUTICAL S U LIMITED	METFORMIN 500	METFORMIN	500MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9- 12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008

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3705	NDA/MAL/HDP/8 308	NAME AFRICURE PHARMACEUTICAL S (INDIA) PRIVATELIMITED	AFRICURE PHARMACEUTICAL S U LIMITED	PREDNISOLONE 5MG	PREDNISOLONE	5MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9- 12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008
3706	NDA/MAL/HDP/8 312	CADILA PHARMACEUTICAL S LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	TRICORT 40	TRIAMCINOLONE ACETONIDE	40MG/ML	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL	29/11/2017
3707	NDA/MAL/HDP/8 315	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	PREZISTA 75	DARUNAVIR	75MG	JANSSEN ORTHO LLC.-STATE ROAD 933 KM 0.1 MARNEY WARD GURABO PUERTO RICO 00778	UNITED STATES	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X480.0 TABLET BOTTLE	01/07/2017

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3708	NDA/MAL/HDP/8 316	AUROBINDOM PHARMA LIMITED	GITTOES PHARMACEUTICAL S LIMITED	DOLUTEGRAVIR 50 MG/ LAMIVUDINE 300 MG/ TENOFOVIR DISOPROXIL FUMARATE 300 MG TABLETS	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE	50MG + 300MG + 300MG	AUROBINDO PHARMA LTD, UNIT XNO. 16, APIIC MULTI PRODUCTS SEZ, MENAKUR VILLAGE, NAIDUPETA MANDAL, SPSR, NELLORE DISTRICT, ANDHRA PRADESH, PIN 524421 "AUROBINDO PHARMA LIMITEDUNIT –VII, SEZ, TSIIIC, PLOT NO.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE	30/05/2018
3709	NDA/MAL/HDP/8 319	KOPRAN LIMITED	TATA UGANDA LIMITED	ERYKO-250	ERYTHROMYCIN STEARATE TABLETS BP	250MG	KOPRAN LTDVILLAGE SAVROLI TAL KHARAPUR DIST RAIGAD 410 202	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X50 0.0 TABLET CONTAINER	29/11/2017
3710	NDA/MAL/HDP/8 321	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	PROSTAR- 200 CAPSULES	PROGESTERONE	200 MG	AKUMS DRUGS & PHARMACEUTICALS LTD .PLOT NO. 47, 48, SECTOR 6A, IIE, SIDCUL HARIDWAR, UTTRAKHAND – 249403, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X3.0X10 .0 CAPSULE BLISTER	31/01/2018

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3711	NDA/MAL/HDP/8 322	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICAL S LTD	GLEMONT L	MONTELUKAST SODIUM+LEVOCE TIRIZINE DIHYDROCHLORID E	10 MG + 5 MG	GLENMARK PHARMACEUTICALS LIMITED-UNIT III VILLAGE 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
3712	NDA/MAL/HDP/8 324	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LOOBID TABLETS	OFLOXACIN + ORNIDAZOLE	200MG + 500 MG	CACHET PHARMACEUTICAL PVT LTD. HIMACHALTHANA, BADDI, HIMACHAL PRADESH-173 205, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	29/11/2017
3713	NDA/MAL/HDP/8 326	MEDOPHARM PRIVATE LIMITED	VITACARE LIMITED	MEDOMOX 250 DT	AMOXICILLIN	250MG	MEDOPHARM PVT LTD.NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER (EMBOSSSED WITH "GOU NOT FOR SALE" & NON- EMBOSSSED)	29/11/2017

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3714	NDA/MAL/HDP/8 331	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	TORSINEX-20	TORSEMIDE	20MG	MICRO LABS LTD-NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/11/2017
3715	NDA/MAL/HDP/8 332	DEVA HOLDING A.S	SHREEJI PHARMACEUTICAL S LIMITED	AZITRO 500 MG	AZITHROMYCIN	500MG	DEVA HOLDING A. S.ÇERKEZKÖY ORGANIZE SANAYI BOLGESI. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKİRDAĞ/ TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	29/11/2017
3716	NDA/MAL/HDP/8 333	MICRO LABS LTD 92 SIPCOT INDUSTRIAL	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	AVAS-20	ATORVASTATIN	20MG	MICRO LABS LTD 92 SIPCOT 92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/11/2017

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3717	NDA/MAL/HDP/8 337	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ARTESUNATE 120 MG	ARTESUNATE	120 MG	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA BLISS INDAS LIFESCIENCE P. LTD..PLOT 73-76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X120.0 MG VIAL + 1*2 ML AMPOULE OF SODIUM BICARBONATE + 1*10 ML VIAL OF 0.9%W/V SODIUM CHLORIDE	29/11/2017
3718	NDA/MAL/HDP/8 340	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	MONTEMAC 5	MONTELUKAST SODIUM	5 MG	MACLEODS PHARMACEUTICALS LTD(BLOCK N2)VILLAGE THEDA,P.O LODHI MAJRA,TEHSIL BADDI,HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/11/2017
3719	NDA/MAL/HDP/8 341	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	GENVOYA	ELVITEGRAVIR+C OBICISTAT+EMTRI CISTABINE+TENO FOVIR ALAFENAMIDE	150MG + 150MG + 200MG + 10MG	PATHEON INC.- TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9	CANADA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	31/01/2018

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3720	NDA/MAL/HDP/8 343	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	XYKAA EXTEND 1000	PARACETAMOL BP(IMMEDIATE RELEASE)+ PARACETAMOL BP(EXTENDED RELEASE)	325MG+675MG	TROIKAA PHARMACEUTICALS LTD .SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,2.0X10.0 TABLET BLISTER,1.0X4.0 TABLET BLISTER	29/11/2017
3721	NDA/MAL/HDP/8 344	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CELZA DRY SYRUP	CEFUROXIME AXETIL USP	125 MG/5 ML	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X50.0 ML BOTTLE	29/11/2017
3722	NDA/MAL/HDP/8 345	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CELZA 500	CEFUROXIME AXETIL USP	500 MG	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	29/11/2017

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3723	NDA/MAL/HDP/8 346	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ADERAN 8	CANDESARTAN CILEXETIL	8MG	AJANTA PHARMA LIMITEDB-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/11/2017
3724	NDA/MAL/HDP/8 347	YICHANGHUMANW ELL PHARMACEUTICAL CO., LTD.	KAIYUANTANG (U) LIMITED	FENTWELL 0.05MG/ML	FENTANYL CITRATE	0.05MG/ML	YICHANGHUMANWE LL PHARMACEUTICAL CO., LTD.NO.19,DALIAN ROAD, YICHANG DEVELOPING ZONE,HUBEI PROVINCE ,CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X10.0 ML AMPOULE	30/05/2018
3725	NDA/MAL/HDP/8 348	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	IRBECOR PLUS 300MG/12.5MG	IRBESARTAN + HYDROCHLOROT HIAZIDE	300MG + 12.5MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş3. ORGANİZE SANAYİ BÖLGESİ KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	29/11/2017

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3726	NDA/MAL/HDP/8 350	YICHANGHUMANW ELL PHARMACEUTICAL CO., LTD.	KAIYUANTANG (U) LIMITED	FENTWELL 0.05MG/ML	FENTANYL CITRATE	0.05MG/ML	YICHANGHUMANWE LL PHARMACEUTICAL CO., LTD.NO.19,DALIAN ROAD, YICHANG DEVELOPING ZONE,HUBEI PROVINCE ,CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	30/05/2018
3727	NDA/MAL/HDP/8 352	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	KETESSE	DEXKETOPROFEN 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
3728	NDA/MAL/HDP/8 353	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	FEDATE CAPSULES	CARBONYL IRON + FOLIC ACID + VITAMIN B12 + VITAMIN C + ZINC SULFATE MONOHYDRATE	100MG+1.5 MG + 15 MCG + 75 MG + 61.8 MG	AJANTA PHARMA LIMITEDPLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT- 392130 AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	29/11/2017

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3729	NDA/MAL/HDP/8 354	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
3730	NDA/MAL/HDP/8 356	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
3731	NDA/MAL/HDP/8 392	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	IRBECOR PLUS 150MG/12.5MG	İRBESARTAN + HYDROCHLOROT HIAZIDE	150MG + 12.5MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş3. ORGANİZE SANAYİ BÖLGESİ KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	29/11/2017

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3732	NDA/MAL/HDP/8 394	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	RIFAMPICIN 75 MG ISONIAZID 50 MG AND PYRAZINAMIDE 150 MG DISPERSIBLE TABLETS	RIFAMPICIN + ISONIAZID + PYRAZINAMIDE	75MG + 50MG + 150MG	MACLEODS PHARMACEUTICALS LTD., NO. 25-27PLOT NO. 25-26-27, SURVEY NO.366, PREMIER INDUSTRIAL ESTATE ., DAMAN - 396210, KACHIGAM, DAMAN	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X100.0 TABLET CONTAINER,1.0X3.0 X28.0 TABLET BLISTER,1.0X24.0X2 8.0 TABLET BLISTER	29/11/2017
3733	NDA/MAL/HDP/8 395	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,1.0X3.0 X28.0 TABLET BLISTER	29/11/2017
3734	NDA/MAL/HDP/8 396	MARIE STOPE INTERNATIONAL	MARIE STOPE UGANDA LIMITED	BACK-UP	LEVONORGESTRE L	1.5MG	ACME FORMULATION PVT LTD. ROPAR ROAD NALAGARH DIST SOLAN (H.P) -174 101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0 TABLET BLISTER	29/11/2017

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3735	NDA/MAL/HDP/8 407	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	TORTAS 20	TORSEMIDE	20MG	INTAS PHARMACEUTICALS LTD CAMP ROAD, SELAQUI – 248 197 DEHRADUN (UK)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/11/2017
3736	NDA/MAL/HDP/8 411	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	RHEUMAC GEL	DICLOFENAC	1%W/W	LABORATORY & ALLIED LTD-PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE	29/11/2017
3737	NDA/MAL/HDP/8 419	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	VB COMPLEX	VIT B1+ VIT B2 +VIT B3 + NICOTINAMIDE+P ANTOTHENOL	10MG +1MG +1MG +16MG +0.5MG	SCOTT-EDIL PHARMACIA LTD (UNIT I)-56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE,1.0X100. 0X2.0 ML AMPOULE	01/07/2018

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3738	NDA/MAL/HDP/8 434	DAWA LIMITED	SUPER MEDIC LTD	DACINAZOLE	MICONAZOLE NITRATE	2%W/W	DAWA LTDBABA DOGO ROAD RUARAKA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2009
3739	NDA/MAL/HDP/8 468	THEON PHARMACEUTICAL S LIMITED	AIVEEN (U) LIMITED	THEOMOX-500	AMOXICILLIN	500 MG	THEON PHARMACEUTICALS LIMITED. VILLAGE SAINI MAJRA, TEHSIL NALAGARH, DISTT. SOLAN, HIMACHAL PRADESH 174 101 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1X10X10 CAPSULE BLISTER	31/01/2018
3740	NDA/MAL/HDP/8 477	WOCKHARDT LTD	ABACUS PHARMA (AFRICA) LIMITED	GLARITUS 100IU/ML	INSULIN GLARGINE	100IU/ML	WOCKHARDT LIMITED - WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY CARTRIDGES	1.0X10.0 ML VIAL	31/01/2018

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3741	NDA/MAL/HDP/8 485	CACHET PHARMACEUTICAL S PVT LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CACHMAX-400	CEFIXIME	400MG	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0 TABLET BLISTER	31/01/2018
3742	NDA/MAL/HDP/8 489	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	MEDOL	TRAMADOL HYDROCHLORIDE	100 MG / 2 ML	SWISS PARENTERALS LTD809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE,1.0X5.0X 2.0 ML AMPOULE	31/01/2018
3743	NDA/MAL/HDP/8 490	ALTHEA PHARMA PVT LTD.	JOINT MEDICAL STORE (UPMB - UCMB)	SODIUM CHLORIDE	SODIUM CHLORIDE	0.9% W/V	ALTHEA PHARMA PVT LTD -PLOT NO. 374 SHED NO. E.,ALPHA INDUSTRIAL PARK , ATHIYAWAD DABHEL ,NANI DAMAN (U.T) 396210, INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	31/01/2018

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3744	NDA/MAL/HDP/8 491	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CETROTIDE 0.25MG	CETRORELIX	0.25MG	PIERRE FABRE MEDICAMENT AQUITAINE PHARM INTERNATIONAL SITE 1 ABBOTT BIOLOGICALS B.V VEERWEG 12,NL- 8121 AA OLST THE NETHERLANDS	FRANCE	PARENTERAL ORDINARY COMBINATION PACK VIALS	1.0X1.0 VIAL CARTON,1.0X1.0 PREFILLED SYRINGE CARTON	31/01/2018
3745	NDA/MAL/HDP/8 493	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	DESCOVY 200MG/25MG	EMTRICITABINE/T ENOFOVIR ALAFENAMIDE	200MG + 25 MG	PATHEON INC.-- TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9	CANADA GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	31/01/2018
3746	NDA/MAL/HDP/8 497	TWENTY FIRST CENTURY PHARMACEUTICAL S PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYOXIM 500	CEFUROXIME AXETIL	500 MG	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD - UNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE-247668. DIST.-HARIDWAR, UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	31/01/2018

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3747	NDA/MAL/HDP/8 499	YELURI FORMULATIONS PVT LTD	SUPER MEDIC	SOLOCEF 1000 MG	CEFTRIAZONE SODIUM	1000MG	YELURI FORMULATIONS PVT. LTD-SY. NO. 296 / 7 / 6 IDA BOLLARAM,MEDAK DIST.502325, TELANGANA,INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	31/01/2018
3748	NDA/MAL/HDP/8 522	PLANET PHARMACEUTICAL S UGANDA LTD	PLANET PHARMACEUTICAL S UGANDA LTD	DAYPENAM	MEROPENEM	500MG	ZEISS PHARMACEUTICALS PRIVATE LIMITED- PLOT NO. 72 EPIP- PHASE-1 JHARMAJRI BADDI DISTRICT SOLAN (H.P.) - INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X500.0 MG VIAL	07/01/2017
3749	NDA/MAL/HDP/8 566	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	AZINOWEL	AZITHROMYCIN	200MG/5ML	AKUMS DRUGS & PHARMACEUTICALS LTDPLANT II, PLOT NO. 22, SECTOR- 6A, IIE, SIDCUL, RANIPUR, DISTT. : HARIDWAR, UTTARAKHAND	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X15.0 ML BOTTLE	21/11/2019

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3750	NDA/MAL/HDP/8 569	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
3751	NDA/MAL/HDP/8 602	KIMSY MEDS LTD	KIMSY MEDS LTD	KOFLIN COUGH FLU LINCTUS	CHLOPHENIRAMI NE	2MG	MAVID PHARMACEUTICAL INDUSTRIES LIMITEDPLOT 490 BIRONGO, KITIICO	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2005
3752	NDA/MAL/HDP/8 603	KIMSY MEDS LTD	KIMSY MEDS LTD	MAAGA	SODIUM BICARBONATE + LIGHT MAGNESIUM CARBONATE + MAGNESIUM	250 MG + 250 MG + 250 MG	MAVID PHARMACEUTICAL INDUSTRIES LIMITEDPLOT 490 BIRONGO, KITIICO	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	01/07/2005

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3753	NDA/MAL/HDP/8 637	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	AGYCIN	AZITHROMYCIN DIHYDRATE	40MG/ML	BLISS GVS PHARMA LTD PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA- INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X15.0 ML BOTTLE	28/03/2018
3754	NDA/MAL/HDP/8 641	CADILA PHARMACEUTICAL S LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	TELI H	TELMISARTAN + HYDROCHLOROT HIAZIDE	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
3755	NDA/MAL/HDP/8 643	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ARTESUNATE 60MG	ARTESUNATE	60MG	M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA BLISS INDAS LIFESCIENCE P. LTD..PLOT 73-76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X60.0 MG VIAL + 1*1*5ML AMPOULE OF 0.9%W/V NACL + 1*1*1ML AMPOULE OF 5%W/V NAHCO3	28/03/2018

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3756	NDA/MAL/HDP/8 648	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	UNODEX PLUS	TERBUTALINE SULPHATE + BROMHEXINE HYDROCHLORIDE + GUAIFENESIN	2.5MG + 8MG + 100MG	AKUMS DRUGS & PHARMACEUTICALS LTD-PLANT II PLOT NO.22, SECTOR 6-A, IIE, SIDCUL, RANIPUR, DISTRICT: HARIDWAR 249 403, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	28/03/2018
3757	NDA/MAL/HDP/8 649	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	CEFCARE	CEFTRIAZONE SODIUM	1G	INJECTCARE PARENTERALS PVT. LTD.PLOT130 SILVASSA ROAD GIDC VAPI 396195 GUJARAT	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	31/01/2018
3758	NDA/MAL/HDP/8 650	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	CEFDIA 400MG	CEFIXIME TRIHYDRATE	400MG	NOBEL İLAÇ SAN. VE TİC. A.Ş.81100 SANCAKLAR, DÜZCE- TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X5.0 TABLET BLISTER, 1.0X2.0X1. 0X5.0 TABLET BLISTER	28/03/2018

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3759	NDA/MAL/HDP/8 655	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE XR 1000MG	METFORMIN HYDROCHLORIDE	1000MG	MERCK SANTÉ S.A.S.2 RUE DU PRESOIR VERT 45400 SEMOY FRANCE MERCK KGAA-PHARMA PRODUCTION DARMSTADT FRANKFURTER STRABE 250, D- 64293, DARMSTADT	GERMANY FRANCE	ORAL SOLID RETARD TABLETS	1.0X4.0X15.0 TABLET BLISTER,1.0X6.0X10 .0 TABLET BLISTER	28/03/2018
3760	NDA/MAL/HDP/8 660	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	VEMLIDY	TENOFOVIR ALAFENAMIDE	25MG	PATHEON INC.- TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9	CANADA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE	28/03/2018
3761	NDA/MAL/HDP/8 661	AUROBINDO PHARMA LIMITED	GITTOES PHARMACEUTICAL S LIMITED	DOLUTEGRAVIR TABLETS 50MG	DOLUTEGRAVIR SODIUM	50MG	AUROBINDO PHARMA LTD UNIT VII (SEZ) APIICPLOT NO. S1 SURVEY NO. 411,425,434,435 & 458 GREEN INDUSTRIAL PARK POLEPALLY VILLAGE MAHABOONNAGAR DISTRICT ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE	28/03/2018

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3762	NDA/MAL/HDP/8 662	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	AMOXIREN-DS	AMOXICILLIN TRIHYDRATE	250MG/5ML	RENE INDUSTRIES LTD .PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X100.0 ML BOTTLE	28/03/2018
3763	NDA/MAL/HDP/8 665	CACHET PHARMACEUTICAL S PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	PAMAGIN-C	CETIRIZINE HYDROCHLORIDE + DEXTROMETHOR PHAN HYDROBROMIDE + ACETAMINOPHEN + PHENYLEPHRINE HYDROCHLORIDE + ZINC GLUCONATE	5.0 MG +15 MG + 500 MG + 5 MG + 7.5 MG	CACHET PHARMACEUTICALS PVT LTDVILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	28/03/2018
3764	NDA/MAL/HDP/8 684	TENTH OF RAMADAN FOR PHARMACEUTICAL S INDUSTRIES AND DIAGNOSTICS REAGENTS(RAMED A)	GAMA PHARMACEUTICAL S (U) LIMITED	MEGAFEN N	IBUPROFEN	100MG/5ML	TENTH OF RAMADAN FOR PHARMACEUTICAL INDUSTRIES & DIAGNOSTIC REAGENTS (RAMEDA)SECOND INDUSTRIAL ZONE, PLOT NO.5 SIXTH OF OCTOBER- EGYPT	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	26/11/2019

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3765	NDA/MAL/HDP/8 685	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
3766	NDA/MAL/HDP/8 688	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	DURART 600	DARUNAVIR	600 MG	MYLAN LABORATORIES LTD - H-12 & H-13, MIDC, WALUJ, AURANGABA D- 431136 MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	30/05/2018
3767	NDA/MAL/HDP/8 689	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	DURART 800	DARUNAVIR	800 MG	MYLAN LABORATORIES LTD - H-12 & H-13, MIDC, WALUJ, AURANGABA D- 431136 MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	30/05/2018

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3768	NDA/MAL/HDP/8 691	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	QUETRA 1000	LEVETIRACETAM	1000MG	REMEDICA LTD.AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE,3056 LIMASSOL CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	30/05/2018
3769	NDA/MAL/HDP/8 694	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ERBITUX	CETUXIMAB	5MG/ML	MERCK KGAA-250 FRANKFURTERSTRAS SE, D-6100 DARMSTADT	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X20.0 ML VIAL	07/11/2018
3770	NDA/MAL/HDP/8 699	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	ACETAZOLAMIDE	ACETAZOLAMIDE	250 MG	REMEDICA LTD.AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE,3056 LIMASSOL CYPRUS	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	30/05/2018

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3771	NDA/MAL/HDP/8778	I 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
3772	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
3773	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

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3774	NDA/MAL/HDP/8781	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVXIM-400	CEFIXIME	400MG	ASSOCIATED BIOTECH-KRISHANPURA, P. O GURUMAJRA, BADDI, DIST. SOLAN	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X6.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER,1.0X10.0X1.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	21/11/2019
3775	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
3776	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

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3777	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/SYR UPS/DROPS	1.0X60.0 ML BOTTLE	21/11/2019
3778	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
3779	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

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3780	NDA/MAL/HDP/8 788	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVPOD-200	CEFPODOXIME PROXETIL	200MG	ASSOCIATED BIOTECH- KRISHANPURA, P. O GURUMAJRA, BADDI, DIST. SOLAN	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	21/11/2019
3781	NDA/MAL/HDP/8 795	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN 60/360	ARTEMETHER + LUMEFANTRINE	60MG + 360MG	AJANTA PHARMA LIMITEDPLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT- 392130 AJANTA PHARMA LIMITEDB- 4/5/6 MIDC PAITHAN DISTRICT AURANGABAD MAHARASHTRA STATE INDIA 431 128	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0X1.0X6.0 TABLET BLISTER	26/11/2019
3782	NDA/MAL/HDP/8 796	PSYCHOTROPICS INDIA LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	AMITRIP-25	AMITRIPTYLINE HYDROCHLORIDE	25MG	PSYCHOTROPICS INDIA LTD PLOT NO. 46 & 49, SECTOR- 6A,IIE, SIDCUL,HARIDWAR - 249403(UTTARAKHARD)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	21/11/2019

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3783	NDA/MAL/HDP/8797	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
3784	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
3785	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

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3786	NDA/MAL/HDP/8 815	ZIM LABORATORIES LTD	REDDYS PHARMA LIMITED	ZIMAGRA – ODS 50	SLIDENAFIL CITRATE	50 MG	ZIM LABORATORIES LTDB-21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA,	INDIA	OTHER SYSTEMIC SPECIAL SOLIDS	1.0X1.0X10.0 SACHET CARTON	30/05/2018
3787	NDA/MAL/HDP/8 816	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABPARA	PARACETAMOL	1%W/V	ABACUS PARENTERAL DRUGS LIMITEDBLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION BAGS	1.0X1.0X100.0 ML BOTTLE	30/05/2018
3788	NDA/MAL/HDP/8 817	MEDIPHARM INDUSTRIES (E.A) LTD	MEDIPHARM INDUSTRIES (E.A) LTD	MEDISOLONE-15	PREDNISOLONE SODIUM PHOSPHATE	15MG/5ML	MEDIPHARM INDUSTRIES(EA) LTD PLOT 65 KAKAJJO ROAD BWEYOGERERE P.O.BOX 6218,KAMPALA,UGA NDA	UGANDA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X5.0 ML BOTTLE	30/05/2018

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3789	NDA/MAL/HDP/8 818	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	LEVOTOP-PF	LEVOFLOXACIN HEMIHYDRATE	1.5%W/V	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML VIAL	30/05/2018
3790	NDA/MAL/HDP/8 819	UNOSOURCE PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	LORFACT-D SYRUP	DES LorATADINE	5MG/5ML	AKUMS DRUGS & PHARMACEUTICALS LTD-PLANT II PLOT NO.22, SECTOR 6-A, IIE, SIDCUL, RANIPUR, DISTRICT: HARIDWAR 249 403, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	30/05/2018
3791	NDA/MAL/HDP/8 820	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	T-DOL P RAPID	TRAMADOL HYDROCHLORIDE + PARACETAMOL	37.5MG + 325MG	TROIKAA PHARMACEUTICALS LTD .C-1 SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	30/05/2018

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3792	NDA/MAL/HDP/8 823	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	EPCLUSA	SOFOSBUVIR + VELPATASIR	400MG + 100MG	PATHEON INC.- TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9	CANADA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X28.0 TABLET BOTTLE	30/05/2018
3793	NDA/MAL/HDP/8 824	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	NEPAFLAM	NEPAFENAC	0.1% W/V	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	OPHTHALMIC SUSPENSIONS	1.0X1.0X5.0 ML VIAL	30/05/2018
3794	NDA/MAL/HDP/8 826	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ABACAVIR SULFATE AND LAMIVUDINE TABLETS FOR ORAL SUSPENSION 120/60 MG	ABACAVIR SULFATE + LAMIVUDINE	120MG + 60MG	CIPLA LIMITED PLOT NO A – 33, A – 2 (UNIT – I), MIDC PATALGANGA, DISTRICT RAIGAD, 410 220 MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X1.0X60.0 TABLET BOTTLE	30/05/2018

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3795	NDA/MAL/HDP/8 827	HETERO LABS LTD	AIVEEN (U) LIMITED	SOFGEN	SOFOSBUVIR	400 MG	HETERO LABS LIMITED UNIT-VI - APIIC FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOB NAGAR DIST -509301, TELANGANA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X28.0 TABLET BOTTLE	30/05/2018
3796	NDA/MAL/HDP/8 829	HETERO LABS LTD	AIVEEN (U) LIMITED	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFVIR DISOPROXIL FUMARATE	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFVIR DISOPROXIL FUMARATE	50 MG + 300 MG + 300 MG	M/S. ANNORA PHARMA PRIVATE LIMITEDSY. NO. 261, ANNARAM VILLAGE, GUMMADIDALA MANDAL, SANGAREDDY DISTRICT, TELENGANA STATE – 502313, INDIA HETERO LABS PRIVATE LIMITED UNIT IISURVEY NO. 51, PLOT 22-110, INDUSTRIAL	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X90 TABLET BOTTLE	20/12/2018
3797	NDA/MAL/HDP/8 830	HETERO LABS LTD	AIVEEN (U) LIMITED	IRBIS-HT	IRBESARTAN + HYDROCHLOROT HIAZIDE	300MG + 12.5MG	HETERO LABS LIMITED (UNIT V)SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOONAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019

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3798	NDA/MAL/HDP/8 831	HETERO LABS LTD	AIVEEN (U) LIMITED	PREGA 75	PREGABALIN	75MG	HETERO LABS PRIVATE LIMITED UNIT IISURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) JEEDIMETLA, HYDERABAD-500 055, TELANGANA STATE HETERO LABS LIMITED (UNIT I)VILLAGE KALYANPUR, CHAKKAN ROAD,	INDIA	ORAL SOLID ORDINARY CAPSULES	1X3X10 CAPSULE BLISTER	26/11/2019
3799	NDA/MAL/HDP/8 836	EXPHAR S.A. ZONING INDUSTRIEL DE NIVELLES SUD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	GASTRICID	FAMOTIDINE BP + MAGNESIUM HYDROXIDE BP + CALCIUM CARBONATE BP	10 MG + 165 MG + 800 MG	MILAN LABORATORIES (INDIA) PVT LTD PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTR A-410209,INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X4.0 TABLET STRIP	07/11/2018
3800	NDA/MAL/HDP/8 839	MACK BROWN PHARMACEUTICAL S PVT LIMITED	SHURIK LTD	HEALTH RICH	FERRIC AMMONIUM CITRATE + FOLIC ACID + VITAMIN B1 HCL + VITAMIN B6 HCL + NICOTINAMIDE + VITAMIN B12	900MG + 10MG + 20MG + 40MG + 200MG + 360MG /5ML	TORQUE PHARMACEUTICALS PVT LTD VILL. ISSAPUR, P.O. DAPPAR, PUNJAB- 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1X100 ML BOTTLE, 1X1X100 ML BOTTLE	26/11/2019

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3801	NDA/MAL/HDP/8 844	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VENAXAN 500 MG	LEVOFLOXACIN HEMIHYDRATE	500 MG	SOUTH EGYPT DRUG INDUSTRIES CO-1ST INDUSTRIAL ZONE, 6 OCTOBER CITY, EGYPT.	EGYPT	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X5.0 TABLET BLISTER	07/11/2018
3802	NDA/MAL/HDP/8 845	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	FUROSEMIDE	FUROSEMIDE	10MG/ML	SWISS PARENTERALS PVT LTD ..809, KERALA INDUSTRIAL ESTAE, GIDC NEAR BAVLA, AHMEDABAD 382220, GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	21/11/2019
3803	NDA/MAL/HDP/8 914	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	PEFLOREN 400	PEFLOXACIN MESILATE DIHYDRATE	400 MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER	25/07/2018

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3804	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
3805	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
3806	NDA/MAL/HDP/8917	OXIMIO LIMITED	GITTOES PHARMACEUTICALS LIMITED	SCC-2 LLW TABLETS	RIFAMPICIN + ISONIAZID	150MG + 75MG	SVIZERA LABS PRIVATE LIMITED PLOT D-16/6 TTC INDUSTRIAL AREA MIDC TURBHE NAVI MUMBAI 400703, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X24.0X28.0 TABLET BLISTER	25/07/2018

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3807	NDA/MAL/HDP/8 918	OXIMIO LIMITED	GITTOES PHARMACEUTICAL S LIMITED	SCC-3 LLW TABLETS	RIFAMPICIN + ISONIAZID + ETHAMBUTOL HYDROCHLORIDE	150MG + 75MG + 275MG	SVIZERA LABS PRIVATE LIMITEDPLOT D-16/6 TTC INDUSTRIAL AREA MIDC TURBHE NAVI MUMBAI 400703, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X24.0X28.0 TABLET BLISTER	25/07/2018
3808	NDA/MAL/HDP/8 919	OXIMIO LIMITED	GITTOES PHARMACEUTICAL S LIMITED	SCC-4 TABLETS	RIFAMPICIN + ISONIAZID + PYRAZINAMIDE + ETHAMBUTOL HYDROCHLORIDE	150MG + 75MG + 400MG + 275MG	SVIZERA LABS PRIVATE LIMITEDPLOT D-16/6 TTC INDUSTRIAL AREA MIDC TURBHE NAVI MUMBAI 400703, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X24.0X28.0 TABLET BLISTER	25/07/2018
3809	NDA/MAL/HDP/8 920	MERCK	UNITED HEALTHCARE DISTRIBUTORS LTD	CRINONE 8% GEL	PROGESTERONE	90MG/APPLICATO R	DENDRON BRANDS LIMITED94 RICKMANSWORTH ROAD,WATFORD , WD18 7JJ, UNITED KINGDOM	UNITED KINGDOM	VAGINAL GELS AND SOLS	1.0X1.0X15.0 POUCH CARTON	25/07/2018

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3810	NDA/MAL/HDP/8 926	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GLUSIS 1000 ER	METFORMIN HYDROCHLORIDE	1000 MG	MSN LABORATORIES PRIVATE LIMITED (FORMULATIONS DIVISION) - PLOT NO.: 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, 502 325, INDIA	INDIA	ORAL SOLID RETARD TABLETS	1X3X10 TABLET BLISTER	25/07/2018
3811	NDA/MAL/HDP/8 927	BIOLOGICAL E. LTD	GITTOES PHARMACEUTICAL S LIMITED	DIPHTHERIA AND TETANUS VACCINE (ADSORBED REDUCED ANTIGEN(S) CONTENT)	DIPHTHERIA TOXOID + TETANUS TOXOID	2 LF (NOT LESS THAN 2 IU) + 8.8 LF (NOT LESS THAN 20 IU)/ 0.5ML	BIOLOGICAL E. LIMITED-PLOT NO.1 SHAPOORJI PALLONJI BIOTECH PARK PHASE II, KOLTHUR VILLAGE, SHAMEERPET, MANDAL, R.R. DISTRICT, ANDRA PRADESH 500078, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X24.0X1.0X10.0 DOSE VIAL,1.0X48.0X1.0 DOSE VIAL	25/07/2018
3812	NDA/MAL/HDP/8 929	OCTAPHARMA AG	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	ALBUNORM	HUMAN ALBUMIN	20%W/V	OCTAPHARMA PRODUKTIONSGESEL LSCHAFT DEUTSCHLAND MBH- WOLFGANG- MARGUERRE-ALLEE 1 31832 SPRINGE GERMANY	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X50.0 ML BOTTLE,1.0X1.0X10 0.0 ML BOTTLE	25/07/2018

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3813	NDA/MAL/HDP/8 931	CARITAS HEALTHCARE PVT. LTD	REDDYS PHARMA LIMITED	SODIUM CHLORIDE INTRAVENOUS INFUSION BP	SODIUM CHLORIDE	0.9%W/V	SICHUAN KELUN PHARMACEUTICAL CO., LTDSOUTH OF NO.2 ROAD, XINDU SATELLITE CITY INDUSTRIAL DEVELOPMENT ZONE, CHENGDU, SICHUAN PROVINCE 610500, P. R. CHINA	CHINA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	25/07/2018
3814	NDA/MAL/HDP/8 933	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	Q-TIB	SULFAMETHOXAZ OLE + TRIMETHOPRIM + ISONIAZID + PYRIDOXINE HYDROCHLORIDE	800MG + 160MG + 300MG +25MG	CIPLA LTD ,PLOT NO. A-33, A-2 (UNIT 1), A42 (UNIT II), MIDC PATALGANGA, DISTRICT-RAIGAD MAHARASHTRA, 410220 INDIA CIPLA LIMITED>A-33, A- 37/2/2 & A-2, M.I.D.C, PATALANGA 410 220, DISTRICT RAIGAD, M.S, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X30.0 TABLET BOTTLE	25/07/2018
3815	NDA/MAL/HDP/8 934	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	CYCLO P EYE DROPS	CYCLOPENTOLATE HYDROCHLORIDE	1.0%W/V	ABACUS PARENTERAL DRUGS LIMITEDBLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	25/07/2018

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3816	NDA/MAL/HDP/8 936	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD	HEALTHCARE LTD.	ESOFOLE	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40MG	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD-PLOT 20,21,22- DEFENCE INDUSTRIAL ZONE- MOMAN PURA, 16KM SHEIKHUPURA ROAD, (LAHORE) - PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER	25/07/2018
3817	NDA/MAL/HDP/8 940	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
3818	NDA/MAL/HDP/8 941	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

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3819	NDA/MAL/HDP/8 943	HETERO LABS LTD	AIVEEN (U) LIMITED	IRBIS-HT 150/12.5	IRBESARTAN + HYDROCHLOROT HIAZIDE	150MG + 12.5MG	HETERO LABS LIMITED (UNIT V)SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
3820	NDA/MAL/HDP/8 944	B&O PHARM	TRIDEM PHARMA UGANDA LIMITED	GAMOK 625MG	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	500MG + 125MG	SINOPHARM WEIQIDA PHARMACEUTICAL CO., LTD-OSD WORKSHOP OF ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, SECOND MEDICAL ZONE DATONG, SHANXI, CHINA	CHINA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	25/07/2018
3821	NDA/MAL/HDP/8 946	B & O PHARM ZAC	TRIDEM PHARMA UGANDA LIMITED	GAMOK 0.6G	AMOXICILLIN SODIUM + CLAVULANATE POTASSIUM	500MG + 100MG	SINOPHARM WEIQIDA PHARMACEUTICAL CO., LTD-OSD WORKSHOP OF ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, SECOND MEDICAL ZONE DATONG, SHANXI, CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X0.6 G VIAL	25/07/2018

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3822	NDA/MAL/HDP/8 947	B & O PHARM ZAC	TRIDEM PHARMA UGANDA LIMITED	GAMOK 1.2G	AMOXICILLIN SODIUM + CLAVULANATE POTASSIUM	1G + 0.2G	SINOPHARM WEIQIDA PHARMACEUTICAL CO., LTD-OSD WORKSHOP OF ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, SECOND MEDICAL ZONE DATONG, SHANXI, CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X1.2 G VIAL	25/07/2018
3823	NDA/MAL/HDP/8 949	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CETAL SUPOSITORIES	PARACETAMOL	120MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B1,EGYPT	EGYPT	RECTAL SYSTEMIC SUPOSITORIES	1.0X1.0X5.0 SUPOSITORY BLISTER	25/07/2018
3824	NDA/MAL/HDP/8 952	THEON PHARMACEUTICAL S LTD	AIVEEN (U) LIMITED	THEOFLEX -500	CEFALEXIN MONOHYDRATE	500 MG	THEON PHARMACEUTICALS LIMITED. VILLAGE SAINI MAJRA, TEHSIL NALAGARH, DISTT. SOLAN, HIMACHAL PRADESH 174 101 INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1X10X10 CAPSULE BLISTER	25/07/2018

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3825	NDA/MAL/HDP/8 953	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	BENYLIN CHILDREN'S WET COUGH	GUAIFENESIN	100MG PER 10ML	JOHNSON&JOHNSO N PTY LTD.EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE	25/07/2018
3826	NDA/MAL/HDP/8 954	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	BENYLIN WET COUGH	GUAIFENESIN	200MG PER 10ML	JOHNSON&JOHNSO N PTY LTD.EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X50.0 ML BOTTLE,1.0X1.0X10 0.0 ML BOTTLE,1.0X1.0X20 0.0 ML BOTTLE	25/07/2018
3827	NDA/MAL/HDP/9 053	F. HOFFMANN LA- ROCHE	LABOREX UGANDA LIMITED	MABTHERA® 100MG/10ML	RITUXIMAB	100MG/10ML	ROCHE DIAGNOSTICS GMBH MANNHEIM- SANDHOFER STRASSE 116 -68305 MANNHEIM GERMANY.	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X2.0X10.0 ML VIAL	26/09/2018

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3828	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
3829	NDA/MAL/HDP/9057	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP®	DIHYDROARTEMI SININ + PIPERAQUINE PHOSPHATE	60MG + 480MG	GUILIN PHARMACEUTICAL CO LTD-NO. 43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER,1.0X6.0X25 .0 TABLET BLISTER	26/09/2018
3830	NDA/MAL/HDP/9058	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP® DISPERSIBLE	DIHYDROARTEMI SININ + PIPERAQUINE PHOSPHATE	30MG + 240MG	GUILIN PHARMACEUTICAL CO LTD-NO. 43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X2.0X3.0 TABLET BLISTER,1.0X3.0X25 .0 TABLET BLISTER	26/09/2018

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3831	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/SYR UPS/DROPS	1.0X10.0 ML BOTTLE	26/09/2018
3832	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
3833	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

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3834	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
3835	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
3836	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

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3837	NDA/MAL/HDP/9 067	MEDISEL(K) LTD	AIVEEN (U) LIMITED	BRONCHOWIN	DOXOFYLLINE	400 MG	CORONA REMEDIES PVT LIMITEDVILLAGE JATOLI, POST OFFICE - OACHGHAT, TEHSIL SOLAN, DIST. SOLAN HIMACHAL PRADESH – 173223. INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	26/09/2018
3838	NDA/MAL/HDP/9 068	MEDISEL(K) LTD	AIVEEN (U) LIMITED	MOXIDOC TABLET	MOXIFLOXACIN HYDROCHLORIDE	400 MG	CORONA REMEDIES PVT LIMITEDVILLAGE JATOLI, POST OFFICE - OACHGHAT, TEHSIL SOLAN, DIST. SOLAN HIMACHAL PRADESH – 173223. INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X1X10 TABLET BLISTER	26/09/2018
3839	NDA/MAL/HDP/9 130	AUROLAB	SWASTIK PHARMACEUTICAL LTD	MFLOX-DM	MOXIFLOXACIN + DEXAMETHASON E SODIUM PHOSPHATE	0.5%W/V + 0.1%W/V	AUROLAB LIMITEDNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU INDIA	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	21/11/2019

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3840	NDA/MAL/HDP/9 137	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	DOM R	RABEPRAZOLE SODIUM + DOMPERIDONE SR	20MG + 30MG	CORONA REMEDIES PVT. LTDVILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	21/11/2019
3841	NDA/MAL/HDP/9 140	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	CLOMIPHENE CITRATE	CLOMIPHENE CITRATE	50MG	CORONA REMEDIES PVT. LTDVILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	21/11/2019
3842	NDA/MAL/HDP/9 141	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	RABZOLE	RABEPRAZOLE SODIUM + LEVOSULPIRIDE	20MG + 75MG	CORONA REMEDIES PVT. LTDVILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	21/11/2019

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3843	NDA/MAL/HDP/9 142	THEON PHARMACEUTICAL S LIMITED	AIVEEN (U) LIMITED	THEOFIX -50 DS	CEFIXIME TRIHYDRATE	50MG/5ML	THEON PHARMACEUTICALS LTD ,VILLAGE SAINI MAJRA, TEHSIL, NALAGARH, DIST. SOLAN HP	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1X60 ML BOTTLE	26/11/2019
3844	NDA/MAL/HDP/9 146	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,1.0X24.0X2 8.0 TABLET BLISTER,1.0X1000.0 TABLET BOTTLE	21/11/2019
3845	NDA/MAL/HDP/9 147	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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3846	NDA/MAL/HDP/9 165	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	VAGID-100	CLOTRIMAZOLE	100 MG	M/S BLISS GVS PHARMA LIMITED PLOT 10, SURVEY NO. 38/1, DEWAN UDYOG NAGAR, ALIYALI VILLAGE PALGHAR, DIST. THANE - 401404	INDIA	VAGINAL SUPPOSITORIES	1.0X1.0X7.0 PESSARY BLISTER,1.0X1.0X6. 0 PESSARY BLISTER	21/11/2019
3847	NDA/MAL/HDP/9 166	HETERO LABS LTD	AIVEEN (U) LIMITED	VIRDAC 30	DACLATASVIR DIHYDROCHLORID E	30 MG	HETERO LABS LIMITED (UNIT V)SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X28.0 TABLET BOTTLE	27/11/2019
3848	NDA/MAL/HDP/9 189	SAGA LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	ESOFLUX 40	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40 MG	SAGA LIFESCIENCES LIMITEDSURVEY NO. 198/2 & 198/3, CHACHRAWADI VASNA, TA-SANAND, DIST. AHMEDABAD - 382210, INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	28/09/2020

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3849	NDA/MAL/HDP/9 190	SAKAR HEALTHCARE LIMITED	TATA UGANDA LIMITED	RABEKAR	RABEPRAZOLE SODIUM	20MG	SAKAR HEALTH CARE PVT LTD-10/13 CHONGODAR SARKHEJ BAVLA ROAD DIST AHEMABAD 382213 GUJARATI	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 MG VIAL + 1*5ML WFI IN LDPE	15/02/2023
3850	NDA/MAL/HDP/9 191	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANDOX-DS 50	CEFPODOXIME PROXETIL	50 MG/5ML	SANCE LABORATORIES PVT LTDVI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE	08/09/2020
3851	NDA/MAL/HDP/9 192	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANDOX- 200	CEFPODOXIME PROXETIL	200 MG	SANCE LABORATORIES PVT LTDVI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	08/09/2020

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3852	NDA/MAL/HDP/9 193	SHANGHAI DESANO BIO- PHARMACEUTICAL CO., LTD	TATA UGANDA LIMITED	LAMIVUDINE AND ZIDOVUDINE TABLETS 150 MG/300 MG	LAMIVUDINE + ZIDOVUDINE	150 MG + 300 MG	SHANGHAI DESANO BIO- PHARMACEUTICAL CO., LTD1479 ZHANGHENG ROAD, CHINA (SHANGHAI) PILOT FREE TRADE ZONE SHANGHAI, CHINA	CHINA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X60.0 TABLET CONTAINER	08/09/2020
3853	NDA/MAL/HDP/9 194	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MAGNABIOTIC	AMOXICILLINTRIH YDRATE + POTASSIUM CLAVULANATE	875 MG + 125 MG	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)-1ST INDUSTRIAL ZONE, 6 OCTOVER CITY, P.O. BOX 43	EGYPT	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BOTTLE	08/09/2020
3854	NDA/MAL/HDP/9 195	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	SOBISIS	SODIUM BICARBONATE	500 MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRI AL 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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3855	NDA/MAL/HDP/9 196	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	SOBISIS FORTE	SODIUM BICARBONATE	1000 MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRI AL AREA,MEHATPUR- 174 315, HIMACHAL PRADESH.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/09/2020
3856	NDA/MAL/HDP/9 197	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	SEVLAREN 400	SEVELAMER CARBONATE	400 MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRI AL AREA,MEHATPUR- 174 315, HIMACHAL PRADESH.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/09/2020
3857	NDA/MAL/HDP/9 198	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	PBREN 75	PREGABALIN	75 MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRI AL AREA,MEHATPUR- 174 315, HIMACHAL PRADESH.	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	08/09/2020

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3858	NDA/MAL/HDP/9 199	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	KCHEK	CALCIUM POLYSTYRENE SULPHONATE	15 MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRI AL AREA,MEHATPUR- 174 315, HIMACHAL PRADESH.	INDIA	ORAL LIQUID ORDINARY OTHER POWDERS/GRANU LES	1.0X15.0 G SACHET	08/09/2020
3859	NDA/MAL/HDP/9 200	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	LEVIGRESS 250	LEVETIRACETAM	250 MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRI AL AREA,MEHATPUR- 174 315, HIMACHAL PRADESH.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/09/2020
3860	NDA/MAL/HDP/9 201	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	LEVIGRESS 500	LEVETIRACETAM	500MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRI AL 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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3861	NDA/MAL/HDP/9 202	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	ESCIGRESS 5	ESCITALOPRAM OXALATE	5MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRI AL AREA,MEHATPUR- 174 315, HIMACHAL PRADESH.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/09/2020
3862	NDA/MAL/HDP/9 203	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	ESCIGRESS 10	ESCITALOPRAM OXALATE	10MG	STANFORD LABORATORIES PVT LIMITED8,INDUSTRI AL AREA,MEHATPUR- 174 315, HIMACHAL PRADESH.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/09/2020
3863	NDA/MAL/HDP/9 204	SUN PHARMACEUTICAL INDUSTRIES LTD	STAR PHARMACEUTICAL S LTD	CHERIFLU PLUS WITH VITAMIN C	CHLORPHENAMIN E MALEATE + PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE +VITAMIN C	4 MG + 650 MG + 10 MG + 30 MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED INDUSTRIAL AREA 3, A.B. ROAD, DEWAS 455001, MADHYA PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	08/09/2020

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3864	NDA/MAL/HDP/9 205	SYNOKEM PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GASTROSYN	ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE	250 MG + 250 MG + 50 MG / 5ML	SYNOKEM PHARMACEUTICALS LTD-PLOT NO.- 35- 36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL)	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	08/09/2020
3865	NDA/MAL/HDP/9 210	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VIVAZAC	IRBESARTAN	300 MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/09/2020
3866	NDA/MAL/HDP/9 211	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HI DEE 10000 IU	CHOLECALCIFERO L	10,000IU	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X1.0X30.0 CAPSULE CONTAINER	08/09/2020

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3867	NDA/MAL/HDP/9 212	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HI DEE 50000 IU	CHOLECALCIFERO L	50,000IU	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X1.0X8.0 CAPSULE CONTAINER	08/09/2020
3868	NDA/MAL/HDP/9 213	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	COMBIART SUSPENSION	ARTEMETHER + LUMEFANTRINE	15 MG + 90 MG/5ML	MADRAS PHARMACEUTICALS 137-B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI – 600 096, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE	08/09/2020
3869	NDA/MAL/HDP/9 214	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HI DEE 2000 IU	CHOLECALCIFERO L	2000IU	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X1.0X30.0 CAPSULE CONTAINER	08/09/2020

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3870	NDA/MAL/HDP/9 215	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HI DEE 2000 IU/5 DROPS	CHOLECALCIFERO L	2000IU/ 5 DROPS	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL LIQUID ORDINARY DROPS	1.0X1.0X10.0 ML BOTTLE	08/09/2020
3871	NDA/MAL/HDP/9 217	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	ABACAVIR, DOLUTEGRAVIR AND LAMIVUDINE TABLETS	ABACAVIR SULFATE + DOLUTEGRAVIR SODIUM + LAMIVUDINE	600 MG + 50 MG + 300 MG	LAURUS LABS LTD (UNIT 2)PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	08/09/2020
3872	NDA/MAL/HDP/9 219	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TESS	TRIAMCINOLONE ACETONIDE	0.1% W/W	TROIKAA PHARMACEUTICALS LTDBLOCK NO. 2019, 2020, 2023, VILLAGE VIROCHANNAGAR, TAL-SANAND CITY: AHMEDABAD, DIST. AHMEDABAD- 382170, GUJARAT STATE	INDIA	TOPICAL EXTERNAL PASTES	1.0X1.0X5.0 G TUBE	08/09/2020

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3873	NDA/MAL/HDP/9 222	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	DARUNAVIR TABLETS	DARUNAVIR	800 MG	LAURUS LABS LTD (UNIT 2)PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	08/09/2020
3874	NDA/MAL/HDP/9 223	WALLACE PHARMACEUTICAL S PVT. LTD	STAR PHARMACEUTICAL S LTD	LAXIWAL	LACTULOSE	10 G/15 ML	WALLACE PHARMACEUTICALS PVT LTDBHATIAN, NALAGARH, DIST. SOLAN HP 174101	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X20 0.0 ML BOTTLE	08/09/2020
3875	NDA/MAL/HDP/9 225	ZIM LABORATORIES LTD	ROYAL PHARMA 2011 LIMITED	ZIMADOL 50	TRAMADOL HYDROCHLORIDE	50 MG	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	08/09/2020

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3876	NDA/MAL/HDP/9 228	LIFEWAY PHARMACEUTICAL INDUSTRIES LIMITED	LIFEWAY PHARMACEUTICAL INDUSTRIES LIMITED	SUREDOL	PARACETAMOL	500MG	LIFEWAY PHARMACEUTICAL INDUSTRIES LIMITED- BLOCK 198, PLOT 478,	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/09/2020
3877	NDA/MAL/HDP/9 229	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	TRADMIN	TRAMADOL HYDROCHLORIDE	50MG	AKUMS DRUGS & PHARMACEUTICALS LTD19-20,21, SECTOR 6-4, SIDCUL, IIE, RANIPUR HARIDWAR-249403	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	08/09/2020
3878	NDA/MAL/HDP/9 237	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	AZITHRO-DENK 250 MG	AZITHROMYCIN MONOHYDRATE	250MG	ARTESAN PHARMA GMBH & CO. KGWENDLANDSTR.1, 29439, LUCHOW	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	08/09/2020

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3879	NDA/MAL/HDP/9 238	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	AZITHRO-DENK 500 MG	AZITHROMYCIN MONOHYDRATE	500MG	ARTESAN PHARMA GMBH & CO. KGWENDLANDSTR.1, 29439, LUCHOW	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	08/09/2020
3880	NDA/MAL/HDP/9 241	BKRS PHARMA PVT. LTD.	VEERAM HEALTHCARE (U) LIMITED	LEXAR	LEVOFLOXACIN HEMIHYDRATE	500MG	HIGGS HEALTHCARE PVT. LIMITED KHASRA NO. 480/1, BHATOLIKALAN BADDI, DIST SOLAN, (H.P) - INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	08/09/2020
3881	NDA/MAL/HDP/9 246	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	CLAMOXIN	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500 MG + 125 MG	MEDOPHARM PVT LIMITEDNO. 50 KAYARAMBEDU VILLAGE, GUDUVANCHERY- 603202	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER,1.0X2.0X10 .0 TABLET BLISTER	19/02/2021

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3882	NDA/MAL/HDP/9 248	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	ESOFAG-D	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE + DOMPERIDONE	40MG + 30MG	MICRO LABS LIMITED .92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE STRIP	08/09/2020
3883	NDA/MAL/HDP/9 252	BKRS PHARMA PVT. LTD.	VEERAM HEALTHCARE (U) LIMITED	FLUCO-BKRS	FLUCONAZOLE	0.2% W/V	HIGGS HEALTHCARE PVT. LIMITED KHASRA NO. 480/1, BHATOLIKALAN BADDI, DIST SOLAN, (H.P) - INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	08/09/2020
3884	NDA/MAL/HDP/9 264	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	APRITANT IV	FOSAPRIPITANT DIMEGLUMINE	150 MG/VIAL	MSN LABORATORIES (PVT) LTD- FORMULATIONS DIVISIONPLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 VIAL VIAL	08/09/2020

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3885	NDA/MAL/HDP/9 266	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ABACAVIR (AS SULFATE) / LAMIVUDINE DISPERSIBLE TABLETS	ABACAVIR SULFATE + LAMIVUDINE	120 MG + 60 MG	MYLAN LABORATORIES LTD PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR - 454775; DIST; DHAR; MADHYA PRADESH; MYLAN LABORATORIES LIMITED NO. H-12 & H-13, MIDC, WALUJ	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X30.0 TABLET CONTAINER, 1.0X60. 0 TABLET CONTAINER	08/09/2020
3886	NDA/MAL/HDP/9 278	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	CANDIFORCE-100	ITRACONAZOLE	100 MG	RA CHEM PHARMA LTD PLOT NO. A- 19/C, ROAD NO. 18, IDA NACHARAM, HYDERABAD- 500076, TELENGANA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	08/09/2020
3887	NDA/MAL/HDP/9 279	RAPTAKOS, BRETT & CO. LTD.	EUROPA HEALTHCARE (U) LTD	SILVIRIN	SILVER SULFADIAZINE	1% W/W	RAPTAKOS BRETT & CO. LTD 1ST POKHRAN ROAD, THANE 400 606	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	08/09/2020

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3888	NDA/MAL/HDP/9 280	RAPTAKOS, BRETT & CO. LTD.	EUROPA HEALTHCARE (U) LTD	NORASH	DIMETHICONE + ZINC OXIDE + CALAMINE + CETRIMIDE	20% W/W + 7.5% W/W + 1.5% W/W + 1.125% W/W	RAPTAKOS BRETT & CO.LTD1ST POKHRAN ROAD,THANE 400 606	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	08/09/2020
3889	NDA/MAL/HDP/9 286	GALENTIC PHARMA LTD	VITACARE LIMITED	SELDRAF	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
3890	NDA/MAL/HDP/9 287	GLENMARK PHARMACEUTICAL S LTD	ABACUS PHARMA (AFRICA) LIMITED	CANDID-V3	CLOTRIMAZOLE	200MG	GLENMARK PHARMACEUTICALS LTD .PLOT E-37, 39, D ROAD, MIDC, SATPUR, NASHIK 422007, MAHARASHTRA STATE	INDIA	VAGINAL TABLETS	1.0X1.0X3.0 TABLET STRIP	08/09/2020

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3891	NDA/MAL/HDP/9 288	HETERO DRUGS LTD	AIVEEN (U) LIMITED	VIRDAC 60	DACLATASVIR DIHYDROCHLORID E	60 MG	HETERO LABS LIMITED (UNIT V)SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X28.0 TABLET BOTTLE	28/09/2020
3892	NDA/MAL/HDP/9 290	INFUGEN PHARMA PVT. LTD.	TATA UGANDA LIMITED	INFIXIME 200	CEFIXIME TRIHYDRATE	200MG	INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	08/09/2020
3893	NDA/MAL/HDP/9 291	INTAS PHARMACEUTICAL S LIMITED	STAR BIOTECH UGANDA LTD	SARTEL-80 LH	TELMISARTAN + HYDROCHLOROT HIAZIDE	80 MG + 12.5 MG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI- 248197, DEHRADUN (UTTARAKHAND)	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/09/2020

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3894	NDA/MAL/HDP/9 294	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	BENYLIN WET COUGH MENTHOL	GUAIFENESIN	200 MG/10 ML	JOHNSON & JOHNSON (PTY) LTD241 MAIN ROAD, RETREAT, 7945, CAPE TOWN	SOUTH AFRICA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	08/09/2020
3895	NDA/MAL/HDP/9 295	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	TRIMIC	METRONIDAZOLE + MICONAZOLE NITRATE	500 MG + 100 MG	BLISS GVS PHARMA LIMITED10,11 & 12,DEWAN UDYOG NAGAR,ALIYALI,PAL GHAR,MAHARASHTR A 401404,INDIA	INDIA	VAGINAL SUPPOSITORIES	1.0X2.0X7.0 SUPPOSITORY STRIP	25/09/2020
3896	NDA/MAL/HDP/9 296	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,PAL GHAR,MAHARASHTR A 401404,INDIA	INDIA	VAGINAL SUPPOSITORIES	1.0X1.0X3.0 SUPPOSITORY STRIP	08/09/2020

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3897	NDA/MAL/HDP/9 305	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
3898	NDA/MAL/HDP/9 306	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	FUNBACT-A	CLOTRIMAZOLE + BETAMETHASONE DIPROPIONATE + NEOMYCIN SULFATE	1.0 % W/W + 0.05 % W/W + 0.5 % W/W	KREMOINT PHARMA PVT LTD. B-8, ADDITIONAL AMBERNATH M.I.D.C, OPP. ANAND NAGIAR POLICE CHECK POST, AMBERNATH (E), DIST. THANE.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	08/09/2020
3899	NDA/MAL/HDP/9 313	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GSUNATE-30	ARTESUNATE	30 MG/VIAL	BLISS INDAS LIFESCIENCE P. LTD..PLOT 73-76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 VIAL CARTON + 0.5 ML OF 5.0 %W/V SODIUM BICARBONATE VIAL + 2.5 ML OF 0.9% W/V SODIUM CHLORIDE VIAL	08/09/2020

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3900	NDA/MAL/HDP/9 314	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	GVITHER FORTE INJECTION	ARTEMETHER	80 MG/ML	BLISS INDAS LIFESCIENCE P. LTD.- PLOT 73-76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE,1.0X6.0X 1.0 ML AMPOULE	08/09/2020
3901	NDA/MAL/HDP/9 315	CENTAUR PHARMACEUTICAL S PVT. LTD	GITTOES PHARMACEUTICAL S LIMITED	ACETAMOX	ACETAZOLAMIDE	250 MG	CENTAUR PHARMACEUTICALS PVT. LTD (PLANT 1)PLOT 3,5B, 2C TIVIM INDUSTRIAL ESTATE, KARASVADA, MAPUSA, GOA 403526	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/09/2020
3902	NDA/MAL/HDP/9 316	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	TERBIDERM	TERBINAFINE HYDROCHLORIDE	1% W/W	ATCO LABS LTD,B- 18, S.I.T.E, KARACHI	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE	08/09/2020

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3903	NDA/MAL/HDP/9 318	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD	HEALTHCARE LTD.	FLOTIZOL	CLOTRIMAZOLE	1%W/W	AL FAZAL PHARMA INDUSTRIES (PVT) LTD-PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	25/09/2020
3904	NDA/MAL/HDP/9 322	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	DOLUTEGRAVIR, LAMIVUDINE AND TENOFIVIR DISOPROXIL FUMARATE TABLETS	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFIVIR DISOPROXIL FUMARATE	50 MG + 300 MG + 300 MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED (CIPLAQCIL)PLOT 1- 7, 1ST RING ROAD, LUZIRA INDUSTRIAL PARK	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER,1.0X90. 0 TABLET CONTAINER,1.0X18 0.0 TABLET CONTAINER	08/09/2020
3905	NDA/MAL/HDP/9 324	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	PROP PLUS	IBUPROFEN + PARACETAMOL	400 MG + 325 MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,10.0X1.0X1 0.0 TABLET BLISTER	08/09/2020

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3906	NDA/MAL/HDP/9 325	BESINS HEALTHCARE SA	SURGIPHARM (U) LIMITED	OESTROGEL	ESTRADIOL HEMIHYDRATE	0.06W/W	BESINS MANUFACTURING BELGIUM (BMB)GROOT BIJGAARDENSTRAAT, 128. 1620	BELGIUM	TOPICAL EXTERNAL GELS AND SOLS	1.0X1.0X80.0 G CONTAINER	08/09/2020
3907	NDA/MAL/HDP/9 327	ATCO LABORATORIES LIMITED	HARLEYS UGANDA LIMITED	OXCIN-D	MOXIFLOXACIN + DEXAMETHASON E SODIUM PHOSPHATE	0.5%W/V + 0.1% W/V	ATCO LABS LTD,B- 18, S.I.T.E, KARACHI	PAKISTAN	OPHTHALMIC DROPS	1.0X1.0X5.0 ML CONTAINER	08/09/2020
3908	NDA/MAL/HDP/9 331	BKRS PHARMA PVT. LTD.	VEERAM HEALTHCARE (U) LIMITED	PARA-BKRS	PARACETAMOL	1.0%W/V	HIGGS HEALTHCARE PVT. LIMITEDKHASRA NO. 480/1, BHATOLIKALAN BADDI, DISTT SOLAN, (H.P) - INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	26/10/2020

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3909	NDA/MAL/HDP/9345	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	FLUCONAZOLE INJECTION USP (2MG/ML)	FLUCONAZOLE	2MG/ML	ABARIS HEALTHCARE PVT. LTDSURVEY NO. 1407/11, VILLAGE RAJPUR, TAL KADI DIST. MEHSANA, GUJARAT-382740	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1X100 ML BOTTLE	22/12/2020
3910	NDA/MAL/HDP/9350	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
3911	NDA/MAL/HDP/9353	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	LUMITER DT	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	OXALIS LABS LIMITEDVILLAGE THEDA, P.O LODHIMAJRA, TEHSIL,BADDI, DIST.SOLAN, INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X6.0 TABLET BLISTER,1.0X2.0X6.0 TABLET BLISTER,1.0X30.0X6.0 TABLET BLISTER,1.0X30.0X2.0X6.0 TABLET BLISTER,1.0X1.0X12.0 TABLET BLISTER,30.0X1.0X12.0 TABLET BLISTER	09/12/2020

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3912	NDA/MAL/HDP/9 355	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	PLATINEX	CISPLATIN	1MG/ML	KHANDELWAL LABORATORIES PVT. LTDB-1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1X1X10 ML VIAL	22/12/2020
3913	NDA/MAL/HDP/9 356	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	IRIS	DESLORATADINE	5MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/12/2020
3914	NDA/MAL/HDP/9 365	HETERO BIOPHARMA LIMITED,	AIVEEN (U) LIMITED	BEVAAS 100	BEVACIZUMAB	100MG/4ML	HETERO BIOPHARMA LIMITEDSY. NO. 458 (PART), TSIIC- FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL MAHABOBNAGAR DISTRICT – 509 301, TELANGANA STATE, INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X4.0 ML VIAL	09/12/2020

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3915	NDA/MAL/HDP/9 366	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TOBRASON	TOBRAMYCIN + DEXAMETHASON E	3 MG + 1 MG/1G	AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	JORDAN	OPHTHALMIC OINTMENTS	1.0X1.0X5.0 MG TUBE	09/12/2020
3916	NDA/MAL/HDP/9 368	HETERO BIOPHARMA LIMITED,	AIVEEN (U) LIMITED	BEVAAS 400	BEVACIZUMAB	400MG/16ML	HETERO BIOPHARMA LIMITEDSY. NO. 458 (PART), TSIIIC- FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL MAHABOONAGAR DISTRICT – 509 301, TELANGANA STATE, INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X16.0 ML VIAL	09/12/2020
3917	NDA/MAL/HDP/9 370	RAINBOW LIFE SCIENCES PVT.LTD.	EUROPA HEALTHCARE (U) LTD	MONTLIV	MONTELUKAST + LEVOCETIRIZINE DIHYDROCHLORID E	10 MG+ 5 MG	GLOBELA PHARMA PVT.LTD.357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	09/12/2020

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3918	NDA/MAL/HDP/9 371	MEDINOVATION ENTERPRISES LTD	MEDINOVATION ENTERPRISES LTD	MEDSUNATE- 60	ARTESUNATE	60MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY 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
3919	NDA/MAL/HDP/9 376	KOPRAN LIMITED	TATA UGANDA LIMITED	AZ-1 500	AZITHROMYCIN DIHYDRATE	500 MG	KOPRAN LIMITED VILLAGE - SAVROLI (KHOPOLI), TALUKA - KHALAPUR, DIST. RAIGAD 410202, MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X1.0X3.0 TABLET BLISTER	09/12/2020
3920	NDA/MAL/HDP/9 377	KOPRAN LIMITED	TATA UGANDA LIMITED	AMYN DT 250	AMOXICILLIN TRIHYDRATE	250 MG	KOPRAN LIMITED VILLAGE - 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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3921	NDA/MAL/HDP/9 379	KOPRAN LIMITED	TATA UGANDA LIMITED	AMYN DT 125	AMOXICILLIN TRIHYDRATE	125 MG	KOPRAN LIMITEDVILLAGE - SAVROLI (KHOPOLI), TALUKA - KHALAPUR, DIST. RAIGAD 410202, MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X3.0X15.0 TABLET STRIP,10.0X10.0 TABLET STRIP	09/12/2020
3922	NDA/MAL/HDP/9 381	POPULATION SERVICES INTERNATIONAL, UGANDA (PSIU)	POPULATION SERVICES INTERNATIONAL - UGANDA	PRONTA 1	LEVONORGESTRE L	1.5 MG	MYLAN LABORATORIES LIMITEDPLOT 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
3923	NDA/MAL/HDP/9 383	SUN PHARMACEUTICAL INDUSTRIES LTD	STAR PHARMACEUTICAL S LTD	DOLUTEGRAVIR, LAMIVUDINE, TENOFIVIR DISOPROXIL FUMARATE TABLETS	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFIVIR DISOPROXIL FUMARATE	50 MG + 300 MG + 300 MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER,1.0X1.0 X9.0 TABLET CONTAINER	09/12/2020

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3924	NDA/MAL/HDP/9 385	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BRUZOLIN	XYLOMETAZOLINE HYDROCHLORIDE	0.05% W/V	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	NASAL SYSTEMIC DROPS	1.0X1.0X15.0 ML BOTTLE	09/12/2020
3925	NDA/MAL/HDP/9 387	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,1.0X5.0X10.0X 1.0 DOSE AMPOULE	09/12/2020
3926	NDA/MAL/HDP/9 388	CONCEPT PHARMACEUTICAL S LTD	JEET PHARMACEUTICAL S LIMITED	IRON SUCROSE INJECTION USP 20 MG/ML	FERRIC HYDROXIDE + SUCROSE	20 MG /ML	CONCEPT PHARMACEUTICALS LIMITEDKISHANPUR JAMALPUR ROORKEE DIST HARIDWAR - 247667 UTTARAKHAND, INDIA.	INDIA	PARENTERAL ORDINARY INFUSION AMPOULES	1.0X5.0X10.0 ML AMPOULE	18/12/2020

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3927	NDA/MAL/HDP/9 389	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
3928	NDA/MAL/HDP/9 393	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	LESS-K	CALCIUM POLYSTYRENE SULFONATE	5 GM/SACKET	MEGA LIFESCIENCES PUBLIC COMPANY 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/SYR UPS/DROPS	1.0X100.0X5.0 G SACHET	09/12/2020
3929	NDA/MAL/HDP/9 394	HETERO LABS LTD	AIVEEN (U) LIMITED	TEMOTERO 100	TEMOZOLOMIDE	100MG	HETERO LABS LIMITED (UNIT VI)APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGER DISTRICT ANDHRA PRADESH-509301	INDIA	ORAL SOLID ORDINARY CAPSULES	1X1X5 CAPSULE BOTTLE	22/12/2020

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3930	NDA/MAL/HDP/9 395	HETERO LABS LTD	AIVEEN (U) LIMITED	TEMOTERO 250	TEMOZOLOMIDE	250MG	HETERO LABS LIMITED (UNIT VI)APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGER DISTRICT ANDHRA PRADESH-509301	INDIA	ORAL SOLID ORDINARY CAPSULES	1X1X5 CAPSULE BOTTLE	22/12/2020
3931	NDA/MAL/HDP/9 401	BESINS HEALTHCARE SA	SURGIPHARM (U) LIMITED	UTROGESTAN	PROGESTERONE	100 MG	CYNDEA PHARMA, S.LPOLIGONO INDUSTRIAL EMILIANO REVILLA SANZ. AVDA. DE AGREDA, 31 OLVEGA 42110 (SORIA)	SPAIN	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X15.0 CAPSULE BLISTER	09/12/2020
3932	NDA/MAL/HDP/9 403	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	LARTEM	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	S KANT HEALTHCARE LIMITED1802 – 1805, G.I.D.C., PHASE III, VAPI - 396195 GUJARAT, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X24.0 TABLET BLISTER	09/12/2020

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3933	NDA/MAL/HDP/9 404	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SOFTDROPS	CARBOXYMETHYL CELLULOSE SODIUM + GLYCERIN	0.5% W/V + 0.5% W/V	CIRON DRUGS AND PHARMACEUTICALS PVT LTD .N-118, 118/1, 119, 119/1, 119/2, 113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, MAHARASHTRA STATE AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128	INDIA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML BOTTLE	09/12/2020
3934	NDA/MAL/HDP/9 408	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	ZIRIN	CETIRIZINE DIHYDROCHLORID E	10 MG	MEGA LIFESCIENCES PUBLIC COMPANY LTDPLANT 2; 515/1 MOO 4, SOI 8 BANGPOO INDUSTRIAL ESTATE PATTANA 3 ROAD, PHRAEKSA, MUEANG, SAMUTPRAKARN 10280, THAILAND	THAILAND	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X5.0X10.0 CAPSULE BLISTER	09/12/2020
3935	NDA/MAL/HDP/9 409	HETERO LABS LTD	AIVEEN (U) LIMITED	STAVANCE 500	VANCOMYCIN HYDROCHLORIDE	500 MG/VIAL	ASPIRO PHARMA LIMITEDSY. NO. 321, BIOTECH PARK, PHASE-III, KARKAPATLA, MARKOOK MANDAL, SIDDIPET DISTRICT- 502 281, TELANGANA, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X500.0 MG VIAL	09/12/2020

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3936	NDA/MAL/HDP/9 410	HETERO LABS LTD	AIVEEN (U) LIMITED	STAVANCE 1	VANCOMYCIN HYDROCHLORIDE	1G/VIAL	ASPIRO PHARMA LIMITEDSY. NO. 321, BIOTECH PARK, PHASE-III, KARKAPATLA, MARKOOK MANDAL, SIDDIPET DISTRICT- 502 281, TELANGANA, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL	09/12/2020
3937	NDA/MAL/HDP/9 411	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CONCOR AMLO 5 +5	BISOPROLOL FUMARATE + AMLODIPINE BESILATE	5MG + 5MG	EGIS PHARMACEUTICALS PLCBOKENYFOLDI UT 118-120, 1165 BUDAPEST	HUNGARY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/12/2020
3938	NDA/MAL/HDP/9 412	SAGA LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	EBASTO - 10	EBASTINE	10 MG	SAGA LIFESCIENCES LIMITEDSURVEY NO. 198/2 & 198/3, CHACHRAWADI VASNA, TA-SANAND, DIST. AHMEDABAD - 382210, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	09/12/2020

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3939	NDA/MAL/HDP/9 413	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CONCOR AMLO 10 + 5	BISOPROLOL FUMARATE + AMLODIPINE BESILATE	10MG + 5MG	EGIS PHARMACEUTICALS PLCBOKENYFOLDI UT 118-120, 1165 BUDAPEST	HUNGARY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/12/2020
3940	NDA/MAL/HDP/9 415	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CONCOR AMLO 10 + 10	BISOPROLOL FUMARATE + AMLODIPINE BESILATE	10MG + 10MG	EGIS PHARMACEUTICALS PLCBOKENYFOLDI UT 118-120, 1165 BUDAPEST	HUNGARY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/12/2020
3941	NDA/MAL/HDP/9 416	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CONCOR AMLO 5 + 10	BISOPROLOL FUMARATE + AMLODIPINE BESILATE	5MG + 10MG	EGIS PHARMACEUTICALS PLCBOKENYFOLDI UT 118-120, 1165 BUDAPEST	HUNGARY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/12/2020

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3942	NDA/MAL/HDP/9 418	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	EFAVIRENZ, LAMIVUDINE AND TENOFVIR DISOPROXIL FUMARATE TABLETS	EFAVIRENZ + LAMIVUDINE + TENOFVIR 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,1.0X90. 0 TABLET CONTAINER,1.0X18 0.0 TABLET CONTAINER	09/12/2020
3943	NDA/MAL/HDP/9 421	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MUCOSIL AM	TERBUTALINE SULFATE + GUAIFENESIN + AMBROXOL HYDROCHLORIDE + MENTHOL	1.25 MG + 50 MG + 15 MG + 2.5 MG/5 ML	RAVIAN LIFE SCIENCE PVT LTD PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	09/12/2020
3944	NDA/MAL/HDP/9 424	PHARCO B INTERNATIONAL,	GAMA PHARMACEUTICAL S (U) LIMITED	CEFAXONE 1G I.V.	CEFTRIAZONE SODIUM HYDRATE	1G	PHARCO-B INTERNATIONAL PHARMACEUTICALS 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

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3945	NDA/MAL/HDP/9 426	PHARCO B INTERNATIONAL,	GAMA PHARMACEUTICAL S (U) LIMITED	CEFAXONE 2G I.V.	CEFTRIAZONE SODIUM HYDRATE	2G	PHARCO-B INTERNATIONAL PHARMACEUTICALS 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
3946	NDA/MAL/HDP/9 428	LUPIN LIMITED	AIVEEN (U) LIMITED	RIFAMPIN AND ISONIAZID DISPERSIBLE TABLETS	RIFAMPIN + ISONIAZID	75 MG + 50 MG	LUPIN LIMITED A- 28/1 MIDC CHIKALTHANA AURANGABAD	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X14.0X6.0 TABLET STRIP	09/12/2020
3947	NDA/MAL/HDP/9 430	SAGA LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	VALK PLUS SP	ACECLOFENAC + PARACETAMOL+ SERRATIOPEPTID ASE	100 MG + 500 MG +10 MG	SAGA LIFESCIENCES LIMITEDSURVEY NO. 198/2 & 198/3, CHACHRAWADI VASNA, TA-SANAND, DIST. AHMEDABAD - 382210, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1.0X10 .0 TABLET BLISTER	09/12/2020

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3948	NDA/MAL/HDP/9 431	INTAS PHARMACEUTICAL S LIMITED	NORVIK ENTERPRISES LIMITED	NALTRAS 50	NALTREXONE HYDROCHLORIDE	50 MG	INTAS PHARMACEUTICALS LTD.PLOT NO. 457, 458, & 191/218P,VILLAGE: MATODA, TAL. SANAND, AHMEDABAD, GUJARAT, 382210 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	09/12/2020
3949	NDA/MAL/HDP/9 432	MEDISEL(K) LTD	SUPER MEDIC LTD	ECOFREE 120	ETORICOXIB	120MG	CORONA REMEDIES PVT. LTDVILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	22/12/2020
3950	NDA/MAL/HDP/9 433	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ADACIN	ADAPALENE + CLINDAMYCIN PHOSPHATE	0.1 %W/W + 1.0% W/W	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X1.0X15.0 G TUBE	09/12/2020

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3951	NDA/MAL/HDP/9 436	SAKAR HEALTHCARE PVT LTD	TATA UGANDA LIMITED	SEFIXI-200	CEFIXIME TRIHYDRATE	200MG	SAKAR HEALTHCARE PVT LIMITED PLOT 10/13 SARKHEJ- BAVLA ROAD, AHMEDABAD, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	09/12/2020
3952	NDA/MAL/HDP/9 439	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	HYFRESH	SODIUM HYALURONATE	0.2% W/V	JAMJOOM PHARMACEUTICALS CO. PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	OPHTHALMIC LIQUIDS	1.0X1.0X10.0 ML BOTTLE	18/12/2020
3953	NDA/MAL/HDP/9 440	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	XOLAMOL	DORZOLAMIDE HYDROCHLORIDE + TIMOLOL MALEATE	2%W/V + 0.5%W/V/ML	JAMJOOM PHARMACEUTICALS CO. PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	09/12/2020

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3954	NDA/MAL/HDP/9 444	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	LATANOCOM	LATANOPROST + TIMOLOL MALEATE	0.005% W/W + 0.5% W/W	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	OPHTHALMIC DROPS	1.0X1.0X2.5 ML BOTTLE	18/12/2020
3955	NDA/MAL/HDP/9 445	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	SURECURE GEL	ADAPALENE	0.1% W/W	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	TOPICAL EXTERNAL GELS AND SOLS	1X1X30 G TUBE	18/12/2020
3956	NDA/MAL/HDP/9 446	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	FUSIBACT	SODIUM FUSIDATE	2%W/W	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X15.0 G TUBE	18/12/2020

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3957	NDA/MAL/HDP/9 447	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	FUSIBACT-B	FUSIDIC ACID + BETAMETHASONE VALERATE	2% W/W + 0.1% W/W	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	09/12/2020
3958	NDA/MAL/HDP/9 448	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	ELICA	MOMETASONE FUROATE	0.1%W/W	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X30.0 G TUBE	18/12/2020
3959	NDA/MAL/HDP/9 449	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	ELICASAL	MOMETASONE FUROATE + SALICYLIC ACID	0.1% W/W + 5.0% W/W	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X30.0 G TUBE	18/12/2020

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3960	NDA/MAL/HDP/9 452	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BNOXIPARIN 40	ENOXAPARIN SODIUM	40 MG/0.4 ML	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X0.4 ML PRE- FILLED SYRINGE	09/12/2020
3961	NDA/MAL/HDP/9 453	BRAWN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BNOXIPARIN 60	ENOXAPARIN SODIUM	60 MG/0.6 ML	BRAWN LABORATORIES LIMITED13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X0.6 ML PRE- FILLED SYRINGE	09/12/2020
3962	NDA/MAL/HDP/9 455	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	BISPEC-5	SOLIFENACIN SUCCINATE	5MG	CIPLA LTD, GOA UNIT V & UNIT XL- 139, S-103&M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	09/12/2020

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3963	NDA/MAL/HDP/9 456	CIPLA LTD	ABACUS PHARMA (AFRICA) LIMITED	BISPEC-10	SOLIFENACIN SUCCINATE	10MG	CIPLA LTD, GOA UNIT V & UNIT XL- 139, S-103&M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	09/12/2020
3964	NDA/MAL/HDP/9 481	BKRS PHARMA PVT. LTD.	VEERAM HEALTHCARE (U) LIMITED	OFLO-BKRS	OFLOXACIN	0.2% W/V	HIGGS HEALTHCARE PVT. LIMITED KHASRA NO. 480/1, BHATOLIKALAN BADDI, DIST SOLAN, (H.P) - INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	09/12/2020
3965	NDA/MAL/HDP/9 490	INFUGEN PHARMA PVT. LTD.	TATA UGANDA LIMITED	IPEN-CIL	IMIPENEM + CILASTATIN	500 MG + 500 MG/VIAL	ZEISS PHARMACEUTICALS PVT LTD - PLOT 72, EPIP, PHASE 1, JHARMAJRI BADDI, 173205, DIST: SOLAN HIMACHAL PRADESH, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	09/12/2020

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3966	NDA/MAL/HDP/9 494	ZIM LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	ONDANSET ODS 8	ONDANSETRON HYDROCHLORIDE	8 MG/STRIP	ZIM LABS LTD.B 21/22, MIDC AREA, KALMESHWAR 441501, DIST- NAGPUR	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0X1.0 TABLET STRIP	24/02/2021
3967	NDA/MAL/HDP/9 500	POPULATION SERVICES INTERNATIONAL, UGANDA (PSIU)	POPULATION SERVICES INTERNATIONAL - UGANDA	MEURI	DESOGESTREL + ETHINYLESTRADI OL	150MCG + 30MCG	MYLAN LABORATORIES LIMITEDPLOT 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
3968	NDA/MAL/HDP/9 501	BESINS HEALTHCARE SA	SURGIPHARM (U) LIMITED	UTROGESTAN VAGINAL 100 MG	PROGESTERONE	100 MG	CYNDEA PHARMA, S.LPOLIGONO INDUSTRIAL EMILIANO REVILLA SANZ. AVDA. DE AGREDA, 31 OLVEGA 42110 (SORIA)	SPAIN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X15.0 CAPSULE BLISTER	24/02/2021

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3969	NDA/MAL/HDP/9 502	BESINS HEALTHCARE SA	SURGIPHARM (U) LIMITED	UTROGESTAN VAGINAL 200 MG	PROGESTERONE	200 MG	CYNDEA PHARMA, S.LPOLIGONO INDUSTRIAL EMILIANO REVILLA SANZ. AVDA. DE AGREDA, 31 OLVEGA 42110 (SORIA)	SPAIN	VAGINAL CAPSULES	1.0X1.0X7.0X1.0X8. 0 CAPSULE BLISTER	24/02/2021
3970	NDA/MAL/HDP/9 503	BESINS HEALTHCARE SA	SURGIPHARM (U) LIMITED	UTROGESTAN 200 MG SOFT CAPSULES	PROGESTERONE	200 MG	CYNDEA PHARMA, S.LPOLIGONO INDUSTRIAL EMILIANO REVILLA SANZ. AVDA. DE AGREDA, 31 OLVEGA 42110 (SORIA)	SPAIN	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X8.0X3.0X7. 0 CAPSULE BLISTER	24/02/2021
3971	NDA/MAL/HDP/9 504	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	BETA COOL DOUBLE ACTION ANTACID SUSPENSION	SODIUM ALGINATE + SODIUM BICARBONATE	(500 MG + 267 MG)/10 ML	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO LR 209/6534 MOGADISHU ROAD	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	24/02/2021

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3972	NDA/MAL/HDP/9 505	CADILA HEALTHCARE LIMITED "ZYDUS TOWER" -	ABACUS PHARMA (AFRICA) LIMITED	ODIMONT-LC	LEVOCETIRIZINE DIHYDROCHLORID E + MONTELUKAST	5 MG + 10 MG	RAVIAN LIFE SCIENCE PVT LTDPLOT 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
3973	NDA/MAL/HDP/9 506	TROIKAA PHARMACEUTICAL S LTD	ABACUS PHARMA (AFRICA) LIMITED	TROFENTYL	FENTANYL CITRATE	50 MCG/ML	TROIKAA PHARMACEUTICALS LIMITED,,C-1, SARA INDUSTRIAL ESTATE, SELAQUI, DEHRADUN-248197, UTTARAKHAND	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE	24/02/2021
3974	NDA/MAL/HDP/9 510	PLANET PHARMACEUTICAL S UGANDA LTD	PLANET PHARMACEUTICAL S UGANDA LTD	GEODERM	BETAMETHASONE DIPROPIONATE + GENTAMICIN SULFATE + CLOTRIMAZOLE	(0.5 MG + 1.0 MG + 10.0 MG)/G	KREMOINT PHARMA PVT LTD PLANT IIB-8, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST) DIST. THANE 421506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE,1.0X30.0 G TUBE	24/02/2021

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3975	NDA/MAL/HDP/9 511	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	SPASNIL FORTE TABLET	MEFENAMIC ACID + DICYCLOMINE HYDROCHLORIDE	250 MG + 10 MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/02/2021
3976	NDA/MAL/HDP/9 513	ALTHEA PHARMA PVT LTD.	JOINT MEDICAL STORE (UPMB - UCMB)	METRONIDAZOLE INFUSION BP	METRONIDAZOLE	0.5% W/V	ALTHEA PHARMA PRIVATE LIMITEDWORKS: PLOT NO. 374, SHED NO. 'E', ALPHA INDL. PARK, ATHIAWAD, DABHEL, NANI DAMAN - 396210 (U.T.), INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	24/02/2021
3977	NDA/MAL/HDP/9 514	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	BACTAFUZ	FUSIDIC ACID	2% W/W	ENCUBE ETHICALS PVT LTD PLOT C-1, MADKAIM INDUSTRIAL ESTATE, MADKAIM, POST: MARDOL, PONDA GOA-403404	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	24/02/2021

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3978	NDA/MAL/HDP/9 515	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	BACTAFUZ-B	FUSIDIC ACID + BETAMETHASONE VALERATE	2% W/W + 0.1%W/W	ENCUBE ETHICALS PVT LTD PLOT C-1, MADKAIM INDUSTRIAL ESTATE, MADKAIM, POST: MARDOL, PONDA GOA-403404	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	24/02/2021
3979	NDA/MAL/HDP/9 525	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	SPAQ-CO DISP	(SULFADOXINE + PYRIMETHAMINE) + AMODIAQUINE HYDROCHLORIDE	(250 MG + 12.5 MG) +76.5 MG	GUILIN PHARMACEUTICAL CO LTD .NO. 43, QULIDIAN ROAD, GUILIN 541004	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X1.0X4.0 TABLET BLISTER, 1.0X25.0X1.0X12.0 TABLET BLISTER	24/02/2021
3980	NDA/MAL/HDP/9 526	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	SPAQ-CO DISP	(SULFADOXINE + PYRIMETHAMINE) + AMODIAQUINE HYDROCHLORIDE	(500 MG + 25 MG) +153 MG	GUILIN PHARMACEUTICAL CO LTD .NO. 43, QULIDIAN ROAD, GUILIN 541004	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X1.0X4.0 TABLET BLISTER	24/02/2021

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3981	NDA/MAL/HDP/9 533	LUPIN LTD	AIVEEN (U) LIMITED	ISONIAZID TABLETS BP 100MG	ISONIAZID	100 MG	LUPIN LTDA-28/1, M.I.D.C., CHIKALTHANA, AURANGABAD- 431210, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	24/02/2021
3982	NDA/MAL/HDP/9 534	B&O PHARM	TRIDEM PHARMA UGANDA LIMITED	PHLORO-G	PHLOROGLUCINO L DIHYDRATE	80MG	GUILIN PHARMACEUTICAL CO LTD .NO. 43, QULIDIAN ROAD, GUILIN 541004	CHINA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X1.0X10.0 TABLET BLISTER	24/02/2021
3983	NDA/MAL/HDP/9 535	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO DURATAZ INJECTION 4.5 G	PIPERACILLIN + TAZOBACTAM	(4 G + 0.5 G)/VIAL	ARISTO PHARMACEUTICALS PVT LTD PLOT 208, NEW INDUSTRIAL AREA NO. 2, MANDIDEEP 462046 DIST. RAISEN (MP)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X4.5 G VIAL	24/02/2021

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3984	NDA/MAL/HDP/9 537	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	SENSOCAIN SPINAL 0.5% INJECTION	BUPIVACAINE HYDROCHLORIDE	5MG/ML	BROOKES PHARMA (PRIVATE) LIMITED58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X5.0X4.0 ML AMPOULE	24/02/2021
3985	NDA/MAL/HDP/9 538	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	ECZEMUS 0.1 % OINTMENT	TACROLIMUS MONOHYDRATE	0.1% W/W	BROOKES PHARMA (PRIVATE) LIMITED58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	TOPICAL EXTERNAL OINTMENTS	1.0X10.0 G TUBE	24/02/2021
3986	NDA/MAL/HDP/9 541	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	ERLOCIPI 25	ERLOTINIB HYDROCHLORIDE	25MG	CIPLA LTDUNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	24/02/2021

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3987	NDA/MAL/HDP/9 542	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	ERLOCIP 100	ERLOTINIB HYDROCHLORIDE	100MG	CIPLA LTDUNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	24/02/2021
3988	NDA/MAL/HDP/9 543	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	ERLOCIP 150	ERLOTINIB HYDROCHLORIDE	150MG	CIPLA LTDUNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	24/02/2021
3989	NDA/MAL/HDP/9 549	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	DUOSKIN	ISOCONAZOLE NITRATE + DIFLUCORTOLON E VALERATE	1% W/W + 0.1% W/W	BILIM ILAC SAN.VE TIC.A.SGEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY	TURKEY	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	04/03/2021

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3990	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
3991	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
3992	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

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3993	NDA/MAL/HDP/9 576	SAVA HEALTHCARE LIMITED -	PHILLIPS PHARMACEUTICAL S (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
3994	NDA/MAL/HDP/9 586	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	AMVA DENK 5/160 MG	AMLODIPINE + VALSARTAN	5 MG + 160 MG	BALKANPHARMA- DUPNITSA AD3, SAMOKOVSKO SHOSSE STR. 2600 DUPNITSA	BULGARIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	02/06/2021
3995	NDA/MAL/HDP/9 588	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	AMVA DENK 10/160 MG	AMLODIPINE BESILATE + VALSARTAN	10 MG + 160 MG	BALKANPHARMA- DUPNITSA AD3, SAMOKOVSKO SHOSSE STR. 2600 DUPNITSA	BULGARIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	02/06/2021

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3996	NDA/MAL/HDP/9 589	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	CLOFAZIMINE TABLETS 100MG	CLOFAZIMINE	100 MG	OXALIS LABVILLAGE THEDA, P.O. LODHIMAJRA, TEHSIL BADDI, DIST. SOLAN (HP) PIN CODE 174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	02/06/2021
3997	NDA/MAL/HDP/9 590	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	AMVA DENK 5/80 MG	AMLODIPINE BESILATE + VALSARTAN	5 MG + 80 MG	BALKANPHARMA- DUPNITSA AD3, SAMOKOVSKO SHOSSE STR. 2600 DUPNITSA	BULGARIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	02/06/2021
3998	NDA/MAL/HDP/9 591	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	AZITZOZ-500	AZITHROMYCIN DIHYDRATE	500 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	1X1X3 TABLET BLISTER	04/06/2021

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3999	NDA/MAL/HDP/9 594	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	ROSUVASTATIN DENK 10 MG	ROSUVASTATIN CALCIUM	10 MG	PHARMACEUTICAL WORKS POLPHARMA SA (ZAKLADY FARMACEUTYCZNE POLPHARMA SA)-19 PELPLINSKA STREET, 83-200 STAROGARD GDANSKI	POLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/06/2021
4000	NDA/MAL/HDP/9 595	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	ROSUVASTATIN DENK 20 MG	ROSUVASTATIN CALCIUM	20 MG	PHARMACEUTICAL WORKS POLPHARMA SA (ZAKLADY FARMACEUTYCZNE POLPHARMA SA)-19 PELPLINSKA STREET, 83-200 STAROGARD GDANSKI	POLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/06/2021
4001	NDA/MAL/HDP/9 596	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	ROSUVASTATIN DENK 5 MG	ROSUVASTATIN CALCIUM	5 MG	PHARMACEUTICAL WORKS POLPHARMA SA (ZAKLADY FARMACEUTYCZNE POLPHARMA SA)-19 PELPLINSKA STREET, 83-200 STAROGARD GDANSKI	POLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/06/2021

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4002	NDA/MAL/HDP/9 597	S KANT HEALTHCARE LTD -	ABACUS PHARMA (AFRICA) LIMITED	MALACURE	SULFADOXINE + PYRIMETHAMINE	500 MG + 25 MG	S KANT HEALTHCARE LIMITED1802 – 1805, G.I.D.C., PHASE III, VAPI - 396195 GUJARAT, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER	03/06/2021
4003	NDA/MAL/HDP/9 600	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VIVAZAC 150 MG	IRBESARTAN	150 MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/06/2021
4004	NDA/MAL/HDP/9 601	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SENERGY 5/160MG	AMLODIPINE BESYLATE + VALSARTAN	5 MG + 160 MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/06/2021

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4005	NDA/MAL/HDP/9 602	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SENERGY 10/160MG	AMLODIPINE BESYLATE + VALSARTAN	10 MG + 160 MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/06/2021
4006	NDA/MAL/HDP/9 603	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	KOCITAF	DOLUTEGRAVIR SODIUM + EMTRICITABINE + TENOFVIR ALAFENAMIDE FUMARATE	50 MG + 200 MG + 25 MG	MYLAN LABORATORIES LTD PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR - 454775; DIST; DHAR; MADHYA PRADESH;	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	02/06/2021
4007	NDA/MAL/HDP/9 609	ZIM LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	CETRIZIM L ODS	LEVOCETIRIZINE DIHYDROCHLORID E	5 MG	ZIM LABORATORIES LIMITED B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0 TABLET STRIP	02/06/2021

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4008	NDA/MAL/HDP/9 611	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	ESOMAC-40 MUPS	ESOMEPRAZOLE MAGNESIUM DIHYDRATE	40 MG	CIPLA LIMITED.PLOT NO. L-139, S-103 & M-62, VERNA INDUSTRIAL ESTATE, VERNA SALCETTE, GOA, PIN 403722	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	02/06/2021
4009	NDA/MAL/HDP/9 612	CIPLA LTD	ABACUS PHARMA (AFRICA) LIMITED	ESOMAC-20 MUPS	ESOMEPRAZOLE MAGNESIUM DIHYDRATE	20 MG	CIPLA LIMITED.PLOT NO. L-139, S-103 & M-62, VERNA INDUSTRIAL ESTATE, VERNA SALCETTE, GOA, PIN 403722	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER,1.0X3.0X10 .0 TABLET BLISTER	02/06/2021
4010	NDA/MAL/HDP/9 613	CIPLA LTD	ABACUS PHARMA (AFRICA) LIMITED	IVABEAT 5	IVABRADINE HYDROCHLORIDE	5 MG	CIPLA LTDUNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X14.0 TABLET BLISTER	02/06/2021

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4011	NDA/MAL/HDP/9 614	CIPLA LTD	ABACUS PHARMA (AFRICA) LIMITED	IVABEAT 7.5	IVABRADINE HYDROCHLORIDE	7.5 MG	CIPLA LTD UNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X14.0 TABLET BLISTER	02/06/2021
4012	NDA/MAL/HDP/9 615	ARTEPHARM CO., LTD.,	BHL HEALTHCARE LIMITED	ARTEQUICK	ARTEMISININ + PIPERAQUINE	62.5 MG + 375 MG	ARTEPHARM CO. LTD 4 ROAD STREET AVENUE ECONOMY DEVELOPMENT ZONE OF FENGSHUN COUNTY MEIZHOU CITY GUANGDONG PRONVINCE	CHINA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	02/06/2021
4013	NDA/MAL/HDP/9 619	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROMIDE PLUS	TROPICAMIDE + PHENYLEPHRINE HYDROCHLORIDE	0.8% W/V + 5%W/V	AUROLAB LIMITED NO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU INDIA	INDIA	OPHTHALMIC LIQUIDS	1.0X1.0X5.0 ML CONTAINER	02/06/2021

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4014	NDA/MAL/HDP/9 620	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICAL S LTD	DOLUTEGRAVIR TABLETS	DOLUTEGRAVIR SODIUM	50 MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	02/06/2021
4015	NDA/MAL/HDP/9 621	FDC LIMITED -	AIVEEN (U) LIMITED	ELECTRAL-Z KIT	ZINC SULPHATE MONOHYDRATE + (SODIUM CHLORIDE + POTASSIUM CHLORIDE + SODIUM CITRATE + ANHYDROUS GLUCOSE)	20 MG + (2.6 G + 1.5 G + 2.9 G + 13.5 G)/SACHET	FDC LTD.L-56&L-57, PHASE II- D, VERNA INDUSTRIAL ESTATE, VERNA-403 722, SALCETE, GOA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X1.0X10.0 TABLET BLISTER,1.0X2.0X21 .8 G SACHET COMBIPACK	02/06/2021
4016	NDA/MAL/HDP/9 624	ADCOCK INGRAM LIMITED	SURGIPHARM (U) LIMITED	ADCO-IBUPROFEN 400 MG	IBUPROFEN	400 MG	ADCOCK INGRAM LIMITED 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE 560099, KARNATAKA STATE, INDIA	INDIA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X1.0X12.0 TABLET BLISTER	02/06/2021

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4017	NDA/MAL/HDP/9 625	ACME FORMULATION PVT. LTD.	POPULATION SERVICES INTERNATIONAL - UGANDA	AVERTISO	MISOPROSTOL	200 MCG	ACME FORMULATION PVT. LTDROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X4.0 TABLET BLISTER	02/06/2021
4018	NDA/MAL/HDP/9 626	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	BIKTARVY	BICTEGRAVIR SODIUM + EMTRICITABINE + TENOFVIR 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
4019	NDA/MAL/HDP/9 628	UNICHEM LABORATORIES LIMITEDV	EUROPA HEALTHCARE (U) LTD	IMPLIFY 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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4020	NDA/MAL/HDP/9 629	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DECOZAL	XYLOMETAZOLINE HYDROCHLORIDE	0.5 MG/ML	AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	JORDAN	NASAL SYSTEMIC METERED-DOSE LIQUIDS	1.0X1.0X10.0 ML BOTTLE	02/06/2021
4021	NDA/MAL/HDP/9 631	DAWA LIMITED	SUPER MEDIC LTD	DAWASOLONE	PREDNISOLONE SODIUM PHOSPHATE	5 MG/5 ML	DAWA LIMITED PLOT NO. 7879/8 BABADOGO ROAD, RUARAKA P. O. BOX 16633-00620 NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X60.0 ML BOTTLE	02/06/2021
4022	NDA/MAL/HDP/9 632	AGIO PHARMACEUTICAL S LIMITED	ROYAL PHARMA 2011 LIMITED	CANISON VAGINAL 100	CLOTRIMAZOLE	100 MG	AGIO PHARMACEUTICALS LIMITED.T- 81, 82, MIDC, BHOSARI, PUNE - 411 026 INDIA	INDIA	VAGINAL TABLETS	1.0X1.0X6.0 TABLET STRIP	02/06/2021

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4023	NDA/MAL/HDP/9 633	AGIO PHARMACEUTICAL S LIMITED	ROYAL PHARMA 2011 LIMITED	AGILAX	LACTULOSE SOLUTION	3.35G/5ML	AGIO PHARMACEUTICALS LIMITED.T- 81, 82, MIDC, BHOSARI, PUNE - 411 026 INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE	02/06/2021
4024	NDA/MAL/HDP/9 634	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
4025	NDA/MAL/HDP/9 636	ALTHEA PHARMA PVT LTD.	JOINT MEDICAL STORE (UPMB - UCMB)	ALTHEMOL	PARACETAMOL	1.0 % W/V (1G/100 ML)	ALTHEA PHARMA PRIVATE LIMITEDWORKS: PLOT NO. 374, SHED NO. 'E', ALPHA INDL. PARK, ATHIAWAD, DABHEL, NANI DAMAN - 396210 (U.T.), INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	02/06/2021

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4026	NDA/MAL/HDP/9 637	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
4027	NDA/MAL/HDP/9 638	LUPIN LIMITED-	AIVEEN (U) LIMITED	RIFAMPICIN AND ISONIAZID TABLETS	RIFAMPICIN + ISONIAZID	150 MG + 75 MG	LUPIN LTDA-28/1, M.I.D.C., CHIKALTHANA, AURANGABAD- 431210, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X24.0X28.0 TABLET BLISTER	02/06/2021
4028	NDA/MAL/HDP/9 639	ZOTA HEALTHCARE LTD	HARLEYS UGANDA LIMITED	ZOMEPR-ES-40	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40 MG	ZOTA HEALTHCARE LIMITEDPLOT 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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4029	NDA/MAL/HDP/9 640	BERLIN-CHEMIE AG -	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	PRILIGY 30 MG	DAPOXETINE HYDROCHLORIDE	30 MG	MENARINI - VON HEYDEN GMBHLEIPZIGER STRABE 7-13, 01097 DRESDEN	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	02/06/2021
4030	NDA/MAL/HDP/9 641	BERLIN-CHEMIE AG -	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	PRILIGY 60 MG	DAPOXETINE HYDROCHLORIDE	60 MG	MENARINI - VON HEYDEN GMBHLEIPZIGER STRABE 7-13, 01097 DRESDEN	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	02/06/2021
4031	NDA/MAL/HDP/9 642	GLENMARK PHARMACEUTICAL S LTD	ABACUS PHARMA (AFRICA) LIMITED	OFLOMIL	AMOROLFINE HYDROCHLORIDE	5% W/V	GLENMARK PHARMACEUTICALS LTD .PLOT E-37, 39, D ROAD, MIDC, SATPUR, NASHIK 422007, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X1.0X2.5 ML VIAL + 1*12, ISOPROPYL ALCOHOL 70% SWAB SACHETS	03/06/2021

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4032	NDA/MAL/HDP/9 643	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	ABACAVIR (AS SULFATE) AND LAMIVUDINE TABLETS	ABACAVIR SULFATE + LAMIVUDINE	600MG + 300 MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X90.0 TABLET CONTAINER	02/06/2021
4033	NDA/MAL/HDP/9 645	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	HALOPERIDOL INJECTION BP 5 MG/ML	HALOPERIDOL	5 MG/ML	SWISS PARENTERALS PVT LTD ..809, KERALA INDUSTRIAL ESTAE, GIDC NEAR BAVLA, AHMEDABAD 382220, GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE,1.0X10.0 X1.0 ML AMPOULE	02/06/2021
4034	NDA/MAL/HDP/9 648	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	FUSIBACT CREAM	FUSIDIC ACID	2%W/W	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	TOPICAL EXTERNAL CREAMS	1X1X15 G TUBE	04/06/2021

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4035	NDA/MAL/HDP/9 651	PT SANBE FARMA	MEDVIN PHARMA LIMITED	SANTOCYN	OXYTOCIN	10 IU/ML	PT SANBE FARMA UNIT 3.JL INDUSTRI CIMAREME NO.8 PADALARANG 40533 BANDUNG	INDONESIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE	02/06/2021
4036	NDA/MAL/HDP/9 652	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICAL S LTD	LAMIVUDINE AND TENOFIVIR DISOPROXIL FUMARATE 300 MG/300 MG TABLETS	LAMIVUDINE + TENOFIVIR DISOPROXIL FUMARATE	300 MG + 300 MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BLISTER	02/06/2021
4037	NDA/MAL/HDP/9 653	LABORATE PHARMACEUTICAL S INDIA LIMITED	HEALTHCARE LTD.	FERROUS SULPHATE WITH FOLIC ACID TABLETS	FERROUS SULPHATE + FOLIC ACID	60 MG + 0.6 MG	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	02/06/2021

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4038	NDA/MAL/HDP/9 655	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	METOCLOPRAMI DE INJECTION BP 5 MG/ML	METOCLOPRAMI DE HYDROCHLORIDE	5 MG/ML	PSYCHOTROPICS INDIA LTD PLOT NO. 12 & 12A, INDUSTRIAL PARK-II, PHASE-1, VILLAGE SALEMPUR, MEHDOOD-2 HARIDWAR-249403, UTTARAKHAND INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE	02/06/2021
4039	NDA/MAL/HDP/9 663	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	POVIREN	POVIDONE + IODINE	10% W/V	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X200.0 ML BOTTLE, 1.0X1000.0 ML BOTTLE	02/06/2021
4040	NDA/MAL/HDP/9 665	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYNAC-SP	ACECLOFENAC + PARACETAMOL + SERRATIOPEPTID ASE	100 MG + 325 MG + 15 MG	RAVIAN LIFE SCIENCE PVT. LIMITED PLOT NO. 34, SECTOR: 8A, SIDCUL, IIE, HARIDWAR - 249403, UTTARAKHAND	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/06/2021

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4041	NDA/MAL/HDP/9 666	SCOTT-EDIL PHARMACIA LTD.,	ROYAL PHARMA 2011 LIMITED	VOLIGESIC-GEL	DICLOFENAC DIETHYLAMINE	1.0 % W/W	SCOTT-EDIL PHARMACIA LTD (UNIT I)56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X1.0X30.0 G TUBE	04/06/2021
4042	NDA/MAL/HDP/9 667	NATIONAL PHARMACEUTICAL INDUSTRIES CO.	MEDVIN PHARMA LIMITED	SPECTROMAX 500	CLARITHROMYCIN	500MG	NATIONAL PHARMACEUTICAL INDUSTRIES COMPANY OMANP.O.BOX 120, RUSAYL, POSTAL CODE-124, SULTANATE OF OMAN	OMAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X2X7 TABLET BLISTER	04/06/2021
4043	NDA/MAL/HDP/9 668	LABORATE PHARMACEUTICAL S INDIA LIMITED	HEALTHCARE LTD.	AZILAB-200	AZITHROMYCIN DIHYDRATE	200MG/5ML	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X30.0 ML CONTAINER + 30 ML WFI IN LDPE CONTAINER	02/06/2021

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4044	NDA/MAL/HDP/9 669	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	ZOCOLD	PARACETAMOL + CHLORPHENAMIN E MALEATE + PHENYLEPHRINE HYDROCHLORIDE	500 MG + 2 MG + 5 MG	ZOTA HEALTHCARE LIMITEDPLOT 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
4045	NDA/MAL/HDP/9 670	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	CDGREL-75	CLOPIDOGREL BISULFATE	75MG	ZOTA HEALTHCARE LIMITEDPLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY SATTION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X3X10 TABLET BLISTER	04/06/2021
4046	NDA/MAL/HDP/9 671	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	RISOPINE	CARBAMAZEPINE	200 MG	SUNRISE INTERNATIONAL LABS LTD PLOT NO. 100, LANE-5, SECTOR-II, PHASE-II, IDA, CHERLAPALLY INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	02/06/2021

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4047	NDA/MAL/HDP/9 672	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	NASO B12	METHYLCOBALA MIN	250 MCG/ACTUATION	TROIKAA PHARMACEUTICALS LIMITED..SANAND - KADI ROAD, THOL, CITY: THOL - 382 728, DIST. MEHSANA, GUJARAT STATE - INDIA	INDIA	NASAL SYSTEMIC UNIT DOSE AEROSOLS	1.0X1.0X2.3 ML BOTTLE	02/06/2021
4048	NDA/MAL/HDP/9 675	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	OD-TAM 0.4	TAMSULOSIN HYDROCHLORIDE	0.4 MG	AUROBINDO PHARMA LTD, UNIT VIISY. NO. 411/P, 425/P, 434/P, 435/P & 458/P, PLOT NO. S1 (PART), SPECIAL ECONOMIC ZONE (SEZ), 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	04/06/2021
4049	NDA/MAL/HDP/9 678	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	AXABAN-DENK 2.5 MG	APIXABAN	2.5 MG	COMBINO PHARM (MALTA) LIMITEDHF60 HAL FAR INDUSTRIAL ESTATE BBG3000	MALTA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X60.0 TABLET CONTAINER	02/06/2021

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4050	NDA/MAL/HDP/9 679	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	AXABAN-DENK 5 MG	APIXABAN	5MG	COMBINO PHARM (MALTA) LIMITEDHF60 HAL FAR INDUSTRIAL ESTATE BBG3000	MALTA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X60.0 TABLET CONTAINER	02/06/2021
4051	NDA/MAL/HDP/9 681	SYNOKEM PHARMACEUTICAL S 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
4052	NDA/MAL/HDP/9 683	GLOBELA PHARMA PVT. LTD.	ROYAL PHARMA 2011 LIMITED	CAPTOGLO	CAPTOPRIL	25 MG	GLOBELA PHARMA PVT.LTD.357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1X10X10 TABLET STRIP,	23/06/2021

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4053	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
4054	NDA/MAL/HDP/9713	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
4055	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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4056	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
4057	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
4058	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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4059	NDA/MAL/HDP/9 722	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	SEKROL 30 MG/5 ML	AMBROXOL HYDROCHLORIDE	30 MG/5 ML	BILIM ILAC SAN.VE TIC.A.SGEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY	TURKEY	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X150.0 ML BOTTLE	02/06/2021
4060	NDA/MAL/HDP/9 723	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	SEKROL 15MG/5 ML	AMBROXOL HYDROCHLORIDE	15MG/5ML	BILIM ILAC SAN.VE TIC.A.SGEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY	TURKEY	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	05/10/2021
4061	NDA/MAL/HDP/9 725	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	MOCIN	MOXIFLOXACIN HYDROCHLORIDE	0.5%W/V	ABACUS PARENTERAL DRUGS LTD (APDL)PLOT 114, BLOCK 191, KINGA - MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML VIAL	05/10/2021

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4062	NDA/MAL/HDP/9 726	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
4063	NDA/MAL/HDP/9 728	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
4064	NDA/MAL/HDP/9 729	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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4065	NDA/MAL/HDP/9731	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MELANOV-M	GLICLAZIDE + METFORMIN HYDROCHLORIDE	80MG + 500MG	MICRO LABS LIMITED .92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	05/10/2021
4066	NDA/MAL/HDP/9747	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
4067	NDA/MAL/HDP/9748	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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4068	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
4069	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
4070	NDA/MAL/HDP/9756	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	ORILAM ODT-25	LAMOTRIGINE	25MG	MICRO LABS LIMITED .,92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	05/10/2021

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4071	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
4072	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
4073	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

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4074	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
4075	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
4076	NDA/MAL/HDP/9762	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	ADVANTEC	CANDESARTAN CILEXETIL + HYDROCHLOROT HIAZIDE	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

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4077	NDA/MAL/HDP/9 763	RAINE INDUSTRIES	HEALTH LINK PHARMACY LIMITED	ROLXIN 40/320	DIHYDROARTEMI SININ + PIPERAQUINE PHOSPHATE	40 MG + 320 MG	EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X9.0 TABLET BLISTER	05/10/2021
4078	NDA/MAL/HDP/9 765	PANACEA BIOTEC LTD	VITACARE LIMITED	LIVOLUK	LACTULOSE	10.0 G/15 ML	PANACEA BIOTEC PHARMA LIMITED MALPURI BADDI, DISTRICT SOLAN, HIMACHAL PRADESH-173205 - INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE, 1.0X450.0 ML BOTTLE	05/10/2021
4079	NDA/MAL/HDP/9 766	S KANT HEALTHCARE LTD -	ABACUS PHARMA (AFRICA) LIMITED	NEOMYCIN SULFATE CREAM USP	NEOMYCIN SULPHATE	0.5%W/W	S KANT HEALTHCARE LIMITED 1802 – 1805, G.I.D.C., PHASE III, VAPI - 396195 GUJARAT, INDIA.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	05/10/2021

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4080	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
4081	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
4082	NDA/MAL/HDP/9773	GLOBELA PHARMA PVT. LTD.	SHREEJI CARE LIMITED	LOPERAGLOBE	LOPERAMIDE HYDROCHLORIDE	2MG	GLOBELA PHARMA PVT.LTD.357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	11/10/2021

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4083	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
4084	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
4085	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

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4086	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
4087	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
4088	NDA/MAL/HDP/9779	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	EYLEA	AFLIBERCEPT	40 MG/ML	BAYER AG, BERLINMULLERSTRASSE 178, 13353 BERLIN - GERMANY	GERMANY	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL	05/10/2021

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4089	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/SYR UPS/DROPS	1.0X1.0X50.0 ML BOTTLE	12/10/2021
4090	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/SYR UPS/DROPS	1.0X1.0X50.0 ML BOTTLE	12/10/2021
4091	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 ECONOMIC ZONE, MIHAN, NAGPUR 441108, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE	05/10/2021

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4092	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
4093	NDA/MAL/HDP/9786	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	VAROXA-20	RIVAROXABAN	20MG	MICRO LABS LIMITED .92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	05/10/2021
4094	NDA/MAL/HDP/9790	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

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4095	NDA/MAL/HDP/9791	IMPACT RH360	UNITED HEALTHCARE DISTRIBUTORS LTD	AVIBELA	LEVONORGESTREL	52 MG/ SYSTEM	ODYSSEA PHARMA SPRLRUE DU TRAVAIL 16, 4460 GRACE-HOLLOGNE	BELGIUM	VAGINAL INTRA UTERINE DEVICES	1.0X1.0X52.0 MG DEVICE	05/10/2021
4096	NDA/MAL/HDP/9792	ACINO AG	LABOREX UGANDA LIMITED	NBAXO 500 G IV	MEROPENEM TRIHYDRATE	500MG/VIAL	DEMO SA21ST KM NATIONAL ROAD, ATHENS, LAMIA 14568 KRYONERI, ATHENS	GREECE	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X500.0 MG VIAL	05/10/2021
4097	NDA/MAL/HDP/9793	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

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4098	NDA/MAL/HDP/9794	VERVE HUMAN CARE LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	VERMOR-10	MORPHINE SULPHATE	10MG/ML	VERVE HUMAN CARE LABORATORIES PLOT 15A, PHARMACY, SELAQUI DEHRADUN-248011, UTTARAKHAND	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X1.0 ML AMPOULE	05/10/2021
4099	NDA/MAL/HDP/9796	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
4100	NDA/MAL/HDP/9797	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	TRAMASURE-100	TRAMADOL HYDROCHLORIDE	100 MG/2ML	MANKIND PHARMA LTD.VILLAGE KISHANPURA, POAMTA SAHI DISTRICT SIRMOUR HIMACHAL PRADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1X1X4X2 ML AMPOULE	12/10/2021

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4101	NDA/MAL/HDP/9 801	CIPLA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LENOSIDE 10	LENALIDOMIDE	10MG	CIPLA LTDUNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X7.0 CAPSULE BLISTER	05/10/2021
4102	NDA/MAL/HDP/9 802	CIPLA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LENOSIDE 15	LENALIDOMIDE	15MG	CIPLA LTDUNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X7.0 CAPSULE BLISTER	05/10/2021
4103	NDA/MAL/HDP/9 803	CIPLA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LENOSIDE 25	LENALIDOMIDE	25MG	CIPLA LTDUNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X7.0 CAPSULE BLISTER	05/10/2021

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4104	NDA/MAL/HDP/9 804	LABORATOIRE AGUETTANT	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	ATROPINE SULFATE AGUETTANT	ATROPINE SULFATE	0.5MG/5ML	LABORATOIRE AGUETTANT1 RUE ALEXANDER FLEMING 69007, LYON - FRANCE	FRANCE	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X10.0X5.0 ML PRE- FILLED SYRINGE	05/10/2021
4105	NDA/MAL/HDP/9 807	LABORATOIRE AGUETTANT	PHILLIPS PHARMACEUTICAL S (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
4106	NDA/MAL/HDP/9 809	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	REVENTA	ALENDRONATE SODIUM	70MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	29/09/2021

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4107	NDA/MAL/HDP/9 810	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	MONTIGET	MONTELUKAST SODIUM	4MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X1.0X7.0X2.0 TABLET BLISTER	29/09/2021
4108	NDA/MAL/HDP/9 815	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	ADVANT	CANDESARTAN	8MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1X2X10 TABLET BLISTER	29/09/2021
4109	NDA/MAL/HDP/9 816	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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4110	NDA/MAL/HDP/9 817	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	LARINEX	DESLORATIDINE	5MG	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1X1X10 TABLET BLISTER	29/09/2021
4111	NDA/MAL/HDP/9 818	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	CYTOPAN	DICLOFENAC / MISOPROSTOL	75MG/200MCG	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
4112	NDA/MAL/HDP/9 819	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	CYTOPAN	DICLOFENAC SODIUM + MISOPROSTOL	50MG + 200MCG	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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4113	NDA/MAL/HDP/9 820	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	PHENYTOIN INJECTION BP 50 MG/ML, 5 ML	PHENYTOIN SODIUM	50 MG/ML	SWISS PARENTERALS PVT LTD 809 KERALA INDUSTRIAL ESTATE GIDC NR. BAVLA DIST. AHMEDABAD- 380220 GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X5.0 ML AMPOULE	05/10/2021
4114	NDA/MAL/HDP/9 821	JERUSALEM PHARMACEUTICAL S CO. LIMITED	GAMA PHARMACEUTICAL S (U) LIMITED	FRINASE NASAL SPRAY	FLUTICASONE PROPIONATE	50 MCG/0.1 ML (ONE ACTUATION)	JERUSALEM PHARMACEUTICALS CO. LTDAL-BIREH RAMALLAH INDUSTRIAL ZONE, AL-BIREH NABLUS ROAD, P.O. BOX: 3570 PALESTINE	PALESTINE	NASAL TOPICAL SPRAYS WITHOUT GAS	1.0X1.0X120.0 DOSE CONTAINER	05/10/2021
4115	NDA/MAL/HDP/9 823	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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4116	NDA/MAL/HDP/9 827	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	CAPEMAX 500	CAPECITABINE	500MG	INTAS PHARMACEUTICALS LTD.PLOT NO. 457, 458, & 191/218P,VILLAGE: MATODA, TAL. SANAND, AHMEDABAD, GUJARAT, 382210 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	11/10/2021
4117	NDA/MAL/HDP/9 828	SWISS PARENTERALS LTD	SHREEJI PHARMACEUTICAL S LIMITED	OXYTOCIN INJECTION BP 10 IU/ML	OXYTOCIN	10 IU/ML	SWISS PARENTERALS PVT LTD ..809, KERALA INDUSTRIAL ESTAE, GIDC NEAR BAVLA, AHMEDABAD 382220, GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0X1.0 ML AMPOULE	05/10/2021
4118	NDA/MAL/HDP/9 829	RENATA LIMITED	MARIE STOPES UGANDA LIMITED	WELL-PLAN	LEVONORGESTRE L + ETHINYLESTRADI OL	0.15MG + 0.03 MG	RAJENDRAPUR POTENT PRODUCT FACILITY (RPPF), RENATA LIMITEDNOYAPARA, BHAWAL MIRZAPUR, RAJENDRAPUR, GAZIPUR 1700 - BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY COATED TABLETS	1.0X1.0X28.0 TABLET BLISTER	05/10/2021

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4119	NDA/MAL/HDP/9 831	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ABACAVIR (AS SULFATE) AND LAMIVUDINE DISPERSIBLE TABLETS 120/60 MG	ABACAVIR SULFATE + LAMIVUDINE	120 MG + 60 MG	CIPLA LTD ,.PLOT NO. A-33, A-2 (UNIT 1), A42 (UNIT II), MIDC PATALGANGA, DISTRICT-RAIGAD MAHARASHTRA, 410220 INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X30.0 TABLET BOTTLE	05/10/2021
4120	NDA/MAL/HDP/9 834	ABACUS PARENTERAL DRUGS LTD (APDL)	ABACUS PARENTERAL DRUGS LIMITED	TFEN	KETOTIFEN FUMARATE	0.025%W/V	ABACUS PARENTERAL DRUGS LTD (APDL)PLOT 114, BLOCK 191, KINGA - MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML VIAL	08/12/2021
4121	NDA/MAL/HDP/9 835	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	METAPROMIDE	METOCLOPRAMI DE HYDROCHLORIDE	10 MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/12/2021

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4122	NDA/MAL/HDP/9 836	WALLACE PHARMACEUTICAL S PVT. LTD	STAR PHARMACEUTICAL S LTD	DIOVOL FORTE SUSPENSION	ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE	300MG + 250MG + 40MG	WALLACE PHARMACEUTICALS PVT LTDBHATIAN, NALAGARH, DIST. SOLAN HP 174101	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X170.0 ML BOTTLE	19/01/2022
4123	NDA/MAL/HDP/9 839	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	DOLUTEGRAVIR AND LAMIVUDINE TABLETS 50 MG / 300 MG	DOLUTEGRAVIR SODIUM + LAMIVUDINE	50 MG + 300 MG	CIPLA LTD UNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER, 1.0X90. 0 TABLET CONTAINER	16/12/2021
4124	NDA/MAL/HDP/9 842	LABORATOIRE AGUETTANT	PHILLIPS PHARMACEUTICAL S (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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4125	NDA/MAL/HDP/9 843	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	HACTOSEC	LEVODROPROPIZI NE	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
4126	NDA/MAL/HDP/9 845	ALTHEA PHARMA PVT LTD.	JOINT MEDICAL STORE (UPMB - UCMB)	ALTLEVO	LEVOFLOXACIN HEMIHYDRATE	500MG/100ML	ALTHEA PHARMA PRIVATE LIMITEDWORKS: PLOT NO. 374, SHED NO. 'E', ALPHA INDL. PARK, ATHIAWAD, DABHEL, NANI DAMAN - 396210 (U.T.), INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	08/12/2021
4127	NDA/MAL/HDP/9 846	GLOBELA PHARMA PVT. LTD.	TATA UGANDA LIMITED	SQUAM	DIHYDROARTEMI SININ + PIPERAQUINE PHOSPHATE	400MG + 320MG	GLOBELA PHARMA PVT.LTD.357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X1X9 TABLET BLISTER,	16/12/2021

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4128	NDA/MAL/HDP/9 848	ALTHEA PHARMA PVT LTD.	JOINT MEDICAL STORE (UPMB - UCMB)	STERILIZED WATER FOR INJECTION	WATER FOR INJECTION	N/A	ALTHEA PHARMA PRIVATE LIMITEDWORKS: PLOT NO. 374, SHED NO. 'E', ALPHA INDL. PARK, ATHIAWAD, DABHEL, NANI DAMAN - 396210 (U.T.), INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X10.0 ML AMPOULE	08/12/2021
4129	NDA/MAL/HDP/9 849	HETERO BIOPHARMA LIMITED,	AIVEEN (U) LIMITED	PAMERA 40	ADALIMUMAB (R- DNA ORIGIN)	40MG/ SYRINGE	HETERO BIOPHARMA LIMITEDSY. NO. 458 (PART), TSIIC- 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
4130	NDA/MAL/HDP/9 850	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	ZEDGRA 50	SILDENAFIL CITRATE	50 MG	ZOTA HEALTHCARE LIMITEDPLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY SATTION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1X1X4 TABLET BLISTER	16/12/2021

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4131	NDA/MAL/HDP/9 853	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	MYCOREN V	NYSTATIN	100,000 IU	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	PESSARIES	1.0X1.0X15.0 PESSARY BLISTER	08/12/2021
4132	NDA/MAL/HDP/9 854	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	FLUZOLE	FLUCONAZOLE	200MG	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X4.0 CAPSULE STRIP	08/12/2021
4133	NDA/MAL/HDP/9 856	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	LARTEM DISPERSIBLE	ARTEMETHER + LUMEFANTRINE	20MG +120MG	S KANT HEALTHCARE LIMITED 1802 – 1805, G.I.D.C., PHASE III, VAPI - 396195 GUJARAT, INDIA.	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X6.0 TABLET BLISTER	16/12/2021

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4134	NDA/MAL/HDP/9 858	VIIV HEALTHCARE UK LTD-	UNITED HEALTHCARE DISTRIBUTORS LTD	TIVICAY 25MG	DOLUTEGRAVIR SODIUM	25MG	GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS)PRIORY STREET, WARE, SG12 ODJ	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	08/12/2021
4135	NDA/MAL/HDP/9 859	VIIV HEALTHCARE UK LTD-	UNITED HEALTHCARE DISTRIBUTORS LTD	TIVICAY 10MG	DOLUTEGRAVIR SODIUM	10MG	GLAXO WELLCOME S.AAVENIDA EXTREMADURA 3, 09400 ARANDA DE DUERO - SPAIN GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS)PRIORY STREET, WARE, SG12 ODJ	SPAIN UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	08/12/2021
4136	NDA/MAL/HDP/9 860	THE UNITED PHARMACEUTICAL S 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

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4137	NDA/MAL/HDP/9 864	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	EFAVIRENZ, LAMIVUDINE AND TENOFVIR DISOPROXIL FUMARATE TABLETS, 400 MG / 300 MG / 300 MG	EFAVIRENZ, LAMIVUDINE AND TENOFVIR DISOPROXIL FUMARATE	400MG+300MG+3 00MG	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
4138	NDA/MAL/HDP/9 865	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	PINFOL	FOLIC ACID	5MG	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1X10X10 TABLET BLISTER	21/12/2021
4139	NDA/MAL/HDP/9 866	VIIV HEALTHCARE UK LTD-	UNITED HEALTHCARE DISTRIBUTORS LTD	JULUCA 50MG/25MG	DOLUTEGRAVIR SODIUM + RILPIVIRINE HYDROCHLORIDE	50MG + 25MG	GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS)PRIORY STREET, WARE, SG12 ODJ	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	08/12/2021

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4140	NDA/MAL/HDP/9 867	ASTRA PHARMA UGANDA LTD	ASTRA PHARMA (U) LIMITED	CEFTRIAZONE	CEFTRIAZONE SODIUM	1G	INJECT CARE PARENTERALS PVT LTD PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195 CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHANG) CO. LTD NO. 88 YANGZI ROAD, SHIJIAZHANG CITY, HEBEI PROVINCE, (WORKSHOP 402)CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL,1.0X10.0X1.0 G VIAL	21/12/2021
4141	NDA/MAL/HDP/9 872	SAGA LIFESCIENCES LTD	ABACUS PHARMA (AFRICA) LIMITED	COL-COL	PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + CHLORPHENIRAM INE MALEATE USP + CAFFEINE ANHYDROUS	500MG + 5MG + 2MG + 15MG	SAGA LIFESCIENCES LIMITED SURVEY NO. 198/2 & 198/3, CHACHRAWADI VASNA, TA-SANAND, DIST. AHMEDABAD - 382210, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X4.0 TABLET BLISTER,1.0X10.0X1 0.0 TABLET BLISTER	08/12/2021
4142	NDA/MAL/HDP/9 875	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	TALIMUS 0.1%	TACROLIMUS	0.1% W/W	AJANTA PHARMA LIMITED MIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X10.0 G TUBE	08/12/2021

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4143	NDA/MAL/HDP/9 876	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
4144	NDA/MAL/HDP/9 877	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	LACOMA-T	LATANOPROST + TIMOLOL MALEATE	(50MCG + 5MG)/ML	CIRON DRUGS AND PHARMACEUTICALS PVT LTD .N-118, 118/1, 119, 119/1, 119/2, 113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, MAHARASHTRA STATE	INDIA	OPHTHALMIC DROPS	1.0X1.0X2.5 ML BOTTLE	08/12/2021
4145	NDA/MAL/HDP/9 878	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	LACOMA	LATANOPROST	0.005%W/V	CIRON DRUGS AND PHARMACEUTICALS PVT LTD .N-118, 118/1, 119, 119/1, 119/2, 113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, MAHARASHTRA STATE	INDIA	OPHTHALMIC DROPS	1.0X1.0X2.5 ML BOTTLE	08/12/2021

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4146	NDA/MAL/HDP/9 879	LABORATE PHARMACEUTICAL S INDIA LIMITED	HEALTHCARE LTD.	AMILAB-500	AMIKACIN SULFATE	500MG/2 ML	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X2.0 ML VIAL	08/12/2021
4147	NDA/MAL/HDP/9 881	HETERO LABS LTD	AIVEEN (U) LIMITED	DOLUTEGRAVIR, EMTRICITABINE AND TENOFOVIR ALAFENAMIDE TABLETS 50MG/200MG/25 MG	DOLUTEGRAVIR SODIUM + EMTRICITABINE + TENOFOVIR ALAFENAMIDE HEMIFUMARATE	50MG+200MG+25 MG	HETERO LABS LIMITED (UNIT III)...22-110, I.D.A, JEEDIMETLA, HYDERABAD-500 055, ANDHRA PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	08/12/2021
4148	NDA/MAL/HDP/9 882	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	KAMAGRA CT 50	SILDENAFIL CITRATE	50MG	AJANTA PHARMA LIMITEDAJANTA PHARMA LIMITED B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	08/12/2021

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4149	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
4150	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
4151	NDA/MAL/HDP/9888	GLOBELA PHARMA PVT. LTD.	SHREEJI CARE LIMITED	GLOMET 200	METRONIDAZOLE	200MG	GLOBELA PHARMA PVT.LTD.357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	08/12/2021

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4152	NDA/MAL/HDP/9 889	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	MOMADERM	MOMETASONE FUROATE	0.1%W/W	AJANTA PHARMA LIMITEDMIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	08/12/2021
4153	NDA/MAL/HDP/9 897	MEDOPHARM	PLANET PHARMACEUTICAL S UGANDA LTD	CO-TRIMOXAZOLE TABLETS BP	TRIMETHOPRIM + SULPHAMETHOX AZOLE	400MG + 80MG	MEDOPHARM PVT LTD. 50, KAYARAMBEDU VILLAGE, GUDUVANCHERY VILLAGE, 603 203	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	11/12/2021
4154	NDA/MAL/HDP/9 899	MEDICAL UNION PHARMACEUTICAL S.	KARURI PHARMACEUTICAL S LTD.	MUCOSOL ADULT SYRUP	CARBOCYSTEINE	250MG/5ML	MEDICAL UNION PHARMACEUTICAL CO.PLANT: ABU- SULTAN, ISMAILIA, EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X120.0 ML BOTTLE	08/12/2021

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4155	NDA/MAL/HDP/902	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
4156	NDA/MAL/HDP/903	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
4157	NDA/MAL/HDP/904	MEDOPHARM PRIVATE LIMITED	VITACARE LIMITED	CLEDOMOX 228.5 DT	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	200 MG + 28.5 MG	MEDOPHARM PVT LTD. 50, KAYARAMBEDU VILLAGE, GUDUVANCHERY VILLAGE, 603 203	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X2.0X10.0 TABLET STRIP	11/12/2021

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4158	NDA/MAL/HDP/906	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
4159	NDA/MAL/HDP/907	LEGIT MEDEQ 2007 LIMITED	LEGIT MEDEQ 2007 LIMITED	ONDAZEN	ONDANSETRON HYDROCHLORIDE DIHYDRATE	8MG/4ML	ZEN PHARMA PVT LTD75/1, GIDC. VAPI-396 195 GUJARAT,	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X4.0 ML AMPOULE	11/12/2021
4160	NDA/MAL/HDP/911	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

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4161	NDA/MAL/HDP/9 912	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	IBUREN SUSPENSION	IBUPROFEN	100MG/5ML	RENE INDUSTRIES LTD PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X60.0 ML BOTTLE	08/12/2021
4162	NDA/MAL/HDP/9 913	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	BRUTAFLAM-120	ETORICOXIB	120MG	MANKIND PHARMA LTD, UNIT II ,VILLAGE KISHANPURA, PAONTA SAHIB, DIST. SIRMOUR, HP	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/12/2021
4163	NDA/MAL/HDP/9 920	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	CIS-CURON	CIS- ATRACURIUMBES YLATE	10MG/5ML	BROOKES PHARMA (PRIVATE) LIMITED 58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X5.0X5.0 ML AMPOULE	08/12/2021

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4164	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
4165	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
4166	NDA/MAL/HDP/9924	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	OPTIZOLINE EYE DROPS	TETRAHYDROZOLINE 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

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4167	NDA/MAL/HDP/9 925	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	TUSSIDEX LINCTUS	DEXTROMETHOR PHAN	10MG	XEPA-SOUL PATTINSON (MALAYSIA) SDN.BHD.1-5 CHENG INDUSTRIAL ESTATE, 75250, MELAKA	MALAYSIA	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	17/01/2022
4168	NDA/MAL/HDP/9 931	MERIDIAN ENTERPRISES PRIVATE LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	CLOSUPP 100	CLOTRIMAZOLE	100MG	MERIDIAN ENTERPRISES PVT. LTD-PLOT NO. 418, G.I.D.C.,KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	VAGINAL TABLETS	1.0X1.0X6.0 PESSARY STRIP	08/12/2021
4169	NDA/MAL/HDP/9 933	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BISOPROL® 10	BISOPROLOL FUMARATE	10MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANYJORDAN - NUZHAT SAHAB	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/03/2022

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4170	NDA/MAL/HDP/9 935	APEX LABORATORIES PRIVATE LIMITED	NORVIK ENTERPRISES LIMITED	ZINCOFER CAPSULES	FERROUS FUMARATE + FOLIC ACID BP + CYANOCOBALAMI N + ASCORBIC ACID + PYRIDOXINE HYDROCHLORIDE + ZINC SULPHATE MONOHYDRATE	350MG + 1MG + 5MCG +75MG + 1.5 MG +55MG	APEX LABORATORIES PRIVATE LIMITED- PLANT 1-B-23, SIDCO PHARMACEUTICAL COMPLEX ALATHUR, KANCHEEPURAM DISTRICT 603 110	INDIA	ORAL SOLID ORDINARY CAPSULES	1X3X10 CAPSULE BLISTER,	31/03/2022
4171	NDA/MAL/HDP/9 936	GUFIC BIOSCIENCES LTD	EUROPA HEALTHCARE (U) LTD	VAMOCIN 1GM	VANCOMYCINHY DROCHLORIDE	1G/VIAL	GUFIC BIOSCIENCES LIMITED (UNIT 2)SURVEY NO. 171, NATIONAL HIGHWAY NO. 8, NEAR GRID, AT & PO: KABILPORE, NAVSARI - 396424, GUJARAT - INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL	31/03/2022
4172	NDA/MAL/HDP/9 941	ALTHEA PHARMA PVT LTD.	JOINT MEDICAL STORE (UPMB - UCMB)	STERILIZED WATER FOR INJECTION	WATER FOR INJECTION	WATER FOR INJECTION	ALTHEA PHARMA PRIVATE LIMITEDWORKS: PLOT NO. 374, SHED NO. 'E', ALPHA INDL. PARK, ATHIAWAD, DABHEL, NANI DAMAN - 396210 (U.T.), INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X20.0X5.0X5.0 ML AMPOULE	24/03/2022

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4173	NDA/MAL/HDP/9 942	FOSUN PHARMACEUTICAL DISTRIBUTION JIANGSU CO. LTD	TRIDEM PHARMA UGANDA LIMITED	GLUMAC DISPERSIBLE TABLETS	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	GUILIN PHARMACEUTICAL CO LTD .NO. 43, QULIDIAN ROAD, GUILIN 541004	CHINA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1X1X6 TABLET BLISTER	31/03/2022
4174	NDA/MAL/HDP/9 943	FOSUN PHARMACEUTICAL DISTRIBUTION JIANGSU CO. LTD	TRIDEM PHARMA UGANDA LIMITED	GLUMAC DISPERSIBLE TABLETS	ARTEMETHER + LUMEFANTRINE	40MG + 240MG	GUILIN PHARMACEUTICAL CO LTD .NO. 43, QULIDIAN ROAD, GUILIN 541004	CHINA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1X1X6 TABLET BLISTER	31/03/2022
4175	NDA/MAL/HDP/9 944	FOSUN PHARMACEUTICAL DISTRIBUTION JIANGSU CO. LTD	TRIDEM PHARMA UGANDA LIMITED	GLUMAC DISPERSIBLE TABLETS	ARTEMETHER + LUMEFANTRINE	60MG + 360MG	GUILIN PHARMACEUTICAL CO LTD .NO. 43, QULIDIAN ROAD, GUILIN 541004	CHINA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1X1X6 TABLET BLISTER	31/03/2022

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4176	NDA/MAL/HDP/9 948	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	SANTRIAX-1000	CEFTRIAXONE SODIUM	1000MG/VIAL	INJECT CARE PARENTERALS PVT LTD PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X25.0X1000.0 MG VIAL, 1.0X10.0 ML VIAL	24/03/2022
4177	NDA/MAL/HDP/9 949	LABORATE PHARMACEUTICAL S INDIA LIMITED	HEALTHCARE LTD.	GENTAM	GENTAMICIN SULPHATE	80MG/2ML	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	24/03/2022
4178	NDA/MAL/HDP/9 950	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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4179	NDA/MAL/HDP/951	ARCELIA LIFE SCIENCES LTD.	NOVOMED HEALTHCARE LIMITED	ARCELIA ARTESUNATE FOR INJECTION	ARTESUNATE	60MG/VIAL	SANJAR PHARMA LLPSURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA INDASI LIFESCIENCE PRIVATE 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
4180	NDA/MAL/HDP/952	ARCELIA LIFE SCIENCES LTD.	NOVOMED HEALTHCARE LIMITED	ARCELIA DEXAMETHASONE SODIUM PHOSPHATE	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
4181	NDA/MAL/HDP/954	MARVIN PHARMA LTD (BURUNDI)	MARVIN PHARMA LIMITED	MARISUNATE 30MG	ARTESUNATE	30MG/VIAL	SANJAR PHARMA LLPSURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X30.0 MG VIAL + 1 CLEAR GLASS AMPOULE OF SODIUM BICARBONATE + 1 CLEAR GLASS AMPOULE OF SODIUM CHLORIDE	31/03/2022

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4182	NDA/MAL/HDP/9 955	VEERAM HEALTHCARE (U) LIMITED	VEERAM HEALTHCARE (U) LIMITED	DICLONI	DICLOFENAC DIETHYLAMINE + METHYL SALICYLATE + LINSEED OIL + MENTHOL	1.16%W/W+ 1.0% W/W+3.0%W/W+ 10%W/W+2.0% W/W	KESAR PHARMA PVT LTD PLOT SURVEY NO. 50/2. VILLAGE BILSHWARPURA 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
4183	NDA/MAL/HDP/9 956	ARCELIA LIFE SCIENCES LTD.	NOVOMED HEALTHCARE 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
4184	NDA/MAL/HDP/9 957	INDCHEMIE HEALTH SPECIALITIES PVT. LTD.	NUMED STORES SMC LIMITED	TERBICON CREAM	TERBINAFINE HYDROCHLORIDE	1.0%W/W	INDCHEMIE HEALTH SPECIALITIES PVT. LTD VILLAGE-THANA, BADDI, DIST. SOLAN, HIMACHAL PRADESH- 173 205.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X10.0 G TUBE	24/03/2022

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4185	NDA/MAL/HDP/958	INDCHEMIE HEALTH SPECIALITIES PVT. LTD.	NUMED STORES SMC LIMITED	MUPRICON	MUPIROCIN	2.0%W/W	INDCHEMIE HEALTH SPECIALITIES PVT. LTDVILLAGE-THANA, BADDI, DIST. SOLAN, HIMACHAL PRADESH-173 205.	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X5.0 G TUBE	24/03/2022
4186	NDA/MAL/HDP/959	MARVIN PHARMA LTD (BURUNDI)	MARVIN PHARMA LIMITED	MARISUNATE 60MG	ARTESUNATE	60MG/VIAL	SANJAR PHARMA LLPSURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1, CLEAR GLASS AMPOULE OF SODIUM BICARBONATE + 1 CLEAR GLASS AMPOULE SODIUM CHLORIDE	31/03/2022
4187	NDA/MAL/HDP/960	MARVIN PHARMA LTD (BURUNDI)	MARVIN PHARMA LIMITED	MARISUNATE 120MG	ARTESUNATE	120MG/VIAL	SANJAR PHARMA LLPSURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1, CLEAR GLASS AMPOULE OF SODIUM BICARBONATE + 1 CLEAR GLASS AMPOULE SODIUM CHLORIDE	31/03/2022

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4188	NDA/MAL/HDP/9 961	FDC LIMITED -	AIVEEN (U) LIMITED	ALLERCROM EYE DROPS	SODIUM CROMOGLICATE	2%W/V	FDC LIMITED, WALUJ .PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD	INDIA	OPHTHALMIC LIQUIDS	1.0X1.0X10.0 ML BOTTLE	31/03/2022
4189	NDA/MAL/HDP/9 962	ARCELIA LIFE SCIENCES LTD.	NOVOMED HEALTHCARE LIMITED	ARCELIA ARTEMETHER	ARTEMETHER	80MG/ML	SANJAR PHARMA LLPSURVEY NO. 622/2/1/4, DEDHROTA, TA- HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X2.0X3.0X1.0 ML AMPOULE	31/03/2022
4190	NDA/MAL/HDP/9 963	SEARLE PAKISTAN LIMITED	SURGIPHARM (U) LIMITED	SEA-MOX	MOXIFLOXACIN HYDROCHLORIDE	400MG	SEARLE PAKISTAN LTD..F-319, S.I.T.E., OPP. KESC POWER STATION, KARACHI	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X5.0 TABLET BLISTER	31/03/2022

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4191	NDA/MAL/HDP/9 964	VIIV HEALTHCARE UK LTD-	UNITED HEALTHCARE DISTRIBUTORS LTD	TIVICAY 5 MG	DOLUTEGRAVIR SODIUM	5MG	GLAXO WELLCOME S.AAVENIDA EXTREMADURA 3, 09400 ARANDA DE DUERO - SPAIN GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS)PRIORY STREET, WARE, SG12 ODJ	SPAIN	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X60.0 TABLET CONTAINER	31/03/2022
4192	NDA/MAL/HDP/9 966	PHARMATEC PAKISTAN PVT LTD	HEALTHCARE LTD.	FLU-GONE	MULTI- INGREDIENT	MULTI- INGREDIENT	ATCO LABS LTD,-B- 18, S.I.T.E, KARACHI	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	24/02/2022
4193	NDA/MAL/HDP/9 967	MACLEODS PDHARMACEUTICA LS LT	VITACARE LIMITED	VENTOMAC 100	SALBUTAMOL SULFATE	100MCG PER ACTUATION	OXALIS LABS LIMITEDVILLAGE THEDA, P.O LODHIMAJRA, TEHSIL,BADDI, DIST.SOLAN, INDIA	INDIA	LUNG ADMINISTRATION METERED-DOSE LIQUIDS	1.0X1.0X200.0 METERED DOSE CANNISTER	24/03/2022

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4194	NDA/MAL/HDP/9968	ARISTO PHARMACEUTICALS 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
4195	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
4196	NDA/MAL/HDP/9973	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ARBITEL 80 H	TELMISARTAN + HYDROCHLOROT HIAZIDE	80MG + 12.5MG	MICRO LABS LIMITED .92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/03/2022

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4197	NDA/MAL/HDP/9 974	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	NEBTAS-H	NEBIVOLOL HYDROCHLORIDE + HYDROCHLOROT HIAZIDE	5MG + 12.5 MG	INTAS PHARMACEUTICALS LIMITED CAMP ROAD, SELAQUI- 248197, DEHRADUN (UTTARAKHAND)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/03/2022
4198	NDA/MAL/HDP/9 975	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
4199	NDA/MAL/HDP/9 976	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EZIFLO	TAMSULOSIN HYDROCHLORIDE	0.4 MG	UNITED PHARMACEUTICALS MANUFACTURING LTD COAL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/03/2022

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4200	NDA/MAL/HDP/9 977	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	EMTRICITABINE + TENOFVIR DISOPROXIL FUMARATE TABLETS 200 MG/ 300 MG	EMTRICITABINE + TENOFVIR DISOPROXIL FUMARATE	200MG + 300MG	LAURUS LABS LTD (UNIT 2)PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER,1.0X90. 0 TABLET CONTAINER	24/03/2022
4201	NDA/MAL/HDP/9 978	ASPIRO PHARMA LIMITED	AIVEEN (U) LIMITED	PALOX	PALONOSETRON HYDROCHLORIDE	0.25MG/5ML	ASPIRO PHARMA LIMITEDSY. NO. 321, BIOTECH PARK, PHASE-III, KARKAPATLA, MARKOOK MANDAL, SIDDIPET DISTRICT- 502 281, TELANGANA, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X0.25 MG VIAL	31/03/2022
4202	NDA/MAL/HDP/9 983	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE EXTENDED RELEASE TABLETS 25 MG/1000 MG	EMPAGLIFLOZIN + METFORMIN HYDROCHLORIDE	25MG + 1000MG	CIPLA LIMITED.PLOT NO. L-139, S-103 & M-62, VERNA INDUSTRIAL ESTATE, VERNA SALCETTE, GOA, PIN 403722	INDIA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X60.0 TABLET BOTTLE	24/03/2022

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4203	NDA/MAL/HDP/9 984	CIPLA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE EXTENDED RELEASE TABLETS 12.5 MG/1000 MG	EMPAGLIFLOZIN + METFORMIN HYDROCHLORIDE	12.5MG + 1000MG	CIPLA LTD, GOA UNIT V & UNIT XL- 139, S-103&M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA	INDIA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X60.0 TABLET BOTTLE	24/03/2022
4204	NDA/MAL/HDP/9 985	CIPLA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE EXTENDED RELEASE TABLETS 5 MG/1000 MG	EMPAGLIFLOZIN + METFORMIN HYDROCHLORIDE	5MG + 1000MG	CIPLA LTD, GOA UNIT V & UNIT XL- 139, S-103&M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA	INDIA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X60.0 TABLET BOTTLE	24/03/2022
4205	NDA/MAL/HDP/9 986	CIPLA LTD.	ABACUS PHARMA (AFRICA) LIMITED	EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE EXTENDED RELEASE TABLETS 10 MG/1000 MG	EMPAGLIFLOZIN + METFORMIN HYDROCHLORIDE	10MG + 1000MG	CIPLA LTD, GOA UNIT V & UNIT XL- 139, S-103&M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA	INDIA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X60.0 TABLET BOTTLE	24/03/2022

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4206	NDA/MAL/HDP/9987	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
4207	NDA/MAL/HDP/991	CACHET PHARMACEUTICALS PVT LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EASCOF-LS	LEVOSALBUTAMOL SULPHATE + AMBROXOL HYDROCHLORIDE + GUAIPHENESIN	1MG + 30MG + 50 MG	CACHET PHARMACEUTICALS PVT LTD .VILLAGE THANA, BADDI, TEHSIL-NALAGARH DIST. SOLAN, HIMACHAL PRADESH-173205	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	24/03/2022
4208	NDA/MAL/HDP/992	REGAL PHARMACEUTICALS LTD	REGAL PHARMA U LIMITED	ASPEC EXTRA	ASPIRIN + PARACETAMOL + CAFFEINE ANHYDROUS	300MG + 250MG + 30MG	REGAL PHARMACEUTICALS LTD PLOT NO. 7879/18, OFF BABA DOGO ROAD, RUARAKA - NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X2.0 TABLET STRIP	24/03/2022

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4209	NDA/MAL/HDP/995	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	LYDIA FINE TABLET	LEVONORGESTREL + ETHINYLESTRADIOL	0.15 MG + 0.03MG	RAJENDRAPUR POTENT PRODUCT FACILITY (RPPF), RENATA LIMITED NOYAPARA, BHAWAL MIRZAPUR, RAJENDRAPUR, GAZIPUR 1700 - BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X1.0X28.0 TABLET BLISTER	24/03/2022
4210	NDA/MAL/HDP/996	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	MONTEMAC 4	MONTELUKAST SODIUM	4MG	MACLEODS PHARMACEUTICALS LTD BLOCK N2, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	31/03/2022
4211	NDA/MAL/HDP/997	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	RIVATAS 10	RIVAROXABAN	10MG	INTAS PHARMACEUTICALS LTD. PLOT NO. 457, 458, & 191/218P, VILLAGE: MATODA, TAL. SANAND, AHMEDABAD, GUJARAT, 382210 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/03/2022

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4212	NDA/MAL/HDP/998	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	DERMOCIN	MUPIROCIN	2.0%W/W	LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X15.0 G TUBE	24/03/2022
4213	NDA/MAL/HDP/999	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