MEDICINES SUSPENDED FROM JANUARY 2024 REGISTER

S/N	NDA REG NUMBER	LICENSE HOLDER	LOCAL TECHNICAL REPRESENTATIVE	NAME OF DRUG	GENERIC NAME OF DRUG	STRENGTH OF DRUG	NON COMPLIANT (AFFECTED) SITE	ALTERNATIVE MANUFACTURER (COMPLIANT MANUFACTURER)	REASON FOR SUSPENSION	RETENTION STATUS	COUNTRY OF MAN	DOSAGE FORM	PACK SIZE	REG DATE
1	NDA/MAL/HDP/0003	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	UMOXIL CLAV 625	AMOXICILLIN + CLAVULANATE POTASSIUM	500 MG + 125 MG	N/A	UNI MEDICOLABS21-22 PHARMACITY SELAQUI DEHRADUN 248197	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2015
2	NDA/MAL/HDP/0008	STALLION LABORATORIES PVT LTD	HARLEYS UGANDA LIMITED	OMEPRIC	OMEPRAZOLE DELAYED-RELEASE	20MG	N/A	ACME FORMULATION PVT LTD.ROPAR ROAD NALAGARH DIST SOLAN HIMACHAL PRADESH	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	ORAL SOLID RETARD CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2014
3	NDA/MAL/HDP/0009	STALLION LABORATORIES PVT LTD	HARLEYS UGANDA LIMITED	DINASOD-100	DICLOFENAC	100MG	N/A	ACME FORMULATION PVT LTD,ACME FORMULATION PVT LTD ROPAR ROAD NALAGARH DIST SOLAN HIMACHAL PRADESH	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014

4	NDA/MAL/HDP/0010	STALLION LABORATORIES PVT LTD	HARLEYS UGANDA LIMITED	02-LON	OFLOXACIN + ORNIDAZOLE	200MG + 500MG	N/A	ACME FORMULATION PVT LTD.ROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101 INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
5	NDA/MAL/HDP/0014	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	MONTELAIR 10MG TABLET	MONTELUKAST	10MG	HOVID BHD (IPOH SITE)-121 ,JALAN TUNKU ABDUL RAHMAN 30010	N/A	FACILITY NOT APPROVED TO MANUFACTURE NBL TABLETS	RETAINED	MALAYSIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014
6	NDA/MAL/HDP/0022	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	QUININE SULPHATE	QUININE SULPHATE	300MG	N/A	AGOG PHARMA LTDPLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2009

7	NDA/MAL/HDP/0033	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYVATE CREAM	BETAMETHASONE VALERATE	0.1%W/W	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	RETAINED	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997
8	NDA/MAL/HDP/0054	GOOD DAY PHARMACY LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	FUNGOAL	CLOTRIMAZOLE	1%W/W	N/A	KREMOINT PHARMA PVT LTD--B-8 ADDITIONAL AMBERNATH MIDC OPP. ANAND NAGAR POLICE CHECK POST AMBERNATH (E) DIST THANE 421 506	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2013

9	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 S.A - SUCCURSALE D'AUBONNE, ZONE INDUSTRIELLE DE L'OURIETTAZ, 1170 AUBONNE, SWITZERLAND	MERCK SERONO SPA (BARI)-VIA DELLE MAGNOLIE, 15 (LOC FRAZ ZONA INDUSTRIALE) 70026, MODUGNO, BARI	GMP EXPIRED ON THE 24/09/2023 FOR BIOTECHNOLOGY PRODUCTS: SMALL VOLUME LIQUIDS, SVP LYOPHILISATES IN PRE-FILLED SYRINGES & CATRIDGES	RETAINED	ITALY	PARENTERAL ORDINARY PRE-FILLED PENS	1.0X1.0 CARTRIDGE PREFILLED PEN + 8 NEEDLES FOR INJECTION	01/07/2015
10	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 S.A. (MSA) - 1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND	MERCK SERONO SPA (BARI)-VIA DELLE MAGNOLIE, 15 (LOC FRAZ ZONA INDUSTRIALE) 70026, MODUGNO, BARI	GMP EXPIRED ON THE 24/09/2023 FOR BIOTECHNOLOGY PRODUCTS: SMALL VOLUME LIQUIDS, SVP LYOPHILISATES IN PRE-FILLED SYRINGES & CATRIDGES	RETAINED	ITALY	PARENTERAL ORDINARY CARTRIDGES	1.0X1.0 CARTRIDGE PREFILLED PEN + 12 NEEDLES FOR INJECTION	01/07/2015
11	NDA/MAL/HDP/0069	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	LIPITOR	ATORVASTATIN	10MG	N/A	PFIZER LABORATORIESGODECKE MOOSWALDALLE 179090 FR ,PFIZER PHARMACEUTICALS LLC, ROAD 689 KM 1.9 VEGA BAJA, PUERTO RICO	N/A	NOT RETAINED	GERMANY PUERTO RICO	ORAL SOLID ORDINARY TABLETS	1.0X28.0 TABLET BLISTER	01/07/1999

12	NDA/MAL/HDP/0070	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	LIPITOR	ATORVASTATIN	20MG	N/A	PFIZER LABORATORIESGODECKE MOOSWALDALLE 179090 FR ,PFIZER PHARMACEUTICALS LLC, ROAD 689 KM 1.9 VEGA BAJA, PUERTO RICO	N/A	NOT RETAINED	GERMANY PUERTO RICO	ORAL SOLID ORDINARY TABLETS	1.0X28.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/1999
13	NDA/MAL/HDP/0072	VHB MEDI SCIENCES LTD	NORVIK ENTERPRISES LIMITED	AMPHO-B	AMPHOTERICIN	50MG	N/A	VHB MEDI SCIENCES LTDPLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1X50 MG Vial	\N
14	NDA/MAL/HDP/0107	NVS KENYA LTD	SURGIPHARM (U) LIMITED	ASUNRA	DEFERASIROX	400MG	N/A	NOVARTIS PHARMA STEIN AGH-4332 STEIN SCHAFFAUSERTRASSE	N/A	NOT RETAINED	SWITZERLAND	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X5.0X6.0 TABLET BLISTER	01/07/2015

15	NDA/MAL/HDP/0117	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZOCEF 1.5G	CEFUROXIME SODIUM	1.5G	N/A	SANCE LABORATORIES PVT LTDVI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA. ALKEM LABORATORIES LTDVILLAGE – THANA, BADDI TEHSIL – NALAGARH, DIST-SOLAN (HP), INDIA – 173205	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.5 G VIAL + 1 AMPOULE OF WFI	01/07/2013
16	NDA/MAL/HDP/0121	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	PEDZINC	ZINC SULPHATE	20MG	SHELYS PHAMACEUTICALS LTD .- NEW BAGAMOYO RD, MWENGE, PLOT 696, DAR ES SALAAM	BETA HEALTH CARE INTERNATIONAL LIMITED/-PLOT NO. LR 209/ 6534 MOGADISHU ROAD, KENYA	GMP EXPIRED ON THE 28/11/2019 FOR • TABLETS • HARD GELATIN CAPSULES. • ORAL LIQUIDS. • DRY POWDER FOR ORAL SUSPENSION • ORS • CREAMS AND OINTMENTS.	RETAINED	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2015

17	NDA/MAL/HDP/0127	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	CORYCARDON	IRBESARTAN + HYDROCHLOROTHIAZIDE	300MG + 12.5MG	N/A	DELORBIS PHARMACEUTICALS LTD17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
18	NDA/MAL/HDP/0128	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	CORYCARDON	IRBESARTAN + HYDROCHLOROTHIAZIDE	150MG + 12.5MG	N/A	DELORBIS PHARMACEUTICALS LTD17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
19	NDA/MAL/HDP/0132	ABBOTT LABORATORIES S.A. (PTY) LTD	HARLEYS UGANDA LIMITED	KLACID 500MG	CLARITHROMYCIN	500MG	ABBOTT LABORATORIES S.A (PTY) LTD-ABBOTT PLACE,219 GOLF CLUB TERRACE, CONSTANTIA KLOOF 1709 P.O BOX 7208	N/A	FACILITY NOT GMP COMPLIANT	RETAINED	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X14.0 TABLET BLISTER	01/07/1998

20	NDA/MAL/HDP/0133	ABBOTT LABORATORIES S.A. (PTY) LTD	HARLEYS UGANDA LIMITED	KLACID P250	CLARITHROMYCIN	250MG/5ML	ABBOTT LABORATORIES S.A (PTY) LTD-ABBOTT PLACE,219 GOLF CLUB TERRACE, CONSTANTIA KLOOF 1709 P.O BOX 7208	N/A	FACILITY NOT GMP COMPLIANT	RETAINED	SOUTH AFRICA	ORAL LIQUID ORDINARY OTHER POWDERS/GRANULES	1.0X50.0 ML BOTTLE,1.0X 100.0 ML BOTTLE	01/07/1998
21	NDA/MAL/HDP/0135	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	HEMOVIT SYRUP	IRON + FOLIC ACID + PYRIDOXINE + CYANOCOBALAMIN + ZINC	200MG + 1.5MG + 0.5MG + 50 MCG + 2.33MG	SHELYS PHAMACEUTICALS LTD .- NEW BAGAMOYO RD, MWENGE, PLOT 696, DAR ES SALAAM	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO LR 209/6534 MOGADISHU ROAD	GMP EXPIRED ON THE 28/11/2019 FOR • TABLETS • HARD GELATIN CAPSULES. • ORAL LIQUIDS. • DRY POWDER FOR ORAL SUSPENSION • ORS • CREAMS AND OINTMENTS.	RETAINED	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2013
22	NDA/MAL/HDP/0142	PFIZER LABORATORIES	LABOREX UGANDA LIMITED	PREVENAR 13	PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE (13-VALENT.ADSORBED)	2.2MCG OF POLYSACCHARIDE FOR SEROTYPES 1,3,4,5,6A,7F.9V,14,18C,19A,19F,23F,AND 4.4MCG FOR SEROTYPE	WYETH PHARMACEUTICALS INC-401 N MIDDLETOWN RD PEARL RIVER NY 10965	N/A	FACILITY NOT FOUND; A VARIATION APPLICATION FOR CHANGE OF MANUFACTURING SITE HAS NOT YET BEEN APPROVED.	RETAINED	UNITED STATES	PARENTERAL ORDINARY VIALS	1.0X0.5 ML VIAL (1 DOSE)	01/07/2011

23	NDA/MAL/HDP/0152	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	RYCARDON 150	IRBESARTAN	150MG	ZHEJIANG HUAHAI PHARMACEUTICAL CO. LTD-XUNQIAO, LINHAI, ZHEJIANG PROVINCE 317024 PEOPLES' REPUBLIC	DELORBIS PHARMACEUTICALS LTD-17 ATHINON STR., ERGATES INDUSTRIAL AREA, 2643 ERGATES, P.O. BOX 28629, 2081 LEFKOSIA, CYPRUS	FACILITY NOT APPROVED FOR THIS LINE	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
24	NDA/MAL/HDP/0153	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	RYCARDON 300	IRBESARTAN	300MG	ZHEJIANG HUAHAI PHARMACEUTICAL CO. LTD-XUNQIAO, LINHAI, ZHEJIANG PROVINCE 317024 PEOPLES' REPUBLIC	DELORBIS PHARMACEUTICALS LTD-17 ATHINON STR., ERGATES INDUSTRIAL AREA, 2643 ERGATES, P.O. BOX 28629, 2081 LEFKOSIA, CYPRUS	FACILITY NOT APPROVED FOR THIS LINE	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
25	NDA/MAL/HDP/0155	TORRENT PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	ASTHATOR 10	MONTELUKAST SODIUM	10MG	N/A	TORRENT PHARMACEUTICALS LTD .,AHMEDABAD-MEHSANA HIGHWAY, TALUKA-KADI, DIST. MEHSANA, INDRAD-382721, GUJARAT	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

26	NDA/MAL/HDP/0186	WIDE SPECTRUM ENTERPRISES (U) LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BBC SPRAY	BENZOCAINE+BENZYDAMINE+CATALKONIUM 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.	N/A	GMP EXPIRED ON THE 29/9/2023 FOR NON-BETA LACTAM: HARD GELATIN CAPSULES SOFT GELATIN CAPSULES TABLETS (COATED & UNCOATED) DRY POWDERS FOR SUSPENSION POWDERS PACKED IN SACHETS SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED LIQUIDS) SMALL VOLUME PARENTERAL – (ASEPTICALLY PREPARED POWDERS) EYE DROPS (ASEPTICALLY PREPARED) ORAL LIQUIDS NON-STERILE NASAL DROPS EXTERNAL SEMI-SOLIDS (CREAMS & GELS)	RETAINED	EGYPT	ORAL TOPICAL SPRAYS WITHOUT GAS	1.0X25.0 ML BOTTLE	01/07/2014

27	NDA/MAL/HDP/0187	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.	N/A	GMP EXPIRED ON THE 29/9/2023 FOR NON-BETA LACTAM: HARD GELATIN CAPSULES SOFT GELATIN CAPSULES TABLETS (COATED & UNCOATED) DRY POWDERS FOR SUSPENSION POWDERS PACKED IN SACHETS SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED LIQUIDS) SMALL VOLUME PARENTERAL – (ASEPTICALLY PREPARED POWDERS) EYE DROPS (ASEPTICALLY PREPARED) ORAL LIQUIDS NON-STERILE NASAL DROPS EXTERNAL SEMI-SOLIDS (CREAMS & GELS)	RETAINED	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2014

28	NDA/MAL/HDP/0188	AMOUN PHARMACEUTICALS LTD	BOOTS PHARMACEUTICALS LIMITED	LEVOXIN	LEVOFLOXACIN	500MG	AMOUN PHARMACEUTICALS CO. S.A.E1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	N/A	GMP EXPIRED ON THE 29/9/2023 FOR NON-BETA LACTAM: HARD GELATIN CAPSULES SOFT GELATIN CAPSULES TABLETS (COATED & UNCOATED) DRY POWDERS FOR SUSPENSION POWDERS PACKED IN SACHETS SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED LIQUIDS) SMALL VOLUME PARENTERAL – (ASEPTICALLY PREPARED POWDERS) EYE DROPS (ASEPTICALLY PREPARED) ORAL LIQUIDS NON-STERILE NASAL DROPS EXTERNAL SEMI-SOLIDS (CREAMS & GELS)	NOT RETAINED	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X5.0 TABLET BLISTER	01/07/2014

29	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.	N/A	GMP EXPIRED ON THE 29/9/2023 FOR NON-BETA LACTAM: HARD GELATIN CAPSULES SOFT GELATIN CAPSULES TABLETS (COATED & UNCOATED) DRY POWDERS FOR SUSPENSION POWDERS PACKED IN SACHETS SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED LIQUIDS) SMALL VOLUME PARENTERAL – (ASEPTICALLY PREPARED POWDERS) EYE DROPS (ASEPTICALLY PREPARED) ORAL LIQUIDS NON-STERILE NASAL DROPS EXTERNAL SEMI-SOLIDS (CREAMS & GELS)	RETAINED	EGYPT	TOPICAL EXTERNAL CREAMS	, 1X30 G Tube	01/07/2014

30	NDA/MAL/HDP/0192	AMOUN PHARMACEUTICALS COMPANY	BOOTS PHARMACEUTICALS LIMITED	AMOCOMB CREAM	NEOMYCIN + TRIAMCINOLONE ACETONIDE + GRAMICIDIN	0.25GM + 0.1G + 100000IU + 0.025G/100G	AMOUN PHARMACEUTICALS CO. S.A.E1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	N/A	GMP EXPIRED ON THE 29/9/2023 FOR NON-BETA LACTAM: HARD GELATIN CAPSULES SOFT GELATIN CAPSULES TABLETS (COATED & UNCOATED) DRY POWDERS FOR SUSPENSION POWDERS PACKED IN SACHETS SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED LIQUIDS) SMALL VOLUME PARENTERAL – (ASEPTICALLY PREPARED POWDERS) EYE DROPS (ASEPTICALLY PREPARED) ORAL LIQUIDS NON-STERILE NASAL DROPS EXTERNAL SEMI-SOLIDS (CREAMS & GELS)	NOT RETAINED	EGYPT	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2014

31	NDA/MAL/HDP/0207	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE	LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE	300MG +300MG	N/A	MACLEODS PHARMACEUTICALS LTD--PLOT NO 25-27 SURVEY PREMEIRE INDUSTRIAL ESTATE KACHIGAM DAMAN (U.T) 396401 MACLEODS PHARMACEUTICALS LIMITED (BLOCK –N1)VILLAGE THEDA, P.O. LODHI MAJRA,TEHSIL BADDI, HIMACHAL PRADESH - 174101,INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2013
32	NDA/MAL/HDP/0217	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	PALETHER	ARTEMETHER	80MG/ML	LINCOLN PARENTERAL LTD .-11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ 382721 TA: KALOL DIST. GANDHIN	N/A	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: SMALL VOLUME PARENTERAL SOLUTIONS SMALL VOLUME PARENTERAL POWDERS ORAL LIQUIDS	RETAINED	INDIA	PARENTERAL ORDINARY I M AMPOULES	2.0X3.0X1.0 ML AMPOULE	01/07/2014

33	NDA/MAL/ HDP/0218	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	TENOL-100	ATENOLOL	100MG	N/A	LINCOLN PHARMACEUTICALS LTD .10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10 .0 TABLET BLISTER	01/07/2015

34	NDA/MAL/HDP/0226	AMOUM PHARMACEUTICALS LTD	BOOTS PHARMACEUTICALS LIMITED	ULTRASOLV SYRUP	OXOMEMAZINE HCL & CARBOCYSTEINE & GUAIFENESIN	2MG+125MG+100MG/5ML	AMOUN PHARMACEUTICALS CO. S.A.E1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	N/A	GMP EXPIRED ON THE 29/9/2023 FOR NON-BETA LACTAM: HARD GELATIN CAPSULES SOFT GELATIN CAPSULES TABLETS (COATED & UNCOATED) DRY POWDERS FOR SUSPENSION POWDERS PACKED IN SACHETS SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED LIQUIDS) SMALL VOLUME PARENTERAL – (ASEPTICALLY PREPARED POWDERS) EYE DROPS (ASEPTICALLY PREPARED) ORAL LIQUIDS NON-STERILE NASAL DROPS EXTERNAL SEMI-SOLIDS (CREAMS & GELS)	NOT RETAINED	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2014

35	NDA/MAL/HDP/0227	AMOUM PHARMACEUTICALS LTD	BOOTS PHARMACEUTICALS LIMITED	CYRINOL SYRUP	PHOLCODINE +EPHEDRINE HCL +CARBINOXAMINE MALEATE	4MG+7MG +2MG /5ML	AMOUN PHARMACEUTICALS COMPANY1ST INDUSTRIAL ZONE EL OBOUR CITY CAIRO EGYPT	N/A	GMP EXPIRED ON THE 29/9/2023 FOR NON-BETA LACTAM: HARD GELATIN CAPSULES SOFT GELATIN CAPSULES TABLETS (COATED & UNCOATED) DRY POWDERS FOR SUSPENSION POWDERS PACKED IN SACHETS SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED LIQUIDS) SMALL VOLUME PARENTERAL – (ASEPTICALLY PREPARED POWDERS) EYE DROPS (ASEPTICALLY PREPARED) ORAL LIQUIDS NON-STERILE NASAL DROPS EXTERNAL SEMI-SOLIDS (CREAMS & GELS)	NOT RETAINED	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2014
36	NDA/MAL/HDP/0228	KOPRAN LIMITED	TATA UGANDA LIMITED	TRIM-960	TRIMETHOPRIM/SULFAMETHOXAZOLE	160MG/800MG	N/A	KOPRAN LTDVILLAGE SAVROLI TAL KHARAPUR DIST RAIGAD 410 202	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER	01/07/2014

37	NDA/MAL/HDP/0233	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	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X5.0 TABLET BLISTER	01/07/2014
38	NDA/MAL/HDP/0234	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	CEFIMED 200	CEFIXIME TRIHYDRATE	200MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANAS	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X8.0 TABLET BLISTER,1.0X2.0X5.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/2014
39	NDA/MAL/HDP/0235	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	AXETINE 500	CEFUROXIME AXETIL	500MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANAS	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET STRIP	01/07/2014

40	NDA/MAL/HDP/0244	SAKAR HEALTHCARE PVT LTD	ROYAL PHARMA 2011 LIMITED	HYOCIN	HYOSCINE BUTYLBROMIDE	20MG/ML	N/A	SAKAR HEALTHCARE PVT LTDBLOCK NO. 10-13, NR. M.N DESAI PETRO PUMP, SARKHEJ-BAVLA ROAD, CHANGODAR, DIST: AHMEDABAD-382213, GUJARAT	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE	01/07/2014
41	NDA/MAL/HDP/0245	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	EUGLIM 4	GLIMEPIRIDE	4MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014

42	NDA/MAL/HDP/0286	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	GLUMAC	ARTEMETHER +LUMEFANTRINE	20MG+120 MG	GUILIN PHARMACEUTICAL CO. LTD-NO. 17 SHANGHAI ROAD, GUILIN 541002, GUANXI CHINA	N/A	GMP EXPIRED ON THE 28/2/2015 FOR TABLETS. CURRENTLY, THE COMPLIANT ADDRESS IS NO. 43, QILIDIAN ROAD, GUILIN 541004, GUANGXI P.R. OF CHINA. CLIENT REQUIRED TO UPDATE MANUFACTURER DETAILS	RETAINED	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X24.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X18.0 TABLET BLISTER,1.0X12.0 TABLET BLISTER, 1.0X30.0X18.0 TABLET BLISTER, 1.0X30.0X24.0 TABLET BLISTER	01/07/2014
43	NDA/MAL/HDP/0288	UNIVERSAL CORPORATION LTD	PHARMAVILLE LIMITED	DUXCOSPAN	HYOSCINE BUTYL BROMIDE	10MG	N/A	UNIVERSAL CORPORATION LIMITED PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE	N/A	NOT RETAINED	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
44	NDA/MAL/HDP/0293	HETERO LABS LTD	AIVEEN (U) LIMITED	DARUNAVIR	DARUNAVIR	600 MG	N/A	HETERO LABS LTD22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2014

45	NDA/MAL/HDP/0304	HETERO LABS LTD	AIVEEN (U) LIMITED	DARUNAVIR	DARUNAVIR	400MG	N/A	HETERO LABS LTD22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2014
46	NDA/MAL/HDP/0305	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	CEFAX-250 DRY SYRUP	CEFALEXIN	250MG/5ML	N/A	SAKAR HEALTH CARE PVT, LTDBLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382-213,GUJARAT-INDIA	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X1.0X50.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE	01/07/2013
47	NDA/MAL/HDP/0338	KOPRAN LIMITED	TATA UGANDA LIMITED	KORAB 20	RABEPRAZOLE SODIUM	20MG	N/A	KOPRAN LIMITEDVILLAGE-SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2013
48	NDA/MAL/HDP/0353	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DEROX-10	AMLODIPINE BESILATE	10MG	HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH ,	N/A	FACILITY NOT APPROVED TO MANUFACTURE NBL TABLETS	RETAINED	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X3.0X1.0X10.0 TABLET BLISTER	01/07/2015

49	NDA/MAL/HDP/0356	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	LEVO DENK 50O	LEVOFLOXACIN HEMIHYDRATE	500MG	ROTTENDORF PHARMA GMBH-OSTENFELDER STRASSE 51-61	N/A	GMP OF THE FACILITY EXPIRED ON THE 30/7/2023 FOR NBL TABLETS	RETAINED	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X5.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER	01/07/2014
50	NDA/MAL/HDP/0365	UNIVERSAL CORPORATION LTD	PHARMA VILLE LIMITED	SULFRAN-DS	TRIMETHOPRIM/SULFAMETHOXAZOLE	160MG/800MG	N/A	UNIVERSAL CORPORATION LIMITED PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE	N/A	NOT RETAINED	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER	01/07/2015
51	NDA/MAL/HDP/0373	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	TEMELIN	CETIRIZINE HYDROCHLORIDE	10MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANAS	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
52	NDA/MAL/HDP/0375	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	FENAMON SR	NIFEDIPINE	20MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANAS	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2014

53	NDA/MAL/HDP/0377	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	DUINUM	CLOMIFENE	50MG	MEDOCHEMIE LTD-CENTRAL FACTORY A-1-10 CONSTANTINOUPOLEUS STREET	N/A	FACILITY NOT APPROVED FOR THIS LINE	RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2014
54	NDA/MAL/HDP/0380	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	AVERNOL	CARVEDILOL	6.25NG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANAS	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014
55	NDA/MAL/HDP/0382	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD	SURGIPHARM (U) LIMITED	KETAMINE FRESENIUS	KETAMINE HYDROCHLORIDE	50MG/ML	N/A	FRESENIUS KABI MANUFACTURING SA (PTY) LTD6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH	N/A	NOT RETAINED	SOUTH AFRICA	PARENTERAL ORDINARY VIALS	1.0X10.0X10.0 ML VIAL	01/07/2014
56	NDA/MAL/HDP/0400	ZYDUS LIFESCIENCES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	IBSOL 1.2	MESALAMINE DELAYED RELEASE	1.2GM	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID RETARD FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013

57	NDA/MAL/HDP/0405	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	CHEMLET	LETROZOLE	2.5MG	N/A	NEON LABORATORIES LTDPLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO-OPERATIVE ESTATE , BOISAR ROAD	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
58	NDA/MAL/HDP/0414	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	RAMIPRIL 10 MG TABLETS	RAMIPRIL	10MG	LEK S.S POLAND UI PODLIPIE 16 95-01O STRYKOW-INDUSTRIAL ESTATES	N/A	GMP EXPIRED ON THE 23/8/2023 FOR NBL TABLETS AND CAPSULES; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	POLAND	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2014
59	NDA/MAL/HDP/0437	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED	SURGIPHARM (U) LIMITED	NALOXONE HCL NEONATAL FRESENIUS	NALOXONE HYDROCHLORIDE	0.02MG/ML	N/A	FRESENIUS KABI MANUFACTURING SA (PTY) LTD6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH	N/A	NOT RETAINED	SOUTH AFRICA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2014
60	NDA/MAL/HDP/0439	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED	SURGIPHARM (U) LIMITED	NALOXONE HCL FRESENIUS 0.4MG/1ML	NALOXONE HYDROCHLORIDE	0.4MG/1ML	N/A	FRESENIUS KABI MANUFACTURING SA (PTY) LTD6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH	N/A	NOT RETAINED	SOUTH AFRICA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2015

61	NDA/MAL/HDP/0440	AGIO PHARMACEUTICALS LTD	ROYAL PHARMA 2011 LIMITED	AGICLOB-GM	CLOBETASOL/GENTAMICIN/MICONAZOLE	0.5MG+3.4MG+20MG/1G	N/A	AGIO PHARMACEUTICALS LTDPLOT NO. T-81, 82 MIDC, BHOSARI, PUNE-26	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2014
62	NDA/MAL/HDP/0457	UNIVERSAL CORPORATION LTD	DELMAW ENTERPRISES LIMITED	UNIBROL 250MG	AMINOSIDINE	250MG	N/A	UNIVERSAL CORPORATION LTDUNIVERSAL CORPORATION LTD	N/A	NOT RETAINED	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X6.0 TABLET BLISTER,1.0X4.0X6.0 TABLET BLISTER	01/07/2012
63	NDA/MAL/HDP/0468	NECTAR LIFESCIENCES LTD	AIVEEN (U) LIMITED	CEFUAXIT 750	CEFUROXIME	750MG	N/A	NECTAR LIFESCIENCES LIMITED-VILL. BHATOLIKALAN, ADJOININGJHARMJRI, P.O BAROTIWALA DIST SOLAN H.P 173205	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X750.0 MG VIAL + 10ML WFI AMPOULE	01/07/2013
64	NDA/MAL/HDP/0473	GULF PHARMACEUTICALS INDUSTRIES	OMASI MED LIMITED	TRIMOL DS	SULFAMETHOXAZOLE + TRIMETHOPRIM	800MG+160MG	N/A	GULF PHERMACUTICALS INDUSTRIES AIR PORT ROAD DIGDAGA RAKA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	UNITED ARAB EMIRATES	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2013

65	NDA/MAL/HDP/0483	FOUNTIL LIFE SCIENCES PVT LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ULGICID TABLETS	ALGINIC ACID+ MAGNESIUM HYDROXIDE+ ALUMINIUM HYDROXIDE+ MAGNESIUM TRISILICATE + SIMETICONE	200MG + 250MG + 250MG + 250MG + 125MG	N/A	STEDMAN PHARMACEUTICALS PVT LIMITEDNO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013
66	NDA/MAL/HDP/0491	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABCHLOR EYE DROPS	CHLORAMPHENICOL	0.5% W/V	N/A	ABACUS PARENTERAL DRUGS LTDPLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	UGANDA	OPHTHALMIC DROPS	1.0X5.0 ML VIAL,1.0X10.0 ML VIAL	01/07/2013
67	NDA/MAL/HDP/0522	MEDLEY PHARMACEUTICALS LTD	EUROPA HEALTHCARE (U) LTD	VAZORTAN 50	LOSARTAN POTASSIUM	50MG	N/A	MEDLEY PHARMACEUTICALS LTD PLOT NO. 18 AND 19, SURVEY NO. 378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM , DAMAN-396 210, INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2015

68	NDA/MAL/ HDP/0540	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	HYDRICORT	HYDROCORTISONE SODIUM SUCCINATE	100MG	LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE, NEAR KHATRAJ CHOLADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR	LINCOLN PARENTERAL LTD11, TRIMUL ESTATE, NEAR KHATRAJ CHOLADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: SMALL VOLUME PARENTERAL SOLUTIONS SMALL VOLUME PARENTERAL POWDERS ORAL LIQUIDS	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X100.0 MG VIAL	01/07/2014
69	NDA/MAL/ HDP/0549	ABOTT LABORATORIES S.A (PTY) LTD	HARLEYS UGANDA LIMITED	HIDRASEC	RACECADOTRIL	100 MG	LABORATOIRES SOPHARTEX-21 RUE DU PRESSOIR, 28500 VERNOUILLET, FRANCE	N/A	GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS, HARD GELATIN CAPSULES, SACHETS	RETAINED	FRANCE	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2014
70	NDA/MAL/ HDP/0551	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	REDAMOX	AMXYCILIN +CLAVULANIC ACID	125 MG/ 5 ML + 31.25 MG/ 5 ML	SAKAR HEALTH CARE PVT, LTDBLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST	N/A	PENICILLIN LINE NOT INCLUDED IN THE APPLICATION FOR GMP RE-INSPECTION	RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1X100 ML Bottle,	01/07/2014

71	NDA/MAL/HDP/0552	ABOTT LABORATORIES S.A (PTY) LIMITED	HARLEYS UGANDA LIMITED	HIDRASEC INFANTS	RACECADOTRIL	10 MG	LABORATOIRES SOPHARTEX-21 RUE DU PRESSOIR, 28500 VERNOUILLET, FRANCE	N/A	GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS, HARD GELATIN CAPSULES, SACHETS	RETAINED	FRANCE	ORAL LIQUID ORDINARY OTHER POWDERS/GRANULES	1.0X16.0 SACHET CARTON	01/07/2014
72	NDA/MAL/HDP/0556	ABOTT LABORATORIES S.A (PTY) LTD	HARLEYS UGANDA LIMITED	HIDRASEC CHILDREN	RACECADOTRIL	30 MG	LABORATOIRES SOPHARTEX-21 RUE DU PRESSOIR, 28500 VERNOUILLET, FRANCE	N/A	GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS, HARD GELATIN CAPSULES, SACHETS	RETAINED	FRANCE	ORAL LIQUID ORDINARY OTHER POWDERS/GRANULES	1.0X30.0 SACHET CARTON	01/07/2014
73	NDA/MAL/HDP/0557	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	REDAMOX 312.5	AMOXICILLI AND CLAVULATE POTASSIUM	250 MG/5 ML + 62.5 MG/5 ML	SAKAR HEALTH CARE PVT, LTDBLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDA	N/A	PENICILLIN LINE NOT INCLUDED IN THE APPLICATION FOR GMP RE-INSPECTION; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1X100 ML Bottle,	01/07/2013

74	NDA/MAL/HDP/0560	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	GLIMERYL 1	GLIMEPIRIDE	1MG	N/A	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD .-P.O BOX 69 AMMAM 11591 JORDAN NUZHAT SAHID AL-RAQEEM NEAR PUBLIC HOUSING SECURITY	N/A	NOT RETAINED	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
75	NDA/MAL/HDP/0562	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM COTRI	CO-TRIMOXAZOLE	240MG/5ML	N/A	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	100.0 ML BOTTLE,60.0 ML BOTTLE	01/07/1997
76	NDA/MAL/HDP/0572	NORVATIS PHARMA AG-SWITZERLAND	LABOREX UGANDA LIMITED	AZARGA	BRINZOLAMIDE + TIMOLOL	10MG/ML + 5MG/ML	ALCON COUVREUR NVRIJKSWEG 14, B-2870 PUURS BELGIUM	N/A	GMP EXPIRED ON 08/12/2023 FOR Non-Beta Lactam: Semi-solids (Aseptically prepared) Small Volume Liquids (Aseptically prepared) Small Volume Liquids (Terminally Sterilized)	RETAINED	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML VIAL	01/07/2010

77	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	N/A	GMP EXPIRED ON THE 28/9/2023 FOR NON-BETA LACTAM: TABLETS COATED & UNCOATED HARD GELATIN CAPSULES ORAL LIQUIDS SVP LIQUIDS AND POWDER STERILE GELS , (BETA LACTAM) CEPHALOSPORIN: HARD GELATIN CAPSULES DRY POWDER FOR ORAL SUSPENSION SVP POWDER , CORTICOSTEROIDS: OINTMENTS AND CREAMS	RETAINED	MALAYSIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X 100.0 ML BOTTLE	01/07/2014

78	NDA/MAL/HDP/0574	IPCA LABORATOIES LTD	MEDVIN PHARMA LIMITED	ARTESUNATE AND AMODIAQUINE TABLETS 100/270	ARTESUNATE AND AMODIAQUINE	100MG+270MG	IPCA LABORATORIES LIMITED - SEJAVTA VILLAGE, DIST. RATLAM (M.P) 457002 INDIA.	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: TABLETS ORAL LIQUIDS SVP LIQUIDS IN VIALS AND AMPOULES (ASEPTIC FILLING AND TERMINALLY STERILIZED)	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER,1.0X1.0X6.0 TABLET BLISTER	01/07/2013
79	NDA/MAL/HDP/0588	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROFORT	PREDNISOLONE ACETATE	1%W/V	N/A	AUROLABNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA	N/A	NOT RETAINED	INDIA	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML BOTTLE	01/07/2013
80	NDA/MAL/HDP/0592	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROCHROME	CROMOLYN SODIUM	2%W/V	N/A	AUROLABNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA	N/A	NOT RETAINED	INDIA	OPHTHALMIC LIQUIDS	1.0X10.0 ML CONTAINER	01/07/2013

81	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	N/A	GMP EXPIRED ON 20/11/2023 FOR BETA LACTAM (CEPHALOSPORIN): TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, DRY POWDER FOR ORAL SUSPENSION	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	01/07/2013
82	NDA/MAL/HDP/0618	HETERO LABS LTD	AIVEEN (U) LIMITED	VALSAR 160	VALSARTAN	160MG	N/A	HETERO LABS LTD. UNIT (V)439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2015

83	NDA/MAL/HDP/0621	HETERO LABS LTD	AIVEEN (U) LIMITED	ALZER	DONEPEZIL HYDROCHLORIDE	10MG	N/A	HETERO LABS LTD. UNIT (V)439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2015
84	NDA/MAL/HDP/0622	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	TENOL-50	ATENOLOL	50MG	N/A	LINCOLN PHARMACEUTICALS LTD .10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
85	NDA/MAL/HDP/0630	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	NEO LORIDIN	DESLORATADINE	5MG	CADILA HEALTHCARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO.203-213, KUNDAI	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2011

86	NDA/MAL/HDP/0645	KUNMING PHARMACEUTICALS CORP	SUPER PHARMACEUTICALS LIMITED	COMETHER	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	KUNMING PHARMACEUTICALS CORP-NO.166 KEYI ROAD,STATE NEW AND HIGH TECHNOLOGY	N/A	FACILITY NOT GMP COMPLIANT	RETAINED	CHINA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X3.0X8.0 TABLET BLISTER	01/07/2015
87	NDA/MAL/HDP/0664	HETERO LABS LTD UNIT IX	AIVEEN (U) LIMITED	IRBIS-H 75	IRBESARTAN HYDROCHLOROTHIAZIDE	75 MG	N/A	HETERO LABS LTD. UNIT (V)439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA.	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER	01/07/2013
88	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	N/A	FACILITY NOT APPROVED FOR THE MANUFACTURE OF CREAMS	RETAINED	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE,1.0X15.0 G TUBE	01/07/2013

89	NDA/MAL/HDP/0669	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXEL FUNGICORT CREAM	MICONAZOLE NITRATE + HYDROCORTISONE	2% W/W + 1% W/W	KOTRA PHARMA SDN BDN-1, 2, &3, JALANTT C12 CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA	N/A	GMP EXPIRED ON THE 28/9/2023 FOR NON-BETA LACTAM: TABLETS COATED & UNCOATED HARD GELATIN CAPSULES ORAL LIQUIDS SVP LIQUIDS AND POWDER STERILE GELS , (BETA LACTAM) CEPHALOSPORIN: HARD GELATIN CAPSULES DRY POWDER FOR ORAL SUSPENSION SVP POWDER , CORTICOSTEROIDS: OINTMENTS AND CREAMS	RETAINED	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE,1.0X15.0 G TUBE	01/07/2013

90	NDA/MAL/HDP/0675	ABACUS PHARMA (A) LTD.	UNITED HEALTHCARE DISTRIBUTORS LTD	AXCEL METRONIDAZOLE 400	METRONIDAZOLE	400MG	KOTRA PHARMA-BHD 1, JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA, MALAYSIA	N/A	GMP EXPIRED ON THE 28/9/2023 FOR NON-BETA LACTAM: TABLETS COATED & UNCOATED HARD GELATIN CAPSULES ORAL LIQUIDS SVP LIQUIDS AND POWDER STERILE GELS , (BETA LACTAM) CEPHALOSPORIN: HARD GELATIN CAPSULES DRY POWDER FOR ORAL SUSPENSION SVP POWDER , CORTICOSTEROIDS: OINTMENTS AND CREAMS	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2015

91	NDA/MAL/HDP/0678	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL HYDROCORTISONE CREAM	HYDROCORTISONE	1%W/W	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	N/A	GMP EXPIRED ON THE 28/9/2023 FOR NON-BETA LACTAM: TABLETS COATED & UNCOATED HARD GELATIN CAPSULES ORAL LIQUIDS SVP LIQUIDS AND POWDER STERILE GELS , (BETA LACTAM) CEPHALOSPORIN: HARD GELATIN CAPSULES DRY POWDER FOR ORAL SUSPENSION SVP POWDER , CORTICOSTEROIDS: OINTMENTS AND CREAMS	RETAINED	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X5.0 G TUBE	01/07/2014

92	NDA/MAL/HDP/0698	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	WHITFIELD'S OINTMENT	BENZOIC ACID+SALICYLIC CID	6%W/W + 3%W/W	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	NOT RETAINED	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE	01/07/2003
93	NDA/MAL/HDP/0700	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	VAXIRAB N	INACTIVATED RABIES VIRUS(PITMAN MOORE STRAIN)	>2.5 I.U	CADILA HEALTHCARE LTD--SARKHEJ-PLOT 417,419, 420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL:	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL + 1ML AMPOULE OF WFI(1 DOSE VIAL)	01/07/2015

94	NDA/MAL/HDP/0721	MISSION PHARMA	METRO PHARMACEUTICALS LIMITED	ARH-A	ARTEMETHER	80MG/ML	LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE, NEAR KHATRAJ CHOLADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR	LINCOLN PARENTERAL LTD11, TRIMUL ESTATE, NEAR KHATRAJ CHOLADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: SMALL VOLUME PARENTERAL SOLUTIONS SMALL VOLUME PARENTERAL POWDERS ORAL LIQUIDS	RETAINED	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X2.0X3.0 X1.0 ML AMPOULE,1.0X1.0X6.0 ML AMPOULE	01/07/2014
95	NDA/MAL/HDP/0728	IPCA LABORATOIES LTD	MEDVIN PHARMA LIMITED	ARTESUNATE AND AMODIAQUINE 25/67.5	ARTESUNATE +AMODIAQUINE	25MG+67.5 MG	IPCA LABORATORIES LIMITED - SEJAVTA VILLAGE, DIST. RATLAM (M.P) 457002 INDIA.	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: TABLETS ORAL LIQUIDS SVP LIQUIDS IN VIALS AND AMPOULES (ASEPTIC FILLING AND TERMINALLY STERILIZED)	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER	01/07/2013

96	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.	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: TABLETS ORAL LIQUIDS SVP LIQUIDS IN VIALS AND AMPOULES (ASEPTIC FILLING AND TERMINALLY STERILIZED)	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER	01/07/2013
97	NDA/MAL/HDP/0733	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYNAC	ACECLOFENAC	100MG	CADILA HEALTH CARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAI	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
98	NDA/MAL/HDP/0736	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MABRON 50	TRAMADOL HYDROCHLORIDE	50MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANAS	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013

99	NDA/MAL/HDP/0737	SANOFI AVENTIS	SURGIPHARM (U) LIMITED	TAXOTERE 80MG	DOCETAXEL TRIHYDRATE	80MG/4ML	SANOFI-AVENTIS DEUTSCHLAND GMBH INDUSTRIEPARK HOECHST, BRUNINGSTRASSEN, BUILDING H650 65926 FRANKFU	N/A	GMP EXPIRED ON 08/12/2023 FOR Biologicals: Small Volume Parenterals (Aseptically filled), Cytotoxic: Small Volume Parenterals (Aseptically filled)	NOT RETAINED	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X4.0 ML VIAL	01/07/2014
100	NDA/MAL/HDP/0739	SANOFI AVENTIS	SURGIPHARM (U) LIMITED	TAXOTERE 20MG	DOCETAXEL TRIHYDRATE	20MG/ML	SANOFI-AVENTIS DEUTSCHLAND GMBHINDUSTRIEPARK HOESCHST,BRUNINGSTRASSEN BUIDING, H65065926, FRANKFURT AM MAIN	N/A	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED, GMP EXPIRED ON 08/12/2023 FOR Biologicals: Small Volume Parenterals (Aseptically filled), Cytotoxic: Small Volume Parenterals (Aseptically filled)	NOT RETAINED	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0 ML VIAL	01/07/2014

101	NDA/MAL/HDP/0740	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	COTRIM	CO-TRIMOXAZOLE	960MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANAS	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X17.0X6.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/2013
102	NDA/MAL/HDP/0741	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MEDOCIPRIN	CIPROFLOXACIN	500MG	MEDOCHEMIE LTD (FACTORY AZ)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS, INDUSTRIAL AREA, 4101 AGIOS ATHANAS	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/2013
103	NDA/MAL/HDP/0742	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	BROT	METFORMIN HYDROCHLORIDE	500MG	MEDOCHEMIE (FACTORY AZ).-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013

104	NDA/MAL/HDP/0745	CADILA PHARMACEUTICALS LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	TELI 80	TELMISARTAN	80MG	B. BRAUN MELSUNGEN - MISTELWEG-1389, TRABAD ROAD, DHOLKA 387 810, DISTRICT AHMEDABAD	N/A	FACILITY ADDRESS NOT FOUND	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
105	NDA/MAL/HDP/0747	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	ORALYTE ORANGE CO-PACK	GLUCOSE ANHYDROUS + SODIUM CHLORIDE + TRISSODIUM CITRATE DEHYDRATE + POTASSIUM CHLORIDE / ZINC SULPHATE	13.5G + 2.6G + 2.9G + 1.5G/ SACHET + 27.43MG/5 ML	N/A	: MEDIPHARM INDUSTRIES LTDPLOT 65, KAKAJJO ROAD, BWEYOGERERE POSTAL ADDRESS : P.O.BOX 5917, KAMPALA.	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	UGANDA	ORAL LIQUID ORDINARY OTHER SOLID SPECIAL FORMS	1.0X20.8 G SACHET + 60 ML BOTTLE	01/07/2013
106	NDA/MAL/HDP/0756	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TOLFREE 100	TOLPERISONE	100MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014

107	NDA/MAL/HDP/0757	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TOLFREE 150	TOLPERISONE	150MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
108	NDA/MAL/HDP/0760	BEIJING HOLLEY-COTEC PHARMACEUTICALS CO.,LTD	SUPER PHARMACEUTICALS LIMITED	CEFAX	CEFTRIAXONE	1G	REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100 REYOUNG PHARMACEUTICAL CO. LIMITED-	N/A	TO BE RE-INSTATED AFTER INSPECTION OF THE CEPHALOSPORIN LINE. THIS LINE WAS LAST INSPECTED IN 2016	RETAINED	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X1.0 G VIAL	01/07/2013
109	NDA/MAL/HDP/0774	CADILA PHARMACEUTICALS LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	NODON	NEBIVOLOL	10MG	CADILA HEALTH CARE LIMITED - PLOT 203-213, KUNDAIM INDUSTRIAL ESTATE	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X1.0X10.0 TABLET BLISTER	01/07/2012

110	NDA/MAL/HDP/0776	FREDUN PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	FREMOL TABLETS	PARACETAMOL TABLETS	500MG	N/A	FREDUN PHARMACEUTICALS LTD14,15,16 ZORBIAN INDUSTRIAL COMPLEX VEOOR PALGHAR EAST INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1999
111	NDA/MAL/HDP/0780	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ATORVA TABLETS	ATORVASTATIN	10MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X1.0X7.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2001
112	NDA/MAL/HDP/0781	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	TRICOLD	PARACETAMOL/PHENYLEPHRINE HYDROCHLORIDE/CAFFEINE ANHYDROUS/CHLORPHENIRAMINE	500MG/10MG/30MG/2MG	N/A	TRIVENI FORMULATIONS LIMITED -PLOT NO 52-54,62-64 ALEAP INDUSTRIAL ESTATE SURAMPALLI (V) VIJAYAWADA A.P	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X50.0X4.0 TABLET BLISTER	01/07/2013

113	NDA/MAL/HDP/0783	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	CYPOLIVE	CYPROHEPTADINE HYDROCHLORIDE	4 MG	N/A	TRIVENI FORMULATIONS LIMITED-PLOT NO: 52,53,54, 62,63 & 64 ALEAP INDUSTRIAL ESTATE SURAMPALI VILLAGE, GANNAVARAM MANDAL KRISHNA (DT) A.P	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X50.0 TABLET BLISTER	01/07/2013
114	NDA/MAL/HDP/0786	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	DERMA 1	GRISEOFULVIN	500MG	N/A	TRIVENI FORMULATIONS LTD .PLOT NO. 52, 53,54 ALEAP INDUSTRIAL ESTATE SURAMPALLI VILLAGE GANNAVARAM MANDAL KRISHNA (DT) A.P	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
115	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	N/A	GMP EXPIRED ON 2/11/2023 NON-BETA LACTAM: EYE DROPS, EAR DROPS, EXTERNAL PREPARATIONS (CREAMS & OINTMENTS), EYE OINTMENTS, ORAL LIQUIDS	RETAINED	PAKISTAN	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2014

116	NDA/MAL/HDP/0795	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPEN-250	PHENOXYMETHYL PENICILLIN POTASSIUM	250MG	N/A	MILAN LABORATORIES (INDIA) PVT LTD .PLOTS 63,67,87,35,36,64,65, JAWAHAR CO-OP IND. ESTATE LTD, KAMOTHE, PANVEL (NAVI MUMBAI)	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER	01/07/2013
117	NDA/MAL/HDP/0796	HETERO LABS LTD	AIVEEN (U) LIMITED	AMLOSIN 5	AMLODIPINE BESILATE	5MG	N/A	HETERO LABS LTD. UNIT (V) .S.N0.439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA. HETERO DRUGS LTD. VILLAGE KALYANPUR, CHAKKAN ROAD, BADDI, TEHSIL NALAGARH, DIST. SOLAN, HIMACHAL PRADESH PIN: 173 205	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2013

118	NDA/MAL/HDP/0798	HETERO LABS LTD	AIVEEN (U) LIMITED	AMLOSIN 10	AMLODIPINE BESILATE	10MG	N/A	HETERO LABS LTD (UNIT-V)SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2013
119	NDA/MAL/HDP/0808	PIRAMAL HEALTHCARE LTD	TATA UGANDA LIMITED	TERRELL	ISOFLURANE	250ML	N/A	PIRAMAL ENTERPRISES LTD, INDIADIGWAL VILLAGE KOHIR MENDAL MEDAK DISTRICT,ANDHRA PRADESH	N/A	NOT RETAINED	INDIA	OTHER SYSTEMIC LIQUID INHALATIONS	1.0X250.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2005

120	NDA/MAL/HDP/0809	PINEWOOD LABORATORIES LTD	BOOTS PHARMACEUTICALS LIMITED	PARAPAED	PARACETAMOL	120MG/5ML	PINEWOOD LABORATORIES LTD-BALLYMACARBRY, CLONMEL, TIPPERARY, IRELAND	N/A	GMP EXPIRED ON THE 7/9/2021 FOR ORAL LIQUIDS (SYRUPS, SUSPENSIONS, SOLUTIONS) EXTERNAL LIQUIDS (SHAMPOO, LOTIONS) SEMISOLIDS (CREAMS, OINTMENTS, GELS) & ENEMAS; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	IRELAND	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2013

121	NDA/MAL/HDP/0810	PINEWOOD LABORATORIES LTD	BOOTS PHARMACEUTICALS LIMITED	SIX PLUS PARAPAED	PARACETAMOL	250MG/ML	PINEWOOD LABORATORIES LTD-BALLYMACARBRY, CLONMEL, TIPPERARY, IRELAND	N/A	GMP EXPIRED ON THE 7/9/2021 FOR ORAL LIQUIDS (SYRUPS, SUSPENSIONS, SOLUTIONS) EXTERNAL LIQUIDS (SHAMPOO, LOTIONS) SEMISOLIDS (CREAMS, OINTMENTS, GELS) & ENEMAS; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	IRELAND	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2013
122	NDA/MAL/HDP/0820	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	FIXIME 400MG	CEFIXIME	400MG	NKUNZI PHARMACEUTICALS-259 DAVIDSON ROAD, WADEVILLE GERMISTON	N/A	FACILITY NOT APPROVED FOR THE MANUFACTURE OF THIS PRODUCT LINE	RETAINED	SOUTH AFRICA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X5.0 TABLET BLISTER,1.0X1.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER	01/07/2015
123	NDA/MAL/HDP/0823	ZYDUS LIFESCIENCES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TRAP TABLETS	TRAMADOL HCL + PARACETAMOL	37.5MG+325MG	CADILA HEALTHCARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO.203-213, KUNDAI	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013

124	NDA/MAL/HDP/0824	I CARE PHARMA LIMITED	VITACARE LTD	CLOXACILLIN	CLOXACILLIN	250MG	REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG	MEDICO REMEDIES PVT LTD,.-8 & 9 DEWAN AND SONS, UDYOG NAGAR, PALGHAR, DIST. THANE-401404, MAHARSHITRA	FACILITY CHANGED ADDRESS TO NO.1. CLIENT REQUIRED TO APPLY FOR A VARIATION	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/2013
125	NDA/MAL/HDP/0826	I CARE PHARMA LIMITED	VITACARE LTD	AMOXYCILLIN	AMOXYCILLIN	250MG	REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	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	FACILITY CHANGED ADDRESS TO NO.1. CLIENT REQUIRED TO APPLY FOR A VARIATION	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/2013
126	NDA/MAL/HDP/0831	I CARE PHARMA LIMITED	VITACARE LTD	AMPICILLIN CAPSULES	AMPICILLIN	250MG	REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG	MEDICO REMEDIES PVT LTD,.-8 & 9 DEWAN AND SONS, UDYOG NAGAR, PALGHAR, DIST. THANE-401404, MAHARSHITRA	FACILITY CHANGED ADDRESS TO NO.1. CLIENT REQUIRED TO APPLY FOR A VARIATION	RETAINED	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/2013

127	NDA/MAL/HDP/0841	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	ETHOMID	ETHIONAMIDE	250MG	N/A	MACLEODS PHARMACEUTICALS LTD .PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2013
128	NDA/MAL/HDP/0860	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	FLOXSAFE 400	MOXIFLOXACIN HYDROCHLORIDE	400MG	N/A	MSN LABORATORIES LTDPLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X5.0 TABLET BLISTER	01/07/2012
129	NDA/MAL/HDP/0861	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	PROZINE	PROMETHAZINE	25MG/ML	N/A	SAKAR HEALTHCARE PVT. LTDPLOT 10/13 SAKHEJ-BAVLA ROAD, AHMEDABAD,GUJURAT,INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	PARENTERAL ORDINARY AMPOULES	2.0X5.0X2.0 ML AMPOULE	01/07/2013

130	NDA/MAL/ HDP/0869	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	LARTRM	ARTEMETHER	80MG/ML	N/A	SAKAR HEALTH CARE PVT, LTDBLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382-213,GUJARAT-INDIA	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE	01/07/2013
131	NDA/MAL/ HDP/0873	GITTOES PHARMACEU TICALS LIMITED	GITTOES PHARMACEU TICALS LIMITED	OXYTOCIN INJECTION	OXYTOCIN	10I.U/ML	NINGBO DAHONG YING PHARMA CEUTICAL CO LTDNO 396, MINGZH U ROAD NINGBO	SAKAR HEALTH CARE PVT LTD10/13 CHONGODAR SARKHEJ BAVLA ROAD DIST AHEMABAD 382213 GUJARATI	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: TABLETS, CAPSULES, SVP LIQUIDS	RETAINED	CHINA INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1. 0 ML AMPOULE	01/07/2009
132	NDA/MAL/ HDP/0894	HETERO LABS LTD	AIVEEN (U) LIMITED	GIAGRA 100	SILDENAFIL CITRATE	100MG	N/A	HETERO LABS LTD. UNIT (V)439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X10. 0 TABLET BLISTER,1.0X 4.0 TABLET BLISTER	01/07/2014

133	NDA/MAL/HDP/0905	NECTAR LIFESCIENCES LTD	AIVEEN (U) LIMITED	NECPOD	CEFPODOXIME PROXETIL	200MG	N/A	NECTAR LIFESCIENCES LTD UNIT VI-BHATOLIKALAN P.O BAROTIWALA DISTT SOLAN HIMACHAL PRADESH 173205	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2013
134	NDA/MAL/HDP/0907	NECTAR LIFESCIENCES LTD	AIVEEN (U) LIMITED	CEFUAXIT	CEFUROXIME AXETIL	250MG	N/A	NECTAR LIFE SCIENCES LTD--UNIT VI BHATOLIKALAN DIST SOLAN H.P	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET STRIP	01/07/2013
135	NDA/MAL/HDP/0909	NECTAR LIFESCIENCES LTD	AIVEEN (U) LIMITED	FIXINECT	CEFIXIME	100MG	N/A	NECTAR LIFESCIENCES LTD UNIT VI-BHATOLIKALAN P.O BAROTIWALA DISTT SOLAN HIMACHAL PRADESH 173205	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET STRIP	01/07/2013
136	NDA/MAL/HDP/0915	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	CURAM	AMOXICILLIN + CLAVULANIC ACID	875 MG + 125 MG	N/A	SANDOZ GMBHBIOCHEMIESTRASSE 10, A6250 KUNDL, TYROL, AUSTRIA	N/A	NOT RETAINED	AUSTRIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X7.0X2.0 TABLET STRIP	01/07/2014
137	NDA/MAL/HDP/0934	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ODIMONT 4	MONTELUKAST	4MG	CADILA HEALTHCARE LTD SARKHEJ BAVLA NH NO.8A MORAIYA TAL SANAND DISTRICT	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011

138	NDA/MAL/HDP/0945	CLARIS LIFE SCIENCES LIMITED	REDDYS PHARMA LIMITED	ZOFEX	OFLOXACIN	2 MG/ML	CLARIS OTSUKA LIMITED-VILLAGE – VASANA – CHACHA RWADIP, TAL: SANAND, AHMADABAD	N/A	NAME OF FACILITY CHANGED TO OTSUKA PHARMACEUTICAL PVT INDIA LTD. CLIENT REQUIRED TO APPLY FOR A VARIATION; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2013
139	NDA/MAL/HDP/0950	JULPHAR GULF PHARMACEUTICAL INDUSTRIES	OMASI MED LIMITED	EPOTIN	ERYTHROPOIETIN	4000I.U	N/A	JULPHAR GULF PHARMACEUTICAL INDUSTRIESDIGDIGA AREA, AIR PORT ROAD P.O BOX 977 RAS-AL KHAIMAH UAE	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	UNITED ARAB EMIRATES	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X10.0 PREFILLED SYRINGE CARTON	01/07/2012
140	NDA/MAL/HDP/0951	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	NORAD	STERILE NORADRENALINE CONCENTRATE	2MG/2ML	N/A	NEON LABORATORIES LTDPLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO-OPERATIVE ESTATE , BOISAR ROAD	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	PARENTERAL ORDINARY S C AMPOULES	1.0X5.0X2.0 ML AMPOULE	01/07/2013

141	NDA/MAL/HDP/0965	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	AMADAY - 5	AMLODIPINE	5MG	N/A	AJANTA PHARMA LTD31-0, M.I.D.C. CHIKALTHANA, CHIKALTHANA, AURANGABAD, MAHARASHTRA STATE, INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
142	NDA/MAL/HDP/0985	CADILA PHARMACEUTICALS LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	CADITOR 10	ATORVASTATIN	10 MG	B. BRAUN MELSUNGEN - MISTELWEG-1389, TRABAD ROAD, DHOLKA 387 810, DISTRICT AHMEDABAD	N/A	FACILITY ADDRESS NOT FOUND;NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

143	NDA/MAL/HDP/0986	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CONVENTIN	GABAPENTIN	100MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS FOR INTERNAL USE TABLETS (COATED AND UNCOATED) HARD GELATIN CAPSULES ORAL POWDER FOR SUSPENSION OINTMENTS, CREAMS AND GELS	RETAINED	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2013

144	NDA/MAL/HDP/0990	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FUSIDERM CREAM	FUSIDIC ACID	2%W/W	EVA PHARMA FOR PHARMA CEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS FOR INTERNAL USE TABLETS (COATED AND UNCOATED) HARD GELATIN CAPSULES ORAL POWDER FOR SUSPENSION OINTMENTS, CREAMS AND GELS	RETAINED	EGYPT	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2013
145	NDA/MAL/HDP/0991	CADILA PHARMACEUTICALS LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	CADITOR 40	ATORVASTATIN	40MG	B. BRAUN MELSUNGEN - MISTELWEG-1389, TRABAD ROAD, DHOLKA 387 810, DISTRICT AHMEDABAD	N/A	FACILITY DETAILS NOT FOUND;NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

146	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	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS FOR INTERNAL USE TABLETS (COATED AND UNCOATED) HARD GELATIN CAPSULES ORAL POWDER FOR SUSPENSION OINTMENTS, CREAMS AND GELS	RETAINED	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

147	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	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS FOR INTERNAL USE TABLETS (COATED AND UNCOATED) HARD GELATIN CAPSULES ORAL POWDER FOR SUSPENSION OINTMENTS, CREAMS AND GELS	RETAINED	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2014

148	NDA/MAL/HDP/1001	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	THIOEVA	THIOTIC ACID	300MG	EVA PHARMA FOR PHARMA CEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS FOR INTERNAL USE TABLETS (COATED AND UNCOATED) HARD GELATIN CAPSULES ORAL POWDER FOR SUSPENSION OINTMENTS, CREAMS AND GELS	RETAINED	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

149	NDA/MAL/HDP/1003	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ZEFICAM	LORNOXICAM	8MG	EVA PHARMA FOR PHARMA CEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS FOR INTERNAL USE TABLETS (COATED AND UNCOATED) HARD GELATIN CAPSULES ORAL POWDER FOR SUSPENSION OINTMENTS, CREAMS AND GELS	NOT RETAINED	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2013
150	NDA/MAL/HDP/10042	GLOBELA PHARMA PVT. LTD.	SHREEJI CARE LIMITED	BACIPRO	CIPROFLOXACIN HYDROCHLORIDE	500 MG	GLOBELA PHARMA PVT.LTD. 357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, ORAL POWDER IN SACHETS AND BOTTLES. ONCOLOGY: TABLETS, HARD GELATIN CAPSULES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	19/07/2022

151	NDA/MAL/HDP/10060	EMCURE PHARMACEUTICALS LTD -	HARLEYS UGANDA LIMITED	VIROPIL	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE	50 MG + 300 MG + 300 MG	EMCURE PHARMACEUTICALS LIMITEDPLOT NO. P-2. ITBT PARK, PHASE II, MIDC, HINJWADI PUNE 411057	N/A	FACILITY NOT APPROVED TO MANUFACTURE PRODUCT LINE	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1X1X30 TABLET Container,	19/07/2022
152	NDA/MAL/HDP/10071	ARTURA PHARMACEUTICALS PVT LTD	SWASTIK PHARMACEUTICAL LTD	FENAPAR	PARACETAMOL + ACECLOFENAC	500 MG + 100 MG	ARTURA PHARMACEUTICALS PRIVATE LIMITEDNO. 1505, PORTIA ROAD SRI CITY SEZ, SATYAVEDU MANDAL, CHITTOO	N/A	GMP EXPIRED ON 19/10/2020 FOR Non-Beta Lactam: Tablets (Coated & Uncoated) Hard Gelatin Capsules	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	14/07/2022
153	NDA/MAL/HDP/10072	EMCURE PHARMACEUTICALS LTD -	HARLEYS UGANDA LIMITED	INBEC	ABACAVIR SULPHATE + DOLUTEGRAVIR SODIUM + LAMIVUDINE	600 MG + 50 MG + 300 MG	EMCURE PHARMACEUTICALS LIMITEDPLOT NO. P-2. ITBT PARK, PHASE II, MIDC, HINJWADI PUNE 411057	N/A	FACILITY NOT APPROVED TO MANUFACTURE PRODUCT LINE	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1X1X30 TABLET Container,	14/07/2022

154	NDA/MAL/HDP/10074	TAURUS CHEMICALS (P) LTD.	HEALTHCARE LTD.	MAGACID SUSPENSION	ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE	(215 MG + 80 MG + 25 MG)/5ML	AL FAZAL PHARMA INDUSTRIES (PVT) LTD-PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN	N/A	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS, HARD GELATIN CAPSULES, OINTMENTS/CREAMS/GELS	RETAINED	PAKISTAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X120.0 ML BOTTLE,1.0X1.0X200.0 ML BOTTLE	14/07/2022
155	NDA/MAL/HDP/10075	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	TELPER 80	TELMISARTAN	80 MG	GLOBELA PHARMA PVT.LTD. 357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, ORAL POWDER IN SACHETS AND BOTTLES. ONCOLOGY: TABLETS, HARD GELATIN CAPSULES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	14/07/2022

156	NDA/MAL/HDP/1011	COSMOS LTD	ASTRA PHARMA (U) LIMITED	DABORAL SYRUP	AMINOSIDINE	125MG/5ML	N/A	COSMOS LIMITED, KENYARANGWE ROAD, OFF LUNGA ROAD, INDUSTRIAL AREA NAIROBI - KENYA	N/A	NOT RETAINED	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2012
157	NDA/MAL/HDP/1014	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	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	NOT RETAINED	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X20.0X4.0 TABLET BLISTER	01/07/2015
158	NDA/MAL/HDP/10155	MEDIPAK LIMITED	HEALTHCARE LTD.	MEDISOL NS	SODIUM CHLORIDE	0.9%W/V	N/A	MEDIPAK LTD132/2/ INDUSTRIAL ESTATE KOT LAKHPAT, LAHORE	N/A	NOT RETAINED	PAKISTAN	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	02/09/2022
159	NDA/MAL/HDP/10156	MEDIPAK LIMITED	HEALTHCARE LTD.	MEDISOL 5%	DEXTROSE	5%W/V	N/A	MEDIPAK LTD132/2/ INDUSTRIAL ESTATE KOT LAKHPAT, LAHORE	N/A	NOT RETAINED	PAKISTAN	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	02/09/2022

160	NDA/MAL/HDP/10157	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	MOXIPEN ORAL SUSPENSION	AMOXICILLIN	125MG/5ML	XEPA-SOUL PATTINSON (MALAYSIA) SDN.BHD.-1-5 CHENG	N/A	FACILITY NOT APPROVED TO MANUFACTURE BETA LACTAMS	RETAINED	MALAYSIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE	29/08/2022
161	NDA/MAL/HDP/10158	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	ERYSOL ORAL SUSPENSION	ERYTHROMYCIN ETHYLSUCCINATE	200MG/5ML	XEPA-SOUL PATTINSON (MALAYSIA) SDN.BHD.-1-5 CHENG	N/A	FACILITY NOT APPROVED TO MANUFACTURE ORAL DRY POWDERS	RETAINED	MALAYSIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE	29/08/2022
162	NDA/MAL/HDP/10159	MARTIN DOW MARKER LTD	HEALTHCARE LTD.	KLARIBACT	CLARITHROMYCIN	500MG	N/A	MARTIN DOW MARKER LIMITED7, JAIL ROAD, QUETTA - PAKISTAN	N/A	NOT RETAINED	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2012

163	NDA/MAL/HDP/1016	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ASCORBIC ACID	ASCORBIC ACID	200MG	ELYS CHEMICAL INDUSTRIES LIMITED-ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	NOT RETAINED	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X10.0 TABLET BLISTER	01/07/2014
164	NDA/MAL/HDP/10160	MARTIN DOW MARKER LTD	HEALTHCARE LTD.	KLARIBACT	CLARITHROMYCIN	250MG	N/A	MARTIN DOW MARKER LIMITED7, JAIL ROAD, QUETTA - PAKISTAN	N/A	NOT RETAINED	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2013
165	NDA/MAL/HDP/10161	MARTIN DOW MARKER LTD	HEALTHCARE LTD.	KLARIBACT	CLARITHROMYCIN	125MG/5ML	N/A	MARTIN DOW MARKER LIMITED7, JAIL ROAD, QUETTA - PAKISTAN	N/A	NOT RETAINED	PAKISTAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X60.0 ML BOTTLE	01/07/2014
166	NDA/MAL/HDP/10162	MARTIN DOW MARKER LTD	HEALTHCARE LTD.	LEVOMERC	LEVOFLOXACIN	500MG	N/A	MARTIN DOW MARKER LIMITED7, JAIL ROAD, QUETTA - PAKISTAN	N/A	NOT RETAINED	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2013

167	NDA/MAL/ HDP/10164	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ASPIRIN TABLETS	ACETYLSALICYCLIC ACID	300MG	ELYS CHEMICAL INDUSTRIES LIMITED,-OFF ENTERPRISE ROAD, OPP HILLLOCK-INN ROAD B, INDUSTRIAL AREA	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	RETAINED	KENYA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET STRIP,1.0X200.0 TABLET TIN,1.0X1000.0 TABLET TIN	02/09/2022
168	NDA/MAL/ HDP/10167	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	HEDAPAN TABLET	ASPIRIN/PARACETAMOL/CAFFEINE	400MG/500MG/50MG	ELYS CHEMICAL INDUSTRIES LIMITED,-OFF ENTERPRISE ROAD, OPP HILLLOCK-INN ROAD B, INDUSTRIAL AREA	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	NOT RETAINED	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	02/09/2022

169	NDA/MAL/HDP/10168	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	LYFE	ORAL REHYDRATION SALT	N/A	ELYS CHEMICAL INDUSTRIES LIMITED,-OFF ENTERPRISE ROAD, OPP HILLLOCK-INN ROAD B, INDUSTRIAL AREA	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	RETAINED	KENYA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X14.0 G SACHET,1.0X 28.0 G SACHET	02/09/2022
170	NDA/MAL/HDP/10169	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ORODAR	SULFADOXINE +PYRIMETHAMINE	500MG+25 MG	ELYS CHEMICAL INDUSTRIES LIMITED,-OFF ENTERPRISE ROAD, OPP HILLLOCK-INN ROAD B, INDUSTRIAL AREA	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	RETAINED	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X30.0X3.0 TABLET BLISTER,1.0X 10.0X10.0 TABLET BLISTER,1.0X 1000.0 TABLET CONTAINER	02/09/2022

171	NDA/MAL/HDP/1017	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYCLOX	AMPICILLIN/CLOXACILLIN	125MG/125MG	N/A	ELYS CHEMICAL INDUSTRIES LIMITEDROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	N/A	NOT RETAINED	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2015
172	NDA/MAL/HDP/10170	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	PREDNISOLONE TABLETS	PREDNISOLONE	5MG	ELYS CHEMICAL INDUSTRIES LIMITED,-OFF ENTERPRISE ROAD, OPP HILLLOCK-INN ROAD B, INDUSTRIAL AREA	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	NOT RETAINED	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	02/09/2022

173	NDA/MAL/HDP/10174	STRIDES PHARMA SCIENCE LIMITED	DELMAW ENTERPRISES LIMITED	DOLUTEGRAVIR TABLETS 50 MG	DOLUTEGRAVIR SODIUM	50 MG	STRIDES SHASUN LIMITED-NO. 36/7, SURAGAJAKKANAHALLI, INDLAVADI CROSS, ANEKAL TALUK, BENGALURU, KARNATA	N/A	FACILITY NAME CHANGED TO STRIDES PHARMA SCIENCE LIMITED; APPLICANT REQUIRED TO APPLY FOR VARIATION FOR CHANGE OF NAME	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	09/09/2022
174	NDA/MAL/HDP/10205	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	IVAZYD 5	IVABRADINE HYDROCHLORIDE	5 MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/09/2022
175	NDA/MAL/HDP/10214	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ILAXTEN 20 MG TABLETS	BILASTINE	20MG	A. MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.L-VIA SETTE	A. MENARINI MANUFACTURING LOGISTICS AND SERVICES SRL-VIA CAMPO DI PILE 67100 L'AQUILA (AQ)	FACILITY NOT APPROVED FOR THE MANUFACTURE OF THE PRODUCT LINE	RETAINED	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X1.0X4.0 TABLET BLISTER	09/09/2022

176	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	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS FOR INTERNAL USE TABLETS (COATED AND UNCOATED) HARD GELATIN CAPSULES ORAL POWDER FOR SUSPENSION OINTMENTS, CREAMS AND GELS	RETAINED	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2013
177	NDA/MAL/HDP/10225	LUKAS LAB LTD	PLUTO PHARMACEUTICALS LIMITED	LUSNAT 60	ARTESUNATE	60 MG	N/A	BLISS INDAS LIFESCIENCE P. LTD..PLOT 73-76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X60.0 MG VIAL + 1ML 0F 5.0%W/V SODIUM BICARBONATE VIAL + 5ML OF 0.9%W/V SODIUM CHLORIDE	09/09/2022
178	NDA/MAL/HDP/10226	LUKAS LAB LTD	PLUTO PHARMACEUTICALS LIMITED	LUSNAT 120	ARTESUNATE	120 MG	N/A	BLISS INDAS LIFESCIENCE P. LTD..PLOT 73-76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN	N/A	NOT RETAINED	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

179	NDA/MAL/HDP/10244	ZYDUS DISCOVERY DMCC	ABACUS PHARMA (AFRICA) LIMITED	LIPAGLYN	SAROGLITAZAR MAGNESIUM	4MG	CADILA HEALTHCARE LTD. PLOT NO. 417, 419 & 420, SARKHEJ-BAVLA N.H. NO. 8A, MORAIYA, TAL: SANAND, DIST. AHMEDABAD	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER	09/09/2022
180	NDA/MAL/HDP/10297	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	ACECLAV 1000	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	875 MG + 125 MG	MEDICEF PHARMA-NO. 28, PHASE 1, EPIP, JHARRMAJRI, BADDI, DIST SOLAN (HP)	N/A	GMP EXPIRED FOR 30/9/2023 FOR BETA LACTAM (PENICILLIN): TABLETS, DRY POWDER FOR ORAL SUSPENSION	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	09/09/2022
181	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)	N/A	GMP EXPIRED FOR 30/9/2023 FOR BETA LACTAM (PENICILLIN): TABLETS, DRY POWDER FOR ORAL SUSPENSION	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	09/09/2022

182	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)	N/A	GMP EXPIRED FOR 30/9/2023 FOR BETA LACTAM (PENICILLIN): TABLETS, DRY POWDER FOR ORAL SUSPENSION	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	09/09/2022
183	NDA/MAL/ HDP/1031	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MOXIFLOX	MOXIFLOXACIN	400MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS FOR INTERNAL USE TABLETS (COATED AND UNCOATED) HARD GELATIN CAPSULES ORAL POWDER FOR SUSPENSION OINTMENTS, CREAMS AND GELS	RETAINED	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X1.0X5.0 TABLET BLISTER	01/07/2013
184	NDA/MAL/ HDP/10315	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	INDOMETHACIN	INDOMETHACIN	25MG	GREENFIELD PHARMACEUTICAL (JIANGSU) CO. LTD-NO. 38 TAIJIU ROAD TAIZHOU	M/S SCOTT-EDIL PHARMACIA LIMITED-56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA	GMP EXPIRED ON THE 7/9/2012 FOR TABLETS HARD GELATIN CAPSULES SVP SOLUTIONS	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE TIN,1.0X500.0 CAPSULE TIN,1.0X10.0X10.0 CAPSULE BLISTER	01/07/2008

185	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	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS FOR INTERNAL USE TABLETS (COATED AND UNCOATED) HARD GELATIN CAPSULES ORAL POWDER FOR SUSPENSION OINTMENTS, CREAMS AND GELS	RETAINED	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2013

186	NDA/MAL/HDP/10324	APEX LABORATORIES PRIVATE LIMITED	NORVIK ENTERPRISES LIMITED	ZINCOVIT TABLETS	VITAMIN A (AS ACETATE) + VITAMIN D3 (CHOLECALCIFEROL) + VITAMIN E (AS DL-TOCOPHERYL ACETATE) + THIAMINE NITRATE + RIBOFLAVIN + PYRIDOXINE HYDROCHLORIDE + CYANOCOBALAMIN + NICOTINAMIDE + CALCIUM PANTOTHENATE + ASCORBIC ACID + MAGNESIUM OXIDE + MANGANESE SU	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	N/A	GMP EXPIRED ON THE 10/9/2022 FOR NON-BETA LACTAM (HUMAN): TABLETS (COATED AND UNCOATED) SEMI SOLIDS (CREAMS AND OINTMENTS) HARD GELATIN CAPSULES	RETAINED	INDIA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER	09/09/2022

187	NDA/MAL/HDP/10335	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	N/A	GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES	RETAINED	EGYPT	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	09/09/2022
188	NDA/MAL/HDP/1034	VOGEN LABORATORIES LTD	BUFFALO HEALTH CARE LTD	DURAMOX	AMOXICILLIN	250MG/5ML	VOGEN LABORATORIES LTD70, M.HERACLEOUS STR. AYIOS ATHANASIOS INDUSTRI	N/A	GMP EXPIRED ON 08/12/2023 FOR Penicillin: Hard Gelatin Capsules Powders for oral suspension	NOT RETAINED	CYPRUS	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2007
189	NDA/MAL/HDP/10340	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	N/A	GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES	RETAINED	EGYPT	TOPICAL EXTERNAL LOTIONS	1.0X1.0X30.0 ML BOTTLE	09/09/2022

190	NDA/MAL/HDP/1035	B&O PHARM	TRIDEM PHARMA UGANDA LIMITED	G-CIPROX	CIPROFLOXACIN	500MG	N/A	GUILIN PHARMACEUTICAL CO.LTD.NO.43 QUILIDIAN ROAD GUILIN 541002, GUANGXI, CHINA	N/A	NOT RETAINED	CHINA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2014
191	NDA/MAL/HDP/10372	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	IPOPRIN 2	POMALIDOMIDE	2MG	MSN LABORATORIES PRIVATE LIMITED-UNIT II, SY. NO. 1277 & 1319 TO 1324, NANDIGAMA (VILLAGE & MANDAL), RANDAREDDY	N/A	ADDRESS OF THIS FACLITY IS DIFFERENT FROM THE ONE PREVIOUSLY INSPECTED (SY. NO 1277 & 1319-1324, MAHABUBNAGAR, DIST TELANGANA 509216 INDIA). ADDRESS TO BE VERIFIED AFTER GMP INSPECTION	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X21.0 CAPSULE BOTTLE	09/09/2022
192	NDA/MAL/HDP/10373	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	IPOPRIN 4	POMALIDOMIDE	4MG	MSN LABORATORIES PRIVATE LIMITED-UNIT II, SY. NO. 1277 & 1319 TO 1324, NANDIGAMA (VILLAGE & MANDAL), RANDAREDDY	N/A	ADDRESS OF THIS FACLITY IS DIFFERENT FROM THE ONE PREVIOUSLY INSPECTED (SY. NO 1277 & 1319-1324, MAHABUBNAGAR, DIST TELANGANA 509216 INDIA). ADDRESS TO BE VERIFIED AFTER GMP INSPECTION	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X21.0 CAPSULE BOTTLE	09/09/2022

193	NDA/MAL/ HDP/10391	SANDOZ GMBH .	SURGIPHARM (U) LIMITED	HYDROXYU REA 100MG	HYDROXYCAR BAMIDE	100MG	SALUTAS PHARMA GMBH-OTTO-VON-GUERICK E ALLEE-1, 39179 BARLEBE N	HAUPT PHARMA AMAREG GMBH-DONAUSTAUFER STRASSE 378, 93055 REGENSBURG SIEGFRIED BARBERA, S.L.-RONDA SANTA MARIA 158, 08210 BARBERA DEL VALLES, BARCELONA, SPAIN.	GMP EXPIRED ON THE 12/11/2022 FOR HARD GELATIN CAPSULES AND TABLETS	RETAINED	GERMANY SPAIN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X60. 0 TABLET BOTTLE,1.0X 1.0X90.0 TABLET BOTTLE,1.0X 1.0X120.0 TABLET BOTTLE,1.0X 200.0 TABLET BOTTLE	09/09/2022
194	NDA/MAL/ HDP/10392	SANDOZ GMBH .	SURGIPHARM (U) LIMITED	HYDROXYU REA 1000MG	HYDROXYCAR BAMIDE	1000MG	SALUTAS PHARMA GMBH-OTTO-VON-GUERICK E ALLEE-1, 39179 BARLEBE N	HAUPT PHARMA AMAREG GMBH-DONAUSTAUFER STRASSE 378, 93055 REGENSBURG SIEGFRIED BARBERA, S.L.-RONDA SANTA MARIA 158, 08210 BARBERA DEL VALLES, BARCELONA, SPAIN.	GMP EXPIRED ON THE 12/11/2022 FOR HARD GELATIN CAPSULES AND TABLETS	RETAINED	GERMANY SPAIN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30. 0 TABLET BOTTLE	09/09/2022

195	NDA/MAL/HDP/10417	CADILA HEALTHCARE LIMITED "ZYDUS TOWER" -	ABACUS PHARMA (AFRICA) LIMITED	DUONAS	AZELASTINE HYDROCHLORIDE + FLUTICASONE PROPIONATE	137MCG/50MCG PER ACTUATION	CADILA HEALTHCARE LTD. PLOT NO. 417, 419 & 420, SARKHEJ-BAVLA N.H. NO. 8A, MORAIYA, TAL: SANAND, DIST. AHMEDABAD	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	NASAL SYSTEMIC METERED-DOSE LIQUIDS	1.0X1.0X30.0 ML BOTTLE	08/02/2023
196	NDA/MAL/HDP/10426	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SUPAGREL 90	TICAGRELOR	90 MG	MSN LABORATORIES PRIVATE LIMITED-UNIT II, SY. NO. 1277 & 1319 TO 1324, NANDIGAMA (VILLAGE & MANDAL), RANDAREDDY	N/A	ADDRESS OF THIS FACLITY IS DIFFERENT FROM THE ONE PREVIOUSLY INSPECTED (SY. NO 1277 & 1319-1324, MAHABUBNAGAR, DIST TELANGANA 509216 INDIA). ADDRESS TO BE VERIFIED AFTER GMP INSPECTION	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023
197	NDA/MAL/HDP/10428	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	AMOXI-DENK 1000	AMOXICILLIN TRIHYDRATE	1000 MG	PENCEF PHARMA GMBHBREITENBACHSTRABE 13-14, 13509 BERLIN - GERMANY	N/A	GMP EXPIRED ON 29/12/2023 FOR Beta Lactam (Human): Tablets Oral Powders for Oral Suspension Hard Gelatin Capsules	RETAINED	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	08/02/2023

198	NDA/MAL/ HDP/10429	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	AMOXI-DENK 500	AMOXICILLIN TRIHYDRATE	500 MG	PENCEF PHARMA GMBHBR EITENBA CHSTRAB E 13-14, 13509 BERLIN - GERMAN Y	N/A	GMP EXPIRED ON 29/12/2023 FOR Beta Lactam (Human): Tablets Oral Powders for Oral Suspension Hard Gelatin Capsules	RETAINED	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10. 0 TABLET BLISTER,1.0X 3.0X10.0 TABLET BLISTER	08/02/2023
199	NDA/MAL/ HDP/10431	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	CLAMOXIN 375 INJECTION	AMOXICILLIN SODIUM + POTASSIUM CLAVULANAT E	250 MG + 125 MG/VIAL	MEDOPH ARM PVT LIMITED-NO. 50 KAYARA MBEDU VILLAGE, GUDUVA	N/A	FACILITY IS NOT LICENSED TO MANUFACTURE PRODUCT LINE	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X375.0 MG VIAL + 1*20 ML WFI IN LDPE	08/02/2023
200	NDA/MAL/ HDP/10449	PT SANBE FARMA	MEDVIN PHARMA LIMITED	POLIDEMIS IN	NEOMYCIN SULFATE + POLIMYXYN B SULFATE + DEXAMETHAS ONE	(3.5 MG + 6000 IU + 1 MG)ML	PT CAPRIFAR MINDO LABORAT ORIES ,- JALAN INDUSTRI CIMARE ME NO. 8 DESA CIMARE ME, KECAMA TAN PADALAR ANG, KABUPAT	N/A	FACILITY NOT APPROVED FOR THE MANUFACTURE OF THIS PRODUCT LINE	RETAINED	INDONESI A	OPHTHALMIC SUSPENSIONS	1.0X1.0X5.0 ML BOTTLE	08/02/2023

201	NDA/MAL/HDP/10466	ARCELIA LIFE SCIENCES LTD.	PLUTO PHARMACEUTICALS LIMITED	ARCELIA CEFIXIME	CEFIXIME TRIHYDRATE	400 MG	ASSOCIATED BIOTECH-VILLAGE: KISHANPURA, GUGUMAJRA ROAD, BADDI THE: NALAGARH HIMACHAL PRADESH 174101 - INDIA	N/A	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: DRY POWDER FOR ORAL SUSPENSION TABLETS CAPSULES , BETA-LACTAM (CEPHALOSPORIN): DRY POWDER FOR ORAL SUSPENSION	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/02/2023
202	NDA/MAL/HDP/1048	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EXOFEN 120MG	FEXOFENADINE	120MG	N/A	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTDP.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING	N/A	NOT RETAINED	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X15.0 TABLET BLISTER	01/07/2013

203	NDA/MAL/HDP/10489	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	SWASTIK PHARMACEUTICAL LTD	TERBIN	TERBINAFINE HYDROCHLORIDE	250 MG	GLOBAL NAPI PHARMACEUTICALS-2ND INDUSTRIAL ZONE, ST 18, 6TH OCTOBER CITY	N/A	GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES	RETAINED	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	08/02/2023
204	NDA/MAL/HDP/10490	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	SWASTIK PHARMACEUTICAL LTD	BISOCARD PLUS 5MG/12.5 MG	BISOPROLOL FUMARATE + HYDROCHLOROTHIAZIDE	5MG + 12.5MG	GLOBAL NAPI PHARMACEUTICALS-2ND INDUSTRIAL ZONE, ST 18, 6TH OCTOBER CITY	N/A	GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES	RETAINED	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/02/2023
205	NDA/MAL/HDP/10498	ADWIA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	URIPAN	OXYBUTYNIN HYDROCHLORIDE	5MG/ML	ADWIA S.A.E.-1ST INDUSTRIAL ZONE A1, 10TH OF RAMADA	N/A	FACILITY NOT APPROVED TO MANUFACTURE THIS PRODUCT LINE (ORAL LIQUIDS)	RETAINED	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X120.0 ML BOTTLE	08/02/2023

206	NDA/MAL/HDP/10514	ARTURA PHARMACEUTICALS PVT LTD	SWASTIK PHARMACEUTICAL LTD	ORITA-100	SILDENAFIL CITRATE	100MG	ARTURA PHARMACEUTICALS PRIVATE LIMITED-NO. 1505, PORTIA ROAD SRI CITY SEZ, SATYAVEDU MANDAL	N/A	GMP EXPIRED ON 19/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED & UNCOATED), HARD GELATIN CAPSULES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	08/02/2023
207	NDA/MAL/HDP/10518	ARTURA PHARMACEUTICALS PVT LTD	SWASTIK PHARMACEUTICAL LTD	GLYCOFORM 500	METFORMIN HYDROCHLORIDE	500MG	ARTURA PHARMACEUTICALS PRIVATE LIMITED-NO. 1505, PORTIA ROAD SRI CITY SEZ, SATYAVEDU MANDAL	N/A	GMP EXPIRED ON 19/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED & UNCOATED), HARD GELATIN CAPSULES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/02/2023
208	NDA/MAL/HDP/10525	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	PRELYNCA 50 MG	PREGABALIN	50MG	PHARMATHEN INTERNATIONAL S.A-INDUSTRIAL PARK SAPES, RODOPI PREFECTURE, BLOCK	N/A	FACILITY NOT APPROVED TO MANUFACTURE THIS PRODUCT LINE (HARD GELATIN CAPSULES)	RETAINED	GREECE	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X7.0 CAPSULE BLISTER	08/02/2023

209	NDA/MAL/HDP/10526	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	PRELYNCA 75 MG	PREGABALIN	75MG	PHARMATHEN INTERNATIONAL S.A-INDUSTRIAL PARK SAPES, RODOPI PREFECTURE, BLOCK	N/A	FACILITY NOT APPROVED TO MANUFACTURE THIS PRODUCT LINE (HARD GELATIN CAPSULES)	RETAINED	GREECE	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X7.0 CAPSULE BLISTER	08/02/2023
210	NDA/MAL/HDP/10527	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	PRELYNCA 150 MG	PREGABALIN	150MG	PHARMATHEN INTERNATIONAL S.A-INDUSTRIAL PARK SAPES, RODOPI PREFECTURE, BLOCK	N/A	FACILITY NOT APPROVED TO MANUFACTURE THIS PRODUCT LINE (HARD GELATIN CAPSULES)	RETAINED	GREECE	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER	08/02/2023
211	NDA/MAL/HDP/1054	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AZ-250	AZITHROMYCIN	250MG	N/A	AGOG PHARMA LTDPLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X6.0 CAPSULE BLISTER	01/07/2011

212	NDA/MAL/HDP/10543	ADWIA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ADWIFLAM	DICLOFENAC POTASSIUM	75MG	SOUTH EGYPT DRUG INDUSTRIES COMPANY (SEDICO)-FIRST INDUSTRIAL ZONE, 6TH OF OCTOBER CITY - EGYPT	N/A	GMP EXPIRED ON THE 28/09/2023 FOR NON-BETA LACTAM: ORAL VETERINARY POWDERS TABLETS POWDERS FOR ORAL SUSPENSION HARD GELATIN CAPSULES ORAL LIQUIDS OINTMENTS, CREAMS & GELS SUPPOSITORIES STERILE LIQUIDS IN AMPOULES POWDER SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED IN PLASTIC AMPOULE) SMALL VOLUME LYOPHILIZED POWDER (ASEPTICALLY PREPARED) SOFT GELATIN CAPSULES , BIOLOGICALS (SVP): RECOMBINANT INSULIN	RETAINED	EGYPT	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY STRIP	08/02/2023
213	NDA/MAL/HDP/1055	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	ROZITTA 40	ROSUVASTATIN CALCIUM	40MG	N/A	DAR AI DAWANA UR PLANT,AMMAN,JORDAN	N/A	NOT RETAINED	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013

214	NDA/MAL/ HDP/10550	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	AZADUAL 100	AZACITIDINE	100MG	MSN LABORATORIES PRIVATE LIMITED-UNIT II, SY. NO. 1277 & 1319 TO 1324, NANDIGAMA (VILLAGE & MANDAL), RANDAREDDY	N/A	ADDRESS OF THIS FACLITY IS DIFFERENT FROM THE ONE PREVIOUSLY INSPECTED (SY. NO 1277 & 1319-1324, MAHABUBNAGAR, DIST TELANGANA 509216 INDIA). ADDRESS TO BE VERIFIED AFTER GMP INSPECTION	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 X100.0 MG VIAL	08/02/2023
215	NDA/MAL/ HDP/10573	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DABIFIB 110	DABIGATRAN ETEXILATE	110MG	MSN LABORATORIES PRIVATE LIMITED-UNIT II, SY. NO. 1277 & 1319 TO 1324, NANDIGAMA (VILLAGE & MANDAL), RANDAREDDY	N/A	ADDRESS OF THIS FACLITY IS DIFFERENT FROM THE ONE PREVIOUSLY INSPECTED (SY. NO 1277 & 1319-1324, MAHABUBNAGAR, DIST TELANGANA 509216 INDIA). ADDRESS TO BE VERIFIED AFTER GMP INSPECTION	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	08/02/2023

216	NDA/MAL/HDP/10574	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DABIFIB 150	DABIGATRAN ETEXILATE	150MG	MSN LABORATORIES PRIVATE LIMITED-UNIT II, SY. NO. 1277 & 1319 TO 1324, NANDIGAMA (VILLAGE & MANDAL), RANDARE DDY	N/A	ADDRESS OF THIS FACLITY IS DIFFERENT FROM THE ONE PREVIOUSLY INSPECTED (SY. NO 1277 & 1319-1324, MAHABUBNAGAR, DIST TELANGANA 509216 INDIA). ADDRESS TO BE VERIFIED AFTER GMP INSPECTION	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	08/02/2023
217	NDA/MAL/HDP/10577	ARCELIA LIFE SCIENCES LTD.	PLUTO PHARMACEUTICALS LIMITED	ARCELIA MEROPENEM	MEROPENEM TRIHYDRATE	1G	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY	N/A	FACILITY NOT APPROVED TO MANUFACTURE CARBAPENEMS	RETAINED	INDIA	PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES	1.0X1.0X1.0G VIAL	08/02/2023

218	NDA/MAL/HDP/10608	WILSHIRE LABORATORIES (PVT) LTD	HEALTHCARE LTD.	QOSMET 500/50	METFORMIN HYDROCHLORIDE+ SITAGLIPTIN MONOHYDRATE PHOSPHATE	500MG + 50MG	WILSHIRE LABORATORIES (PVT) LTD-124/1 INDUSTRIAL AREA, KOT LAKHPAT LAHORE PAKISTAN	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: COATED AND UNCOATED TABLETS, HARD GELATIN CAPSULES, POWDERS FOR ORAL SUSPENSION, SMALL AND LARGE VOLUME PARENTERAL LIQUIDS, SMALL VOLUME POWDER FOR INJECTION	RETAINED	PAKISTAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X5.0 TABLET BLISTER	15/02/2023
219	NDA/MAL/HDP/10626	GAMA PHARMACEUTICALS (U) LIMITED	GAMA PHARMACEUTICALS (U) LIMITED	XAPRINE 5	CYCLOBENZAPRINE HYDROCHLORIDE	5 MG	BEIT JALA PHARMACEUTICAL COMPANY. BETHLEHEM - PALETINE-81, AL-MADARESS STR. P.O.BOX	N/A	SITE NOT FOUND	RETAINED	PALESTINE	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	15/02/2023

220	NDA/MAL/HDP/10627	GAMA PHARMACEUTICALS (U) LIMITED	GAMA PHARMACEUTICALS (U) LIMITED	XAPRINE 10	CYCLOBENZAPRINE HYDROCHLORIDE	10MG	BEIT JALA PHARMACEUTICAL COMPANY. BETHLEHEM - PALETINE-81, AL-MADARESS STR. P.O BOX	N/A	SITE NOT FOUND	RETAINED	PALESTINE	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	15/02/2023
221	NDA/MAL/HDP/10632	PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS AND PHARMACEUTICALS PVT. LTD)	ROYAL PHARMA 2011 LIMITED	ROSUVAT 10	ROSUVASTATIN CALCIUM	10 MG	GLOBELA PHARMA PVT.LTD. 357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, ORAL POWDER IN SACHETS AND BOTTLES. ONCOLOGY: TABLETS, HARD GELATIN CAPSULES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

222	NDA/MAL/ HDP/10641	BHARAT BIOTECH INTERNATION AL LIMITED.	REDDYS PHARMA LIMITED	TYPBAR TCV	S. TYPHI TY 2 CONJUGATED TO TETANUS TOXOID	25 MCG/0.5M L	BHARAT BIOTECH INTERNA TIONAL LTD-GENOME VALLEY, SHAMEE RPET MANDAL, RANGARE DDY, TELANGA NA STATE-500078 INDIA	N/A	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: SMALL VOLUME PARENTERAL LIQUIDS PACKED IN AMPOULES, PREFILLED SYRINGES AND VIALS SMALL VOLUME PARENTERALS (LYOPHILIZED) PACKED IN VIALS TOPICAL OINTMENTS ORAL POWDERS PACKED IN SACHETS RECOMBINANT HEPATITIS-B VACCINE THIOMEROSAL FREE HEPATITIS-B VACCINE, COMVAC 3 (DIPHTHERIA, TETANUS AND PERTUSSIS VACCINE) COMVAC 4 (DIPHTHERIA, TETANUS, PERTUSSIS AND	RETAINED	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X1.0X1.0 PREFILLED SYRINGE CARTON	15/02/2023

223	NDA/MAL/HDP/10644	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	LORATYN 10	LORATADINE	10MG	HOVID BERHAD (IPOH SITE)- 121, JALAN TUNKU ABDUL RAHMAN	N/A	FACILITY NOT APPROVED FOR THE MANUFACTURE OF NBL TABLETS	RETAINED	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	15/02/2023

224	NDA/MAL/HDP/10650	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	MEROPENEM FOR INJECTION USP	MEROPENEM TRIHYDRATE	1G	CSPC OUYI PHARMACEUTICAL CO. LTD.-WORKSHOPS 112,113 AND 117 PLOT NO. 88 YANGZI ROAD,ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA	N/A	APPLICATION FOR GMP RE-INSPECTION DOES NOT INCLUDE THE CARBAPENEMS; GMP EXPIRED ON THE 17/8/2021 FOR NON BETA LACTAM: • TABLETS (COATED AND UNCOATED) • HARD GELATIN CAPSULES AND GRANULES • SVP - SOLUTIONS IN AMPOULES, ASEPTICALLY FILLED AND TERMINALLY STERILISED BETA LACTAM: • SMALL VOLUME PARENTERALS - STERILE POWDERS FOR INJECTION;	RETAINED	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	15/02/2023

225	NDA/MAL/HDP/10666	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	VANCOLIN-500	VANCOMYCIN HYDROCHLORIDE	500 MG	LINCOLN PARENTERAL LTD .-11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ 382721 TA: KALOL DIST. GANDHINAGAR	LINCOLN PARENTERAL LTD .11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ 382721 TA: KALOL DIST. GANDHINAGAR GUJARAT	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: SMALL VOLUME PARENTERAL SOLUTIONS SMALL VOLUME PARENTERAL POWDERS ORAL LIQUIDS	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X500.0 MG VIAL	15/02/2023
226	NDA/MAL/HDP/10677	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MEDOCRIPTINE 2.5 MG	BROMOCRIPTINE MESILATE	2.5 MG	MEDOCHEMIE LTD (COGOLS FACILITY)-1-10 CONSTANTINOUPOLEUS STREET	N/A	FACILITY NOT APPROVED TO MANUFACTURE TABLETS	RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
227	NDA/MAL/HDP/10691	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEUROGLOPENTIN 400 MG	GABAPENTIN	400MG	GLOBAL NAPI PHARMACEUTICALS-2ND INDUSTRIAL ZONE, ST 18, 6TH OCTOBER CITY	N/A	GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES	RETAINED	EGYPT	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	15/02/2023

228	NDA/MAL/HDP/10692	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEUROGLOPENTIN 300 MG	GABAPENTIN	300MG	GLOBAL NAPI PHARMACEUTICALS-2ND INDUSTRIAL ZONE, ST 18, 6TH OCTOBER CITY	N/A	GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES	RETAINED	EGYPT	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	15/02/2023
229	NDA/MAL/HDP/10700	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	NEPEXTO 50 MG	ETANERCEPT (RDNA ORIGIN)	50 MG/ML	LUPIN LIMITED (BIOTECH DIVISION) GAT NO. 1156, GHOTAW ADDE - VILLAGE, MULSHI-TALUKA, PUNE - 412 115	N/A	GMP EXPIRED ON THE 4/9/2022 FOR NON-BETA LACTAM BIOLOGICAL: SMALL VOLUME PARENTERAL BIOPHARMACEUTICALS IN PREFILLED SYRINGES (ASEPTICALLY FILLED)	RETAINED	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X1.0X1.0 ML PRE-FILLED SYRINGE	15/02/2023

230	NDA/MAL/HDP/10701	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	NEPEXTO 25 MG	ETANERCEPT	25MG/0.5 ML	LUPIN LIMITED (BIOTECH DIVISION) GAT NO. 1156, GHOTAW ADDE - VILLAGE, MULSHI-TALUKA, PUNE - 412 115	N/A	GMP EXPIRED ON THE 4/9/2022 FOR NON-BETA LACTAM BIOLOGICAL: SMALL VOLUME PARENTERAL BIOPHARMACEUTICALS IN PREFILLED SYRINGES (ASEPTICALLY FILLED)	RETAINED	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X1.0X0.5 ML PRE-FILLED SYRINGE	15/02/2023
231	NDA/MAL/HDP/1071	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CO-ANGINET 160/25MG	VALSARTAN + HYDROCHLOROTHIAZIDE	160 MG + 25 MG	N/A	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTDP.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING	N/A	NOT RETAINED	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
232	NDA/MAL/HDP/10711	EAST AFRICAN (INDIA) OVERSEAS	ROYAL PHARMA 2011 LIMITED	VIREXIM-DS	CEFIXIME TRIHYDRATE	100MG/5ML	EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMA CITY SELAQUI DEHRAD	N/A	FACILITY NOT APPROVED FOR THE MANUFACTURE OF THE PRODUCT LINE (CEPHALOSPORIN ORAL PODWERS)	RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X1.0X100.0 ML BOTTLE	15/02/2023

233	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	N/A	GMP EXPIRED ON THE 28/09/2023 FOR NON-BETA LACTAM: ORAL VETERINARY POWDERS TABLETS POWDERS FOR ORAL SUSPENSION HARD GELATIN CAPSULES ORAL LIQUIDS OINTMENTS, CREAMS & GELS SUPPOSITORIES STERILE LIQUIDS IN AMPOULES POWDER SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED IN PLASTIC AMPOULE) SMALL VOLUME LYOPHILIZED POWDER (ASEPTICALLY PREPARED) SOFT GELATIN CAPSULES , BIOLOGICALS (SVP): RECOMBINANT INSULIN	RETAINED	EGYPT	PARENTERAL ORDINARY S C VIALS	1.0X1.0X10.0 ML VIAL	15/02/2023

234	NDA/MAL/HDP/10744	CADILA HEALTHCARE LIMITED "ZYDUS TOWER" -	ABACUS PHARMA (AFRICA) LIMITED	TAZILIN	PIPERACILLIN + TAZOBACTAM	4 G + 0.5 G	ZEISS PHARMACEUTICALS PRIVATE LIMITED-PLOT NO. 72 EPIP-PHASE-1 JHARMAJRI BADDI DISTRICT	N/A	FACILITY NOT APPROVED TO MANUFACTURE PENICILLINS	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X4.5 G VIAL	15/02/2023
235	NDA/MAL/HDP/1075	NECTAR LIFESCIENCES LTD	AIVEEN (U) LIMITED	NECPIME	CEFEPIME	1000MG	N/A	NECTAR LIFESCIENCES LTD UNIT VI-BHATOLIKALAN P.O BAROTIWALA DISTT SOLAN HIMACHAL PRADESH 173205	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL + 1*10 ML WATER FOR INJECTION	01/07/2013
236	NDA/MAL/HDP/10751	MSN LABORATORIES PRIVATE LIMITED,	ABACUS PHARMA (AFRICA) LIMITED	TYKODAS 50	DASATINIB	50 MG	MSN LABORATORIES PRIVATE LIMITED-UNIT II, SY. NO. 1277 & 1319 TO 1324, NANDIGAMA (VILLAGE & MANDAL), RANDARE DRY	N/A	ADDRESS OF THIS FACLITY IS DIFFERENT FROM THE ONE PREVIOUSLY INSPECTED (SY. NO 1277 & 1319-1324, MAHABUBNAGAR, DIST TELANGANA 509216 INDIA). ADDRESS TO BE VERIFIED AFTER GMP INSPECTION	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023

237	NDA/MAL/HDP/10752	MSN LABORATORIES PRIVATE LIMITED,	ABACUS PHARMA (AFRICA) LIMITED	TYKODAS 70	DASATINIB	70 MG	MSN LABORATORIES PRIVATE LIMITED-UNIT II, SY. NO. 1277 & 1319 TO 1324, NANDIGAMA (VILLAGE & MANDAL), RANDAREDDY	N/A	ADDRESS OF THIS FACLITY IS DIFFERENT FROM THE ONE PREVIOUSLY INSPECTED (SY. NO 1277 & 1319-1324, MAHABUBNAGAR, DIST TELANGANA 509216 INDIA). ADDRESS TO BE VERIFIED AFTER GMP INSPECTION	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	15/02/2023
238	NDA/MAL/HDP/10759	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ABA-20M	MANNITOL	20%W/V	NEXT WAVE-RAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR	N/A	FACILITY NOT APPROVED TO MANUFACTURE PARENTERALS	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	15/02/2023
239	NDA/MAL/HDP/10765	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	N/A	GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES	RETAINED	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	15/02/2023

240	NDA/MAL/HDP/1077	NECTAR LIFESCIENCES LTD	AIVEEN (U) LIMITED	NECTRAM	CEFTRIAXONE	1G	N/A	NECTAR LIFESCIENCES LTD UNIT VI-BHATOLIKALAN P.O BAROTIWALA DISTT SOLAN HIMACHAL PRADESH 173205	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL + 1*10 ML WFI AMPOULE	01/07/2013
241	NDA/MAL/HDP/10771	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD.	HEALTHCARE LTD.	MIZICIN	AZITHROMYCIN DIHYDRATE	250MG	AL FAZAL PHARMA INDUSTRIES (PVT) LTD-PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN	N/A	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS, HARD GELATIN CAPSULES, OINTMENTS/CREAMS/GELS	RETAINED	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	15/02/2023

242	NDA/MAL/HDP/10772	WILSHIRE LABORATORIES (PVT) LTD	HEALTHCARE LTD.	QOSMET 1000/50	METFORMIN HYDROCHLORIDE+ SITAGLIPTIN MONOHYDRATE PHOSPHATE	1000MG + 50MG	WILSHIRE LABORATORIES (PVT) LTD-124/1 INDUSTRIAL AREA, KOT LAKHPAT LAHORE PAKISTAN	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: COATED AND UNCOATED TABLETS, HARD GELATIN CAPSULES, POWDERS FOR ORAL SUSPENSION, SMALL AND LARGE VOLUME PARENTERAL LIQUIDS, SMALL VOLUME POWDER FOR INJECTION	RETAINED	PAKISTAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X5.0 TABLET BLISTER	15/02/2023
243	NDA/MAL/HDP/10773	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD.	HEALTHCARE LTD.	GESIDOL	TRAMADOL HYDROCHLORIDE	50MG	AL FAZAL PHARMA INDUSTRIES (PVT) LTD-PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN	N/A	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS, HARD GELATIN CAPSULES, OINTMENTS/CREAMS/GELS	RETAINED	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	15/02/2023

244	NDA/MAL/HDP/10775	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD.	HEALTHCARE LTD.	FICLO SR 100	DICLOFENAC SODIUM	100MG	AL FAZAL PHARMA INDUSTRIES (PVT) LTD-PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN	N/A	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS, HARD GELATIN CAPSULES, OINTMENTS/CREAMS/GELS	RETAINED	PAKISTAN	ORAL SOLID RETARD CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	15/02/2023
245	NDA/MAL/HDP/1081	BRICVED LTD	BOOTS PHARMACEUTICALS LIMITED	ACIDEX	SODIUM BICARBONATE + SODIUM ALGINATE + CALCIUM CARBONATE	267MG + 500MG + 160MG /10ML	PINEWOOD LABORATORIES LTD-BALLYMACARBRY, CLONMEL, TIPPERARY, IRELAND	N/A	GMP EXPIRED ON THE 7/9/2021 FOR ORAL LIQUIDS (SYRUPS, SUSPENSIONS, SOLUTIONS) EXTERNAL LIQUIDS (SHAMPOO, LOTIONS) SEMISOLIDS (CREAMS, OINTMENTS, GELS) & ENEMAS; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	IRELAND	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	01/07/2013

246	NDA/MAL/HDP/10811	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	LAMOTRIX 50MG	LAMOTRIGINE	50 MG	MEDOCHEMIE LIMITED (CENTRAL FACTORY)-1-10 CONSTANTINOUPOLEOS STREET, 3011	N/A	FACILITY NOT APPROVED FOR THE MANUFACTURE OF TABLETS	RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	03/05/2023
247	NDA/MAL/HDP/10815	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYQ	HYDROXYCHLOROQUINE SULFATE	200 MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	03/05/2023
248	NDA/MAL/HDP/10822	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	ACECLAV 228.5	AMOXICILLIN TRIHYDRATE + CLAVULANIC ACID	(200MG + 28.5 MG) PER 5ML	MEDICEF PHARMA NO. 28, PHASE 1, EPIP, JHARRMAJRI, BADDI, DIST SOLAN (HP)	N/A	GMP EXPIRED FOR 30/9/2023 FOR BETA LACTAM (PENICILLIN): TABLETS, DRY POWDER FOR ORAL SUSPENSION	RETAINED	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	03/05/2023

249	NDA/MAL/ HDP/10825	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 NOVARTIS PHARMA AG- LICHTSTRASSE 35 - 4056 BASEL, SWITZERLAND	N/A	GMP FOR NOVARTIS FARMA S.P.A.- NOVARTIS FARMA S.P.A. VIA PROVINCIALE SCHITO 131, 80058 TORRE ANNUNZIATA, ITALY EXPIRED ON THE 30/7/2023 FOR NBL TABLETS; NOVARTIS PHARMA AG- LICHTSTRASSE 35 - 4056 BASEL, SWITZERLAND IS NOT APPROVED FOR THE MANUFACTURE OF THE TABLET LINE	RETAINED	ITALY SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	06/06/2023

250	NDA/MAL/ HDP/10826	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 NOVARTIS PHARMA AG- LICHTSTRASSE 35 - 4056 BASEL, SWITZERLAND	N/A	GMP FOR NOVARTIS FARMA S.P.A.- NOVARTIS FARMA S.P.A. VIA PROVINCIALE SCHITO 131, 80058 TORRE ANNUNZIATA, ITALY EXPIRED ON THE 30/7/2023 FOR NBL TABLETS; NOVARTIS PHARMA AG- LICHTSTRASSE 35 - 4056 BASEL, SWITZERLAND IS NOT APPROVED FOR THE MANUFACTURE OF THE TABLET LINE	RETAINED	ITALY SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	06/06/2023

251	NDA/MAL/HDP/10827	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 NOVARTIS PHARMA AG-LICHTSTRASSE 35 - 4056 BASEL, SWITZERLAND	N/A	GMP FOR NOVARTIS FARMA S.P.A.-NOVARTIS FARMA S.P.A. VIA PROVINCIALE SCHITO 131, 80058 TORRE ANNUNZIATA, ITALY EXPIRED ON THE 30/7/2023 FOR NBL TABLETS; NOVARTIS PHARMA AG-LICHTSTRASSE 35 - 4056 BASEL, SWITZERLAND IS NOT APPROVED FOR THE MANUFACTURE OF THE TABLET LINE	RETAINED	ITALY SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER	06/06/2023
252	NDA/MAL/HDP/10837	BHARAT SERUMS & VACCINES LTD.	ABACUS PHARMA (AFRICA) LIMITED	FOLIGRAF 300I.U	FOLLITROPIN	1*1*300 I.U, PRE-FILLED SYRINGE	BHARAT SERUMS AND VACCINES LTD,-PLOT NO. K-27, ADDITIONAL MIDC	N/A	FACILITY HAS NOT BEEN INSPECTED FOR THIS LINE (PRE-FILLED SYRINGE)	RETAINED	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X1.0X300.0 I.U PRE-FILLED SYRINGE	06/06/2023

253	NDA/MAL/HDP/10858	SYNOKEM PHARMACEUTICALS LIMITED	BIOGEN PHARMA LIMITED	DEFLAGEN	DEFLACORT	6MG	SYNOKEM PHARMACEUTICALS LIMITEDSYNOKEM PHARMACEUTICALS LIMITED, PLOT NO. 35-36, SECTOR-6A, IIE, (SIDCUL), RANIPUR (PHEL)	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM (HUMAN): TABLETS, HARD GELATIN CAPSULES, ORAL LIQUIDS, HORMONES: TABLETS	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X2.0X10.0 TABLET BLISTER	03/05/2023
254	NDA/MAL/HDP/10863	ABBOTT LABORATORIES S.A. (PTY) LTD	HARLEYS UGANDA LIMITED	BETASERC 24	BETAHISTINE DIHYDROCHLORIDE	24MG	MYLAN LABORATORIES SASROUTE DE BELLEVILLE, LIEU DIT MAILLARD, 01400 CHATILLON-SUR-	N/A	GMP EXPIRED ON 08/12/2023 FOR Non-Beta Lactam: Hard Gelatin Capsules Tablets	RETAINED	FRANCE	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	03/05/2023
255	NDA/MAL/HDP/10868	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	IVAZYD 7.5	IVABRADINE HYDROCHLORIDE	7.5MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	03/05/2023

256	NDA/MAL/ HDP/10875	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BLACIDEC 5	SOLIFENACIN SUCCINATE	5 MG	MSN LABORATORIES PRIVATE LIMITED-UNIT II, SY. NO. 1277 & 1319 TO 1324, NANDIGAMA (VILLAGE & MANDAL), RANDAREDDY	N/A	ADDRESS OF THIS FACLITY IS DIFFERENT FROM THE ONE PREVIOUSLY INSPECTED (SY. NO 1277 & 1319-1324, MAHABUBNAGAR, DIST TELANGANA 509216 INDIA). ADDRESS TO BE VERIFIED AFTER GMP INSPECTION	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023
257	NDA/MAL/ HDP/10876	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BLACIDEC 10	SOLIFENACIN SUCCINATE	10MG	MSN LABORATORIES PRIVATE LIMITED-UNIT II, SY. NO. 1277 & 1319 TO 1324, NANDIGAMA (VILLAGE & MANDAL), RANDAREDDY	N/A	ADDRESS OF THIS FACLITY IS DIFFERENT FROM THE ONE PREVIOUSLY INSPECTED (SY. NO 1277 & 1319-1324, MAHABUBNAGAR, DIST TELANGANA 509216 INDIA). ADDRESS TO BE VERIFIED AFTER GMP INSPECTION	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	17/08/2023

258	NDA/MAL/ HDP/10880	TABROS PHARMA	HEALTHCARE LTD.	HEMSAMI C CAPSULE	TRANEXAMIC ACID	500MG	TABROS PHARMA L-20/B SECTOR 22 FB INDUSTRI AL AREA KARACHI PAKISTA N	N/A	GMP EXPIRED ON 08/12/2023 FOR Non- Beta Lactam: Tablets Hard Gelatin Capsules Oral Liquids Creams and Ointments SVP Solutions	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10. 0 CAPSULE BLISTER	24/07/2023
259	NDA/MAL/ HDP/10887	LINCOLN PHARMACEU TICALS LTD	METRO PHARMACEU TICALS LIMITED	OMLINK	OMEPRAZOLE	40 MG/VIAL	LINCOLN PARENTE RAL LTD-11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI , P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHIN AGAR	LINCOLN PARENTERAL LTD11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: SMALL VOLUME PARENTERAL SOLUTIONS SMALL VOLUME PARENTERAL POWDERS ORAL LIQUIDS	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X10. 0 ML VIAL + 1*10ML WATER FOR INJECTION IN LDPE AMPOULE	17/08/2023
260	NDA/MAL/ HDP/10892	B&O PHARM	TRIDEM PHARMA UGANDA LIMITED	GUCEFOR 250MG	CEFUROXIME AXETIL	250MG	REYOUN G PHARMA CEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY	N/A	TO BE RE-INSTATED AFTER INSPECTION OF THE CEPHALOSPORI N LINE. THIS LINE WAS LAST INSPECTED IN 2016	RETAINED	CHINA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10. 0 TABLET BLISTER	17/08/2023

261	NDA/MAL/HDP/10893	B&O PHARM	TRIDEM PHARMA UGANDA LIMITED	GUCEFOR 500MG	CEFUROXIME AXETIL	500 MG	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY	N/A	TO BE RE-INSTATED AFTER INSPECTION OF THE CEPHALOSPORIN LINE. THIS LINE WAS LAST INSPECTED IN 2016	RETAINED	CHINA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	17/08/2023
262	NDA/MAL/HDP/10895	B&O PHARM	TRIDEM PHARMA UGANDA LIMITED	GUCEFOR 750MG	CEFUROXIME SODIUM	750 MG/VIAL	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY	N/A	TO BE RE-INSTATED AFTER INSPECTION OF THE CEPHALOSPORIN LINE. THIS LINE WAS LAST INSPECTED IN 2016	RETAINED	CHINA	PARENTERAL RETARD DRY VIALS	1.0X1.0X10.0 ML VIAL + 1*10ML CLEAR GLASS AMPOULE OF WATER FOR INJECTION,1.0X50.0X10.0 ML VIAL	17/08/2023
263	NDA/MAL/HDP/10913	SURGE LABORATORIES (PVT) LTD,	JEET PHARMACEUTICALS LIMITED	ARTISURGE 60MG	ARTESUNATE	60 MG/VIAL	SURGE LABORATORIES (PVT) LTD.,,-10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA-PAKISTAN	N/A	FACILITY NOT APPROVED TO MANUFACTURE THE PRODUCT LINE (DRY POWDERS FOR INJECTION)	RETAINED	PAKISTAN	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X60.0 MG VIAL +10ML OF 0.9 SODIUM CHLORIDE SOLUTION LDPE AMPOULE + 1ML OF 5.0%W/V SODIUM BICARBONATE SOLUTION GLASS	17/08/2023

264	NDA/MAL/HDP/1093	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	EMTRICITABINE + TENOFOVIR DISOPROXIL FUMARATE	EMTRICITABINE+TENOFOVIR DISOPROXIL FUMARATE	200MG+300MG	STRIDES ARCOLAB LIMITED - 36/7 SURAGAJAKKANAHALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106	N/A	FACILITY NAME CHANGED TO STRIDES PHARMA SCIENCE LIMITED; APPLICANT REQUIRED TO APPLY FOR VARIATION FOR CHANGE OF NAME	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2013
265	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	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, ORAL POWDER IN SACHETS AND BOTTLES. ONCOLOGY: TABLETS, HARD GELATIN CAPSULES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	17/08/2023
266	NDA/MAL/HDP/10939	WOCKHARDT LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	EMROK O	ALALEVONADIFLOXACIN	500 MG	WOCKHARDT LIMITED - BIOTECH PARK, H-14/2, M.I.D.C, WALUJ, AURANGABAD -	WOCKHARDT LIMITED BIOTECH PARK, H-14/2, M.I.D.C, WALUJ, AURANGABAD - 431136, INDIA	FACILITY AWAITS 1ST INSPECTION	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X2.0 TABLET BLISTER	17/08/2023

267	NDA/MAL/HDP/1094	MICRO LABS LTD	LABOREX UGANDA LIMITED	GRAMOCEF-O-100	CEFIXIME	100MG/5ML	MICRO LABS LTD-NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099	N/A	GMP EXPIRED ON 20/11/2023 FOR BETA LACTAM (CEPHALOSPORIN): TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, DRY POWDER FOR ORAL SUSPENSION	RETAINED	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2013
268	NDA/MAL/HDP/10941	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICALS LTD	ENCORATE CHRONO 200	SODIUM VALPROATE + VALPROIC ACID	133.2 MG + 58 MG	SUN PHARMACEUTICALS LTD-SURVEY NO. 214, PLOT NO. 20, GOVT. INDL, AREA, PHASE II, PIPARIA, SILVASSA - 396230	SUN PHARMACEUTICALS LTDSURVEY NO. 214, PLOT NO. 20, GOVT. INDL, AREA, PHASE II, PIPARIA, SILVASSA, 396230, UT OF DADRA & NAGAR HAVELI - INDIA	THE FACILITY WAS LAST AUDITED BY NDA IN 2010 AND HAS NO PREVIOUS REPORT OR CERTIFICATE IN THE SYSTEM. FACILITY AWAITS PHYSICAL INSPECTION.	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	17/08/2023

269	NDA/MAL/HDP/10942	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICALS LTD	ENCORATE CHRONO 300	SODIUM VALPROATE + VALPROIC ACID	199.8 MG + 87 MG	SUN PHARMACEUTICALS LTD-SURVEY NO. 214, PLOT NO. 20, GOVT. INDL, AREA, PHASE II, PIPARIA, SILVASSA -396230	SUN PHARMACEUTICALS LTDSURVEY NO. 214, PLOT NO. 20, GOVT. INDL, AREA, PHASE II, PIPARIA, SILVASSA, 396230, UT OF DADRA & NAGAR HAVELI - INDIA	THE FACILITY WAS LAST AUDITED BY NDA IN 2010 AND HAS NO PREVIOUS REPORT OR CERTIFICATE IN THE SYSTEM. FACILITY AWAITS PHYSICAL INSPECTION.	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	17/08/2023
270	NDA/MAL/HDP/10943	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICALS LTD	ENCORATE CHRONO 500	SODIUM VALPROATE + VALPROIC ACID	333 MG + 145 MG	SUN PHARMACEUTICALS LTD-SURVEY NO. 214, PLOT NO. 20, GOVT. INDL, AREA, PHASE II, PIPARIA, SILVASSA -396230	SUN PHARMACEUTICALS LTDSURVEY NO. 214, PLOT NO. 20, GOVT. INDL, AREA, PHASE II, PIPARIA, SILVASSA, 396230, UT OF DADRA & NAGAR HAVELI - INDIA	THE FACILITY WAS LAST AUDITED BY NDA IN 2010 AND HAS NO PREVIOUS REPORT OR CERTIFICATE IN THE SYSTEM. FACILITY AWAITS PHYSICAL INSPECTION.	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	17/08/2023
271	NDA/MAL/HDP/10955	CACHET PHARMACEUTICALS PRIVATE LIMITED	ASTRA PHARMA (U) LIMITED	CANEM	MEROPENEM TRIHYDRATE	1G	SWISS PARENTERALS PVT LTD ..-809, KERALA INDUSTRIAL ESTAE, GIDC NEAR	N/A	FACILITY NOT APPROVED TO MANUFACTURE CARBAPENEMS	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL (CLEAR GLASS VIAL)	17/08/2023

272	NDA/MAL/HDP/10956	RENATA LIMITED	UHAI PHARMACY	ZITHRIN	AZITHROMYCIN	500MG	RAJENDRAPUR POTENT PRODUCT FACILITY (RPPF), RENATA LIMITED-NOYAPARA, BHAWAL MIRZAPUR, RAJENDRAPUR	N/A	FACILITY ONLY LICENSED TO MANUFACTURE HORMONES	RETAINED	BANGLADESH	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X5.0 TABLET BLISTER	17/08/2023
273	NDA/MAL/HDP/1096	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ARTEMETHER	ARTEMETHER	80MG/ML	HEBEI KAIWEI PHARMACEUTICAL CO, LTD.-27 LING YUAN ROAD, QIAO DONG	SANJAR PHARMA LLP HIMATNAGAR-VIJOPUR HIGHWAY, DEDHROTA HIMATNAGAR 383 220, GUJARAT INDIA	GMP EXPIRED	RETAINED	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE,1.0X1.0X8.0X1.0 ML AMPOULE	01/07/2014
274	NDA/MAL/HDP/10963	PHARMATHEN S.A	GOODMAN INTERNATIONAL LTD	MEPERYA	MEROPENEM TRIHYDRATE	1G	PHARMATHEN S.A-6, DERVENAKION STR. 15351	N/A	FACILITY NOT APPROVED TO MANUFACTURE CARBAPENEMS	RETAINED	GREECE	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL	17/08/2023

275	NDA/MAL/ HDP/11008	CADILA HEALTH CARE LTD	ABACUS PHARMA (AFRICA) LIMITED	FORAIR 250 INHALER	SALMETEROL XINAFOATE + FLUTICASONE PROPIONATE	25MCG/AC TUATION+ 250MCG/ ACTUATION	CADILA HEALTHC ARE LTD. PLOT NO. 417, 419 & 420, SARKHEJ-BAVLA N.H. NO. 8A, MORAIYA , TAL: SANAND, DIST. AHMEDA BAD - 382210, GUJARAT	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	NASAL SYSTEMIC METERED-DOSE LIQUIDS	1X120 Metered Dose Cannister,	25/08/2023
276	NDA/MAL/ HDP/11009	CADILA HEALTH CARE LTD	ABACUS PHARMA (AFRICA) LIMITED	FORAIR 125	SALMETEROL/ FLUTICASONE PROPIONATE	25MCG/ 125MCG PER ACTUATION	CADILA HEALTHC ARE LTD. PLOT NO. 417, 419 & 420, SARKHEJ-BAVLA N.H. NO. 8A, MORAIYA , TAL: SANAND, DIST. AHMEDA BAD - 382210, GUJARAT	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	NASAL SYSTEMIC METERED-DOSE LIQUIDS	1X1 Cannister Carton,	25/08/2023

277	NDA/MAL/ HDP/11010	CADILA HEALTH CARE LTD	ABACUS PHARMA (AFRICA) LIMITED	BIGSENS-XR 500	METFORMIN HYDROCHLORIDE	500MG	CADILA HEALTHCARE LTD. PLOT NO. 417, 419 & 420, SARKHEJ-BAVLA N.H. NO. 8A, MORAIYA, TAL: SANAND, DIST. AHMEDABAD - 382210, GUJARAT	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID RETARD FILM-COATED TABLETS	1X30 TABLET Container,	25/08/2023
278	NDA/MAL/ HDP/11011	CADILA HEALTHCARE LIMITED SARKHEJ	ABACUS PHARMA (AFRICA) LIMITED	BIGSENS-XR 750	METFORMIN HYDROCHLORIDE	750MG	CADILA HEALTHCARE LTD. PLOT NO. 417, 419 & 420, SARKHEJ-BAVLA N.H. NO. 8A, MORAIYA, TAL: SANAND, DIST. AHMEDABAD - 382210, GUJARAT	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID RETARD TABLETS	1X30 TABLET Container,	25/08/2023

279	NDA/MAL/HDP/1106	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DIACEREIN	DIACEREIN	50MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS FOR INTERNAL USE TABLETS (COATED AND UNCOATED) HARD GELATIN CAPSULES ORAL POWDER FOR SUSPENSION OINTMENTS, CREAMS AND GELS	RETAINED	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER,1.0X2.0X10.0 CAPSULE BLISTER	01/07/2013
280	NDA/MAL/HDP/1123	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPAR	PARACETAMOL	500 MG	N/A	AGOG PHARMA LTDPLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER	01/07/2012
281	NDA/MAL/HDP/1133	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	MEDICOL SUSPENSION	CHLORAMPHENICOL	125MG/5ML	N/A	MEDIPHARM INDUSTRIES (E.A) LTDPLOT 65, KAKAJJO ROAD, BWEYOGERERE	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2007

282	NDA/MAL/HDP/1148	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ODIMONT 10	MONTELUKAST	10MG	CADILA HEALTH CARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAI	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2012
283	NDA/MAL/HDP/1149	UNIVERSAL CORPORATION LTD	DELMAW ENTERPRISES LIMITED	NEUROBA	GABAPENTIN	300MG	N/A	UNIVERSAL CORPORATION LTD..PLOT 13777 CLUB ROAD, PAST KIKUYU	N/A	NOT RETAINED	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2015
284	NDA/MAL/HDP/1150	AMANTA HEALTHCARE LTD	PHARMA VILLE LIMITED	FEBRAMOL	PARACETAMOL INFUSION	10MG/ML	N/A	AMANTA HEALTHCARE LIMITED (FORMERLY KNOWN AS MARCK BIOSCIENCES LTD)PLOT NO. 876, N.H. NO. 8, VILLAGE - HARIYALA, DIST - KHEDA 387411, GUJARAT	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2013
285	NDA/MAL/HDP/1155	TRIVENI FORMULATIONS LIMITED	SUPER MEDIC LTD	DOXYCYCLINE	DOXYCYCLINE	100	N/A	TRIVENI FORMULATION LTDPLOT NO.52,53,54,63,62,64, ALEAP INDUSTRIAL ESTATE SURAMPALI, AP-INDIA – 521212	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2012

286	NDA/MAL/HDP/1156	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	FUNGICIP	CLOTRIMAZOLE	1%W/W	N/A	CIPLA LTD ---L139 TO L-146 VERNA INDUSTRIAL ESTATE VERNA SALCETTE GOA 403 722	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2011
287	NDA/MAL/HDP/1157	Y.S.P INDUSTRIES (M) SDN BHD	ROYAL PHARMA 2011 LIMITED	TRETINON	TRETINOIN	0.05%W/W	N/A	Y.S.P.INDUSTRIES(M) SBD,BHDLOT 3,5,& 7,JALANP/7,SECTION 13,KAWASAN PERINDUSTRIAN BANDAR BARUBANGI,43000 KAJANG SELANGOR DARUL EHSAN, MALAYSIA	N/A	NOT RETAINED	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2013
288	NDA/MAL/HDP/1158	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	TRAMADOL	TRAMADOL	50MG	N/A	TRIVENI FORMULATIONS LTD .PLOT NO. 52, 53,54 ALEAP INDUSTRIAL ESTATE SURAMPALLI VILLAGE GANNAVARAM MANDAL KRISHNA (DT) A.P	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2012

289	NDA/MAL/HDP/1159	Y.S.P INDUSTRIES (M) SDN BHD	ROYAL PHARMA 2011 LIMITED	VOREN	DICLOFENAC SODIUM	50MG	N/A	Y.S.P.INDUSTRIES(M) SBD,BHDLOT 3,5,& 7,JALANP/7,SECTION 13,KAWASAN PERINDUSTRIAN BANDAR BARUBANGI,43000 KAJANG SELANGOR DARUL EHSAN, MALAYSIA	N/A	NOT RETAINED	MALAYSIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY STRIP,1.0X10.0X10.0 SUPPOSITORY STRIP	01/07/2013
290	NDA/MAL/HDP/1162	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	WINKLOT	CLOPIDOGREL	75MG	N/A	TRIVENI FORMULATIONS LTD .PLOT NO. 52, 53,54 ALEAP INDUSTRIAL ESTATE SURAMPALLI VILLAGE GANNAVARAM MANDAL KRISHNA (DT) A.P	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2012
291	NDA/MAL/HDP/1164	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	PIROXICAM	PIROXICAM	20MG	N/A	TRIVENI FORMULATIONS LTD .PLOT NO. 52, 53,54 ALEAP INDUSTRIAL ESTATE SURAMPALLI VILLAGE GANNAVARAM MANDAL KRISHNA (DT) A.P	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013

292	NDA/MAL/HDP/1165	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	EXBRO	TERBUTALINE SULPHATE/ BROMOHEXINE/GUAIFENESIN	1.25MG/2MG/50MG	TRIVENI FORMULATIONS LTD .- PLOT NO. 52, 53,54 ALEAP INDUSTRIAL ESTATE SURAMPALLI VILLAGE	N/A	NOT APPROVED FOR THE MANUFACTURE OF THE PRODUCT LINE; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE	01/07/2013
293	NDA/MAL/HDP/1170	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO MEGANEURON	METHYLCOBALAMIN	500MCG	N/A	ARISTO PHARMACEUTICALS PVT. LIMITEDPLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X1.0 ML AMPOULE	01/07/2013

294	NDA/MAL/HDP/1176	AMOUN PHARMACEUTICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FUNGISAFE	TERBINAFINE HYDROCHLORIDE	1%W/W	AMOUN PHARMACEUTICAL CO. S.A.E1ST INDUSTRIAL ZONE A, PLOTS NO. 1B,2,3,4, 5 BLOCK 13015, EL-OBOUR CITY, KALYOUBIA CAIRO EGYPT	N/A	GMP EXPIRED ON THE 29/9/2023 FOR NON-BETA LACTAM: HARD GELATIN CAPSULES SOFT GELATIN CAPSULES TABLETS (COATED & UNCOATED) DRY POWDERS FOR SUSPENSION POWDERS PACKED IN SACHETS SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED LIQUIDS) SMALL VOLUME PARENTERAL – (ASEPTICALLY PREPARED POWDERS) EYE DROPS (ASEPTICALLY PREPARED) ORAL LIQUIDS NON-STERILE NASAL DROPS EXTERNAL SEMI-SOLIDS (CREAMS & GELS)	NOT RETAINED	EGYPT	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2013

295	NDA/MAL/HDP/1179	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	OVITRELLE	CHORIOGONADOTROPIN ALFA	250MCG/0.5ML	MERCK SERONO SA-1170 AUBONNE(SWITZERLAND)	MERCK SERONO S.P.A-VIA DELLE MAGNOLIE,15.70026 MODUGNO (BA).ITALY	GMP EXPIRED ON THE 24/09/2023 FOR BIOTECHNOLOGY PRODUCTS: SMALL VOLUME LIQUIDS, SVP LYOPHILISATES IN PRE-FILLED SYRINGES & CATRIDGES	RETAINED	ITALY	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X1.0 PREFILLED SYRINGE CARTON	01/07/2015
296	NDA/MAL/HDP/1182	TORRENT PHARAMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	ASTHATOR 5	MONTELUKAST SODIUM	5MG	N/A	TORRENT PHARMACEUTICALS LTD .,AHMEDABAD-MEHSANA HIGHWAY, TALUKA-KADI, DIST. MEHSANA, INDRAD-382721, GUJARAT	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

297	NDA/MAL/HDP/1188	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	GMYCIN-80	GENTAMYCIN SULPHATE	80MG/2ML	SHANDONG XIER KANGTAI PHARMACEUTICALS CO. LTD PRIVATE-PRIVATE ECONOMY ZONE,XINYAN TOWN, YANZHOU DISTRICT, JINING CITY,SHANDONG,CHINA PR ANHUI CHENGSHI PHARMACEUTICAL CO. LTD,-NO.5068 HUAISHANG ROAD,HEBEI NEW AREA INDUSTRIAL PARK, BENGBU, ANHUI,CHINA.	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	SHANDONG XIER PHARMACEUTICALS LTD FAILED GMP ON THE 31/8/2018 FOR NON-BETA LACTAM DOSAGE FORMS: • SMALL VOLUME PARENTERALS –SOLUTIONS IN AMPOULES.; ANHUI CHENGSHI PHARMACEUTICAL CO. LTDFAILED GMP ON THE 23/8/2018 FOR NON BETA LACTAM • SVP-SOLUTIONS IN AMPOULES • SVP-LYOPHILIZED POWDERS • TABLETS • HARD GELATIN CAPSULES BETA LACTAM • SVP-POWDERS FOR INJECTION (CEPHALOSPORINS) • SVP-POWDERS FOR INJECTION	RETAINED	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X2.0 ML AMPOULE	01/07/2013

298	NDA/MAL/HDP/1189	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	DICLOMAX-75	DICLOFENAC SODIUM	75MG/ML	SHANDONG XIER KANGTAI PHARMACEUTICALS CO. LTD PRIVATE-PRIVATE ECONOMY ZONE,XINYAN TOWN, YANZHOU DISTRICT	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	FACILITY FAILED GMP ON THE 31/8/2018 FOR NON-BETA LACTAM DOSAGE FORMS: • SMALL VOLUME PARENTERALS –SOLUTIONS IN AMPOULES.;	RETAINED	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X3.0 ML AMPOULE	01/07/2013
299	NDA/MAL/HDP/1194	VENUS REMEDIES LTD	HARLEYS UGANDA LIMITED	PISA	PIPERACILLIN + TAZOBACTAM	4000MG/VIAL + 500MG/VIAL	VENUS REMEDIES LTD, UNIT II,-HILL TOP INDUSTRIAL ESTATE, JHARMAJTI, EPIP, PHASE-1 (EXTENSION)	N/A	FACILITY NOT APPROVED TO MANUFACTURE PENICILLINS	RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X30.0 ML VIAL	01/07/2009
300	NDA/MAL/HDP/1195	UNIVERSAL CORPORATION LTD	HARLEYS UGANDA LIMITED	ALTRINE	CETIRIZINE	5MG/5ML	N/A	UNIVERSAL CORPORATION LIMITED PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE	N/A	NOT RETAINED	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X30.0 ML BOTTLE	01/07/2013
301	NDA/MAL/HDP/1196	UNIVERSAL CORPORATION LTD	DELMAW ENTERPRISES LIMITED	ACNESOL	TRETINOIN	0.05%W/W	N/A	UNIVERSAL CORPORATION LTD..PLOT 13777 CLUB ROAD, PAST KIKUYU	N/A	NOT RETAINED	KENYA	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE	01/07/2012

302	NDA/MAL/HDP/1202	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	QUINIMIX SYRUP	QUININE HYDROCHLORIDE	100MG/5ML	N/A	MEDIPHARM INDUSTRIES (E.A) LTDPLOT 65, KAKAJJO ROAD, BWEYOGERERE	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2003
303	NDA/MAL/HDP/1205	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	EFAVIRENZ	EFAVIRENZ	600MG	N/A	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	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2008

304	NDA/MAL/ HDP/1227	AMOUN PHARMACEU TICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FUNGISAFE	TERBINAFINE HCL	250MG	AMOUN PHARMA CEUTICAL CO. S.A.E1ST INDUSTRI AL ZONE A, PLOTS NO. 1B,2,3,4, 5 BLOCK 13015, EL-OBOUR CITY, KALYOUB IA CAIRO EGYPT	N/A	GMP EXPIRED ON THE 29/9/2023 FOR NON-BETA LACTAM: HARD GELATIN CAPSULES SOFT GELATIN CAPSULES TABLETS (COATED & UNCOATED) DRY POWDERS FOR SUSPENSION POWDERS PACKED IN SACHETS SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED LIQUIDS) SMALL VOLUME PARENTERAL – (ASEPTICALLY PREPARED POWDERS) EYE DROPS (ASEPTICALLY PREPARED) ORAL LIQUIDS NON-STERILE NASAL DROPS EXTERNAL SEMI-SOLIDS (CREAMS & GELS)	NOT RETAINED	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X7.0 TABLET STRIP	01/07/2013

305	NDA/MAL/HDP/1230	MEDOPHARM PRIVATE LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	LOXAMP	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	N/A	MEDOPHARM PVT LTD.NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013
306	NDA/MAL/HDP/1231	NORVIK ENTERPRISES LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	MEDOMOX 125	AMOXYCILLIN	125MG/5ML	N/A	MEDOPHARM PVT LTD.NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2012
307	NDA/MAL/HDP/1232	MEDOPHARM PRIVATE LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	MEDOCILLIN 125	AMPICILLIN	125 MG	N/A	MEDOPHARM PVT LTD.NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE	07/01/2014
308	NDA/MAL/HDP/1238	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	SEPTRIN INJECTION	CO-TRIMOXAZOLE	480MG/5ML	DRAXIS PHARMA INC.-QUEBEC,	N/A	FACILITY NOT GMP COMPLIANT	RETAINED	CANADA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X5.0 ML AMPOULE	01/07/1997

309	NDA/MAL/HDP/1240	PINEWOOD LABORATORIES LTD	BOOTS PHARMACEUTICALS LIMITED	CETIRIZINE HYDRCHLORIDE	CETIRIZINE HYDROCHLORIDE	5MG/5ML	PINEWOOD LABORATORIES LTD. - BALLYMACARBRY, CLONMEL, TIPPERARY, IRELAND	N/A	GMP EXPIRED ON THE 7/9/2021 FOR ORAL LIQUIDS (SYRUPS, SUSPENSIONS, SOLUTIONS) EXTERNAL LIQUIDS (SHAMPOO, LOTIONS) SEMISOLIDS (CREAMS, OINTMENTS, GELS) & ENEMAS; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	IRELAND	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2013
310	NDA/MAL/HDP/1243	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	LEVO DENK 250	LEVOFLOXACIN HEMIHYDRATE	250MG	ROTTENDORF PHARMA GMBH-OSTENFELDER STRASSE 51-61	N/A	GMP OF THE FACILITY EXPIRED ON THE 30/7/2023 FOR NBL TABLETS	NOT RETAINED	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2014
311	NDA/MAL/HDP/1250	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	STRIMOL EXTRA	PARACETAMOL+CAFFEINE	500MG+30MG	N/A	STRIDES ARCOLAB LTD36/7 SURAGAJAKKANAHALI INDLAWADICROSS ANEKAL TALUK BANYALURE-562106	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X4.0 TABLET BLISTER	01/07/2014

312	NDA/MAL/HDP/1272	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR)	OMASI MED LIMITED	MEBO HERBAL OINTMENT	B-SITOSTEROL	0.25%W/W	N/A	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)AIRPORT ROAD, DIGDAGA, P.O.BOX: 997, RAS AL KHAIMAH, U.A.E.	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	UNITED ARAB EMIRATES	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE,1.0X30.0 G TUBE	01/07/1999
313	NDA/MAL/HDP/1275	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	NIFELAT 10 F.C TABLETS	NIFEDIPINE	10MG	N/A	REMEDICA LIMITED AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997
314	NDA/MAL/HDP/1282	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	LOSABERG	LOSARTAN POTASSIUM	50MG	N/A	THE MADRAS PHARMACEUTICALS.. NO. 137B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI 600096	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
315	NDA/MAL/HDP/1285	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANFUR-750	CEFUROXIME	750MG	N/A	SANCE LABORATORIES PRIVATE LTDPB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA.	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X750.0 MG VIAL	01/07/2012

316	NDA/MAL/HDP/1287	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANIX- DS 100	CEFIXIME	100MG/5ML	N/A	SANCE LABORATORIES PVT LTDVI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE,1.0X 60.0 ML BOTTLE	01/07/2014

317	NDA/MAL/ HDP/1288	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VITAMINAT SYRUP	VITAMIN B COMPLEX	MULT-INGREDIENT	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	N/A	GMP EXPIRED ON 28/9/2023 FOR BETA LACTAM (PENICILLIN): ORAL DRY POWDERS FOR SUSPENSION HARD GELATIN CAPSULES TABLETS SVP POWDERS (VIALS), NON-BETA LACTAM: ORAL DRY POWDERS (HUMAN & VETERINARY) HARD GELATIN CAPSULES TABLETS ORAL LIQUIDS ORAL POWDERS IN SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED) CREAMS, OINTMENTS, GELS, SUPPOSITORIES, PESSARIES & OVULES	NOT RETAINED	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/1998

318	NDA/MAL/HDP/1290	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANIX 400 CAP	CEFIXIME	400MG	N/A	SANCE LABORATORIES PVT LTDVI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X10.0 CAPSULE BLISTER	01/07/2013
319	NDA/MAL/HDP/1298	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	NEUROVIT FORTE	THIAMINE MONONITRATE/ PYRIDOXINE/ CYANOCOBALAMIN	245.5MG/ 250MG/ 1.4MG	HOVID BHD (IPOH SITE)-121 ,JALAN TUNKU ABDUL RAHMAN 30010	N/A	FACILITY NOT APPROVED TO MANUFACTURE NBL TABLETS	RETAINED	MALAYSIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
320	NDA/MAL/HDP/1299	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANAXONE PLUS-1000	CEFTRIAXONE +SULBACTAM	1000MG+500MG	N/A	SANCE LABORATORIES PRIVATE LTDPB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA.	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.5 G VIAL,1.0X50.0X1.0 VIAL CARTON	01/07/2012
321	NDA/MAL/HDP/1300	KOPRAN LIMITED	TATA UGANDA LIMITED	ATENOLOL-100	ATENOLOL	100MG	N/A	KOPRAN LIMITEDVILLAGE-SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997

322	NDA/MAL/HDP/1301	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	COSAMINE PLUS	GLUCOSAMINE SULPHATE + CHONDROITIN SULPHATE	250MG + 200MG	N/A	HOVID BERHAD (CHEMOR SITE)-LOT 56442, 71/2, JALAN IPOH/CHEMOR 31200, PERAK. MALAYSIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
323	NDA/MAL/HDP/1319	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	ZESTAVAL 200 F.C TABLETS	ALBENDAZOLE	200MG	N/A	REMEDICA LTDAHARNON STREET, LIMASSOL INDUSTRIAL ESTATE, 3056 LIMASSOL	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	50.0X2.0 TABLET BLISTER,1.0X2.0 TABLET BLISTER	01/07/1997
324	NDA/MAL/HDP/1330	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	RAPICLAV-625	AMOXYCILLIN +CLAVULANIC ACID	500MG+125MG	IPCA LABORATORIES LTD,.-PLOT 69 TO 72 (B), SECTOR II, KASEZ, GANDHIDHAM - 370230, GUJARAT	N/A	GMP EXPIRED ON 28/9/2023 FOR BETA LACTAM (PENICILLIN): TABLETS HARD GELATIN CAPSULES. DRY POWDER FOR SUSPENSION	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X2.0 TABLET STRIP,1.0X7.0X3.0 TABLET STRIP	01/07/2003
325	NDA/MAL/HDP/1341	AUROLAB	SWASTIK PHARMACEUTICAL LTD	G-FLOX	GATIFLOXACIN SESQUIHYDRATE	0.3%W/V	N/A	AUROLABNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA	N/A	NOT RETAINED	INDIA	OPHTHALMIC LIQUIDS	1.0X5.0 ML VIAL	01/07/2016

326	NDA/MAL/HDP/1343	MICRO LABS LTD	PHARMA VILLE LIMITED	PRAZIQUANTEL	PRAZIQUANTEL	600MG	MICRO LABS LIMITED, BOMMASANDRA (ML07),-PLOT 121-124, IV PHASE KIADB, BOMMASANDRA	MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126	FACILITY NOT APPROVED TO MANUFACTURE NBL	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER	01/07/2009
327	NDA/MAL/HDP/1351	MEDLEY PHARMACEUTICALS LTD	EUROPA HEALTHCARE (U) LTD	ATORIN	ATORVASTATIN CALCIUM	20MG	N/A	MEDLEY PHARMACEUTICALS LTD,PLOT 18 & 19 SURVEY NO 378/7 & 379/ 2&3 ZARI CAUSEWAY ROAD KACHIGAM	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
328	NDA/MAL/HDP/1352	MEDLEY PHARMACEUTICALS LTD	EUROPA HEALTHCARE (U) LTD	PLATFREE	CLOPIDOGREL	75MG	N/A	MEDLEY PHARMACEUTICALS LTDPLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014
329	NDA/MAL/HDP/1355	PIRAMAL HEALTHCARE LTD	MEDIWORLD PHARMA AFRICA LTD	SEVOFLURANE	SEVOFLURANE	100% V/V	N/A	PIRAMAL ENTERPRISES LTD, INDIADIGWAL VILLAGE KOHIR MENDAL MEDAK DISTRICT,ANDHRA PRADESH	N/A	NOT RETAINED	INDIA	OTHER SYSTEMIC LIQUID INHALATIONS	1.0X250.0 ML BOTTLE	01/07/2010

330	NDA/MAL/HDP/1366	F. HOFFMANN-LA ROCHE LTD	LABOREX UGANDA LIMITED	HERCEPTIN 440MG	TRASTUZUMAB	440MG	F. HOFFMANN LA-ROCHE-WURMISWEG CH-4303 KAISERA UGST	N/A	GMP OF THE FACILITY EXPIRED ON THE 30/7 2023 FOR BIOTECHNOLOGY PRODUCTS: SVP LIQUIDS IN VIALS SVP LYOPHILISATES PREFILLED SYRINGES , CEPHALOSPORIN: SVP POWDERS IN VIALS	RETAINED	SWITZERLAND	PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES	1.0X440.0 MG VIAL ,2OML VIAL OF SOLVENT	01/07/2016
331	NDA/MAL/HDP/1391	UNIVERSAL CORPORATION LTD	PHARMA VILLE LIMITED	UNIVIR 5%	ACYCLOVIR	5%W/W	N/A	UNIVERSAL CORPORATION LIMITED PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE	N/A	NOT RETAINED	KENYA	TOPICAL EXTERNAL CREAMS	1.0X1.0X10.0 G TUBE	01/07/2010
332	NDA/MAL/HDP/1393	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANFUR	CEFUROXIME	500MG	N/A	SANCE LABORATORIES PRIVATE LTDPB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2016

333	NDA/MAL/HDP/1394	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANPIME - 1000	CEFEPIME	1000MG	N/A	SANCE LABORATORIES PRIVATE LTDPB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA.	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X15.0 ML VIAL	01/07/2010
334	NDA/MAL/HDP/1403	VHB MEDI SCIENCES LTD	NORVIK ENTERPRISES LIMITED	ADROSAL	DOXORUBIAN	10MG	N/A	VHB MEDI SCIENCES LTDPLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1X10 MG Vial	\N
335	NDA/MAL/HDP/1407	PHARMATHEN S.A	GOODMAN INTERNATIONAL LTD	BELIFAX	OMEPRAZOLE	20MG	N/A	PHARMATHEN S.A6,DERVENAKION STR,PALLINI,AHICA GREECE	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	GREECE	ORAL SOLID ORDINARY CAPSULES	1.0X14.0 CAPSULE BOTTLE	01/07/1997
336	NDA/MAL/HDP/1415	ASTRA ZENECA	MACNAUGHTON LIMITED	ATACAND	CANDESARTAN	32MG	N/A	ASTRA ZENECA SWEDEN OPERATIONSTABLET PRODUCTION SE-151 85, GARTUNAVAGEN, SODERTALJE	N/A	NOT RETAINED	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2011

337	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,	N/A	GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES	RETAINED	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2005
338	NDA/MAL/HDP/1423	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	CURAM	AMOXYCILLIN + POTASSIUM CLAVULANATE	500MG+125MG	N/A	SANDOZ GMBHBIOCHEMIESTRASSE 10, A6250 KUNDL, TYROL, AUSTRIA	N/A	NOT RETAINED	AUSTRIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X7.0X2.0 TABLET BLISTER	01/07/2016
339	NDA/MAL/HDP/1425	LEBEN LABORATORIES PVT.LTD	MALIX PHARMA (U) LIMITED	L-TRIM	COTRIMOXAZOLE	240MG/5ML	N/A	LEBEN LABORATORIES PVT. LTDL-4, PHASE –III, M.I.D.C,	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE	01/07/2007
340	NDA/MAL/HDP/1426	LEBEN LABORATORIES PVT.LTD	MALIX PHARMA (U) LIMITED	METROLEB	METRONIDAZOLE	200MG	N/A	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2015

341	NDA/MAL/HDP/1447	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VITONA PLUS	VITAMINS + MINERALS	MULTI-INGREDIENT	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X6.0 CAPSULE BLISTER	01/07/2014

342	NDA/MAL/HDP/1458	STRIDES PHARMA SCIENCE LIMITED	DELMAW ENTERPRISES LIMITED	CLAVICIN INJECTION	AMOXICILLIN + POTASSIUM CLAVULANATE	1.2G	STRIDES ARCOLAB LTD - BILEKAHALLI OPP IIM BANNER GHATTA ROAD BANGALORE 560076 INDIA	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	GMP EXPIRED ON THE 9/11/2012 FOR STERILE PRODUCTS - STERILE DILUENT FRO OMEPRAZOLE STERILE POWDER FOR INJECTION. QUANTUM LIFE SCIENCES - CEPHALOSPORIN SVP LINE BL - SVP POWDERS, CAPSULES, TABLETS	RETAINED	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.2 G VIAL	01/07/2013
343	NDA/MAL/HDP/1459	NVS KENYA LTD	SURGIPHARM (U) LIMITED	TASIGNA 200	NILOTINIB	200MG	N/A	NORVATIS PHARMA STEIN AGSCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	N/A	NOT RETAINED	SWITZERLAND	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER	01/07/2014
344	NDA/MAL/HDP/1464	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ORNIDA	ORNIDAZOLE	500MG	N/A	ARISTO PHARMACEUTICALS PVT. LIMITEDPLOT NO. 208, NEW INDUSTRIAL AREA NO. II, MANDIDEEP-462046, DIST. - RAISEN, MADHYA PRADESH, INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/2014

345	NDA/MAL/HDP/1468	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	OCID 20	OMEPRAZOLE	20MG	CADILA HEALTH CARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	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	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID RETARD CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	01/07/1998
346	NDA/MAL/HDP/1469	VOGEN LABORATORIES LTD	BUFFALO HEALTH CARE LTD	DURAMOX 125	AMOXICILLIN	125MG/5ML	VOGEN LABORATORIES LTD70, M.HERACLEOUS STR. AYIOS ATHANASIOS INDUSTRI	N/A	GMP EXPIRED ON 08/12/2023 FOR Penicillin: Hard Gelatin Capsules	RETAINED	CYPRUS	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2007
347	NDA/MAL/HDP/1484	SHAIGAN PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	CLYCIN.V	CLINDAMYCIN	2%W/W	N/A	SHAIGAN PHARMACEUTICALS (PVT) LIMITED14 KM ADYALA RD, RAWALPINDI, PAKISTAN	N/A	NOT RETAINED	PAKISTAN	TOPICAL EXTERNAL OTHER CREAMS	1.0X40.0 G TUBE + APPLICATOR	01/07/2004

348	NDA/MAL/HDP/1495	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	PELOX-400	PEFLOXACIN	400MG	N/A	WOCKHARDT LIMITED -PLOT 57 VILLAGE KUNJHAL, JHAMAJRI, BAROTIWALA, BADDI, TEHSIL-NALAGARH, DISTRICT SOLAN, 174103 HIMACHAL PRADESH, INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET STRIP	01/07/1997
349	NDA/MAL/HDP/1499	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	PROMETHAZINE	PROMETHAZINE HYDROCHLORIDE	25MG/ML	NINGBO DAHONGYING PHARMACEUTICALS LTD NO. 396 MIN	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: TABLETS, CAPSULES, SVP LIQUIDS	RETAINED	CHINA INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE	01/07/2005
350	NDA/MAL/HDP/1509	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	FEVEREX	PARACETAMOL	500MG	N/A	BETA HEALTHCARE INTERNATIONAL LTDPLOT LR 209/6554 MOGADISHU ROAD, OFF LUNGA LUNGA ROAD, INDUSTRIAL AREA NAIROBI, 00100,	N/A	NOT RETAINED	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/2007

351	NDA/MAL/HDP/1517	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	VEST MENTAMU BALM	COMPOUND METHYLSALICYLATE	MULTI INGREDIENT	N/A	NEM LABORATORIES PVT LTD133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1998
352	NDA/MAL/HDP/1532	BF BIOSCIENCES LTD	HARLEYS UGANDA LIMITED	NOVAPRESSIN	TERLIPRESSIN	1MG/VIAL	BF BIOSCIENCES LTD. -RAIWIND ,PAKISTAN	N/A	GMP EXPIRED ON 19/10/2023 FOR NON-BETA LACTAM: SVP SOLUTIONS & LYOPHILIZATES	RETAINED	PAKISTAN	PARENTERAL ORDINARY VIALS	1.0X1.0 MG VIAL	01/07/2014
353	NDA/MAL/HDP/1537	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYZOLE	ALBENDAZOLE	200MG	ELYS CHEMICAL INDUSTRIES LIMITED-ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	NOT RETAINED	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X20.0X2.0 TABLET BLISTER	01/07/2005

354	NDA/MAL/HDP/1538	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYZOLE SUSPENSION	ALBENDAZOLE	200MG	ELYS CHEMICAL INDUSTRIES LIMITED-ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	RETAINED	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	01/07/2003
355	NDA/MAL/HDP/1543	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	PROMAZINE ELIXIR	PROMETHAZINE HYDROCHLORIDE	5MG/ML	N/A	MEDIPHARM INDUSTRIES(EA) LTDPLOT 65 KAKAJJO ROAD BWEYOGERERE P.O.BOX 6218,KAMPALA,UGANDA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	UGANDA	ORAL LIQUID ORDINARY LIQUIDS	1.0X60.0 ML BOTTLE	01/07/1997

356	NDA/MAL/ HDP/1547	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LUSIA-F	NORGESTREL/ ETHINYL ESTRADIOL + FERROUS FUMARATE	0.3MG/ 0.03MG + 75MG	N/A	MYLAN LABORATORIES LIMITED..PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, AHMEDABAD, GUJARAT, INDIA 382213 MYLAN LABORATORIES LIMITED.-PLOT NO. 1606-1609, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM, TAL-UMERGAM, DIST VALSAD, 396155, GUJARAT, INDIA.	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X28.0 TABLET BLISTER	01/07/2007

357	NDA/MAL/ HDP/1549	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	PREDNICOL EYE DROPS	PREDNISOLONE/CHLORAMPHENICOL	5MG/2MG	REMINGTON PHARMACEUTICAL INDUS. PVT LTD, 117 ALLAM	N/A	GMP EXPIRED ON 2/11/2023 NON-BETA LACTAM: EYE DROPS, EAR DROPS, EXTERNAL PREPARATIONS (CREAMS & OINTMENTS), EYE OINTMENTS, ORAL LIQUIDS	NOT RETAINED	PAKISTAN	OPHTHALMIC DROPS	1.0X10.0 ML VIAL	01/07/1999

358	NDA/MAL/HDP/1554	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL CETIRIZINE	CETIRIZINE DIHYDROCHLORIDE	5MG/5ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	N/A	GMP EXPIRED ON THE 28/9/2023 FOR NON-BETA LACTAM: TABLETS COATED & UNCOATED HARD GELATIN CAPSULES ORAL LIQUIDS SVP LIQUIDS AND POWDER STERILE GELS , (BETA LACTAM) CEPHALOSPORIN: HARD GELATIN CAPSULES DRY POWDER FOR ORAL SUSPENSION SVP POWDER , CORTICOSTEROIDS: OINTMENTS AND CREAMS	RETAINED	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2010

359	NDA/MAL/HDP/1556	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICALS LIMITED	VOMISTAT	ONDASENTRON	2MG/ML	LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE, NEAR KHATRAJ CHOLADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR	LINCOLN PARENTERAL LTD11, TRIMUL ESTATE, NEAR KHATRAJ CHOLADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: SMALL VOLUME PARENTERAL SOLUTIONS SMALL VOLUME PARENTERAL POWDERS ORAL LIQUIDS	RETAINED	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2014
360	NDA/MAL/HDP/1561	LINCOLN P'CALS LTD	METRO PHARMACEUTICALS LIMITED	NEOVAG	NYSTATIN	10000IU	N/A	LINCOLN PHARMACEUTICALS LTD10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI , KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	N/A	NOT RETAINED	INDIA	VAGINAL TABLETS	1.0X14.0 PESSARY STRIP	01/07/2004

361	NDA/MAL/HDP/1577	SEARLE PAKISTAN LTD	HEALTHCARE LTD.	SPIROMIDE	SPIRONOLACTONE + FRUSEMIDE	50MG+20MG	THE SEARLE COMPANY-32-KM MULTAN ROAD, LAHORE	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, ORAL LIQUIDS FOR INTERNAL USE	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET STRIP	01/07/2005

362	NDA/MAL/ HDP/1632	: ALKEM LABORATORIES LIMITEDv	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM 1.2G	AMOXICILLIN SODIUM + CLAVULANATE POTASSIUM	1000MG +200MG	ALKEM LABORATORIES LTD-- PLOT NO. 167/1, MAHATMA GANDHI UDYONG NAGAR, AMALIYA, DABHEL, DAMAN, 396210 INDIA. EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMA CITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	ALKEM LABS LTD.- VILLAGE THANA, BADDI, THE NALAGARH, DIST SOLAN (HP) 173205	EAST AFRICAN OVERSEAS IS NOT APPROVED FOR PENICILLIN LINE; GMP FOR ALKEM EXPIRED ON THE 29/11/2019 FOR HARD GELATIN CAPSULES (NBL, CEPHALOSPORIN & PENICILLIN) TABLETS. (NBL & CEPHALOSPORIN) POWDERS FOR ORAL SUSPENSION (CEPHALOSPORIN) POWDERS FOR ORAL SUSPENSION, (PENICILLIN) POWDERS FOR INJECTION AND TABLETS.(PENICILLIN)	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1 AMPOULE OF WFI	01/07/2005

363	NDA/MAL/HDP/1636	NORVATIS PHARMA AG-SWITZERLAND	LABOREX UGANDA LIMITED	VIGAMOX	MOXIFLOXACIN	5MG/ML	S.A.ALCON COUVREUR N.VRIJKSWEG 14, B-2870 PUURS BELGIUM	N/A	GMP EXPIRED ON 08/12/2023 FOR Non-Beta Lactam: Semi-solids (Aseptically prepared) Small Volume Liquids (Aseptically prepared) Small Volume Liquids (Terminally Sterilized)	RETAINED	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2013

364	NDA/MAL/HDP/1638	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FLADAZOLE	SECNIDAZOLE	500MG	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	N/A	GMP EXPIRED ON THE 29/9/2023 FOR NON-BETA LACTAM: HARD GELATIN CAPSULES SOFT GELATIN CAPSULES TABLETS (COATED & UNCOATED) DRY POWDERS FOR SUSPENSION POWDERS PACKED IN SACHETS SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED LIQUIDS) SMALL VOLUME PARENTERAL – (ASEPTICALLY PREPARED POWDERS) EYE DROPS (ASEPTICALLY PREPARED) ORAL LIQUIDS NON-STERILE NASAL DROPS EXTERNAL SEMI-SOLIDS (CREAMS & GELS)	RETAINED	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	01/07/2005

365	NDA/MAL/HDP/1642	UMEDICA LABORATORIES PVT LTD	VITACARE LIMITED	EUCHLOR-1000	CHLORAMPHENICOL SODIUM SUCCINNATE B.P	1G	N/A	UMEDICA LABORATORIES PVT LTDPLOT NO. 221, 2ND PHASE, GIDC, VAPI 396195, GUJARAT. INDIA.	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 G VIAL	01/07/2004
366	NDA/MAL/HDP/1650	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	TEGRETOL CR 200	CARBAMAZEPINE	200MG	NOVARTIS FARMA S.P.A.-VIA PROVINCIALE SCHITO 131.	N/A	GMP EXPIRED ON THE 30/7/2023 FOR NBL TABLETS	RETAINED	ITALY	ORAL SOLID RETARD TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2006
367	NDA/MAL/HDP/1651	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	MEGATRIM SUSPENSION	CO-TRIMOXAZOLE	240MG/5ML	N/A	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED VANDALUR ROAD	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	, 1X60 ML Bottle	01/07/1997
368	NDA/MAL/HDP/1666	SANOFI AVENTIS	SURGIPHARM (U) LIMITED	AMARYL 1	GLIMEPIRIDE	1MG	SANOFI AVENTIS-2 BOND STREET MIDRAND 1685 SOUTH	N/A	GMP EXPIRED	NOT RETAINED	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2005
369	NDA/MAL/HDP/1669	SANOFI AVENTIS	SURGIPHARM (U) LIMITED	AMARYL 2	GLIMEPIRIDE	2MG	AVENTIS PHARMA-AVENTIS PHARMA, 315 WALTLOO ROAD, SILVERTON 0127 PRETORIA	N/A	GMP EXPIRED ON THE 6/6/2008 FOR NBL TABS, NBL ORAL LIQIUDS, NBL ANTI TB ORAL POWDERS, CREAMS N ONITMENTS	NOT RETAINED	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2005

370	NDA/MAL/HDP/1670	SANOFI AVENTIS	SURGIPHARM (U) LIMITED	AMARYL 4	GLIMIPIRIDE	4MG	AVENTIS PHARMA-AVENTIS PHARMA, 315 WALTLOO ROAD, SILVERTON 0127 PRETORIA	N/A	GMP EXPIRED ON THE 6/6/2008 FOR NBL TABS, NBL ORAL LIQIUDS, NBL ANTI TB ORAL POWDERS, CREAMS N ONITMENTS	NOT RETAINED	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2005
371	NDA/MAL/HDP/1685	LINCOLN P'CALS LTD	METRO PHARMACEUTICALS LIMITED	KONAZOL	KETOCONAZOLE	200MG	N/A	LINCOLN PHARMACEUTICALS LTD10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI , KHATRAJ-382721, GHANDINAGAR,GUJARAT, INDIA	MARKETING AUTHORIZATION FOR ORAL KETOCONAZOLE HAS BEEN WITHDRAWN; 18TH AUTHORITY RESOLUTION DATED 20/2/2023	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2005
372	NDA/MAL/HDP/1691	WIDE SPECTRUM ENTERPRISES (U) LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ZITHRORIV	AZITHROMYCIN	500MG	N/A	RIVA PHARMA FREE ZONENASR CITY CAIRO EGYPT	N/A	NOT RETAINED	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X3.0 CAPSULE BLISTER	01/07/2011

373	NDA/MAL/HDP/1714	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	REMICOL EAR DROPS	CHLORAMPHENICOL	1%W/V	REMINGTON PHARMACEUTICAL INDUS. PVT LTD, 117 ALLAM	N/A	GMP EXPIRED ON 2/11/2023 NON-BETA LACTAM: EYE DROPS, EAR DROPS, EXTERNAL PREPARATIONS (CREAMS & OINTMENTS), EYE OINTMENTS, ORAL LIQUIDS	NOT RETAINED	PAKISTAN	OTIC DROPS	1.0X10.0 ML BOTTLE	01/07/1999
374	NDA/MAL/HDP/1715	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	MUCOLYN SYRUP	AMMONIUM CHLORIDE+CHLORPHENIRAMINE+DEXTROMETHORPHAN+BROMHEXINE	50MG+2MG+5MG+4MG	SHELYS PHARMACEUTICALS LTD,-NEW BAGAMOYO ROAD, MWENGE, PLOT NO 696,BLOCK NO 32, P.O.BOX 3016, DAR ES SALAAM	BETA HEALTHCARE INTERNATIONAL LTD -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	GMP EXPIRED ON THE 28/11/2019 FOR • TABLETS • HARD GELATIN CAPSULES. • ORAL LIQUIDS. • DRY POWDER FOR ORAL SUSPENSION • ORS • CREAMS AND OINTMENTS.	RETAINED	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	01/07/2011

375	NDA/MAL/HDP/1716	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	NIRMIN 5S	MULTI-INGREDIENT	MULTI-INGREDIENT	N/A	ACULIFE HEALTH CARE, FORMALLY NIRMA(HEALTHCARE DIVISION)VILLAGE: SACHANA, TALUKA: VIRAMGAM DISTRICT: AHMEDABAD-382150 GUJARAT, INDIA	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2010
376	NDA/MAL/HDP/1719	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	NIRMIN 10 PLUS	MULTI-INGREDIENT	MULTI-INGREDIENT	N/A	ACULIFE HEALTH CARE, FORMALLY NIRMA(HEALTHCARE DIVISION)VILLAGE: SACHANA, TALUKA: VIRAMGAM DISTRICT: AHMEDABAD-382150 GUJARAT, INDIA	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2010
377	NDA/MAL/HDP/1725	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	MYCORIL CREAM 1%	CLOTRIMAZOLE	1%W/W	N/A	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	N/A	NOT RETAINED	CYPRUS	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2000

378	NDA/MAL/HDP/1732	MICRO LABS LTD	LABOREX UGANDA LIMITED	CEFEX-250	CEPHALEXIN	250MG	MICROLABS LIMITEDPLOT NO. 121-124, KIADB, BOMMASANDRA , -JIGNI LINK ROAD, ANEKUL TALUK,BANGALORE, KARNATAKA, INDIA	N/A	GMP EXPIRED ON 20/11/2023 FOR BETA LACTAM (CEPHALOSPORIN): TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, DRY POWDER FOR ORAL SUSPENSION	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1999
379	NDA/MAL/HDP/1736	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	KLERIMED	CLARITHROMYCIN	500MG	MEDOCHEMIE (FACTORY AZ).-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2009

380	NDA/MAL/HDP/1738	ALCON PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	TEARS NATURALE II	NATURAL TEARS	15ML	ALCON COUVREUR NVRIJKSWEG 14, B-2870 PUURS BELGIUM	ALCON SINGAPORE MANUFACTURING PTE. LIMITED19 TUAS SOUTH AVENUE 14 - SINGAPORE	GMP EXPIRED ON 08/12/2023 FOR Non-Beta Lactam: Semi-solids (Aseptically prepared) Small Volume Liquids (Aseptically prepared) Small Volume Liquids (Terminally Sterilized)	NOT RETAINED	BELGIUM SINGAPORE	OPHTHALMIC DROPS	1.0X15.0 ML BOTTLE	01/07/1997
381	NDA/MAL/HDP/1739	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MELOX	MELOXICAM	15MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANAS	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2009

382	NDA/MAL/HDP/1741	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	N/A	GMP EXPIRED ON 28/09/2023 FOR NON-BETA LACTAM: STERILE EYE DROPS (ASEPTICALLY PREPARED) STERILE EYE OINTMENTS (ASEPTICALLY PREPARED) NON-STERILE NASAL DROPS NON-STERILE METERED DOSE NASAL SPRAYS OINTMENTS, CREAMS & LOTIONS	RETAINED	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005
383	NDA/MAL/HDP/1743	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	DAPRIL	LISINOPRIL DIHYDRATE	10MG	MEDOCHEMIE (FACTORY AZ).-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2009

384	NDA/MAL/HDP/1745	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	N/A	GMP EXPIRED ON 28/09/2023 FOR NON-BETA LACTAM: STERILE EYE DROPS (ASEPTICALLY PREPARED) STERILE EYE OINTMENTS (ASEPTICALLY PREPARED) NON-STERILE NASAL DROPS NON-STERILE METERED DOSE NASAL SPRAYS OINTMENTS, CREAMS & LOTIONS	RETAINED	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005
385	NDA/MAL/HDP/1748	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AZ-500	AZITHROMYCIN	500MG	N/A	AGOG PHARMA LTDPLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0 CAPSULE BLISTER	01/07/2011

386	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	N/A	GMP EXPIRED ON 28/09/2023 FOR NON-BETA LACTAM: STERILE EYE DROPS (ASEPTICALLY PREPARED) STERILE EYE OINTMENTS (ASEPTICALLY PREPARED) NON-STERILE NASAL DROPS NON-STERILE METERED DOSE NASAL SPRAYS OINTMENTS, CREAMS & LOTIONS	RETAINED	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005

387	NDA/MAL/HDP/1751	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OPTIFUCIN	FUSIDIC ACID	1%W/V	AMMAN PHARMACEUTICALS INDUSTRIES .-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	N/A	GMP EXPIRED ON 28/09/2023 FOR NON-BETA LACTAM: STERILE EYE DROPS (ASEPTICALLY PREPARED) STERILE EYE OINTMENTS (ASEPTICALLY PREPARED) NON-STERILE NASAL DROPS NON-STERILE METERED DOSE NASAL SPRAYS OINTMENTS, CREAMS & LOTIONS	RETAINED	JORDAN	OPHTHALMIC DROPS	1.0X5.0 ML AMPOULE	01/07/2005
388	NDA/MAL/HDP/1753	PHARMATEC PAKISTAN PVT LTD	HEALTHCARE LTD.	FLU-GONE-P. PLUS SYRUP	PARACETAMOL + PSEUDOEPHEDRINE HCL + CHLORPHENIRAMINE MALEATE	120MG/5ML + 15MG/5ML + 1MG/5ML	N/A	PHARMATEC PKISTAN (PVT) LTDD-86/A, S.I.T.E., KARACHI - 75700, PAKISTAN	N/A	NOT RETAINED	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X120.0 ML BOTTLE	01/07/2013

389	NDA/MAL/HDP/1754	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APIMOL	TIMOLOL MALEATE	0.5%W/V	AMMAN PHARMACEUTICALS INDUSTRIES .-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	N/A	GMP EXPIRED ON 28/09/2023 FOR NON-BETA LACTAM: STERILE EYE DROPS (ASEPTICALLY PREPARED) STERILE EYE OINTMENTS (ASEPTICALLY PREPARED) NON-STERILE NASAL DROPS NON-STERILE METERED DOSE NASAL SPRAYS OINTMENTS, CREAMS & LOTIONS	RETAINED	JORDAN	OPHTHALMIC DROPS	1.0X1.0X5.0 ML VIAL	01/07/2005
390	NDA/MAL/HDP/1755	MEMPHIS COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DOPAGON TABLETS	BROMOCRIPTINE	2.5MG	MEMPHIS COMPANY--8 EL SAWAH STREET, CAIRO. EGYPT	N/A	GMP EXPIRED ON THE 16/7/2021 FOR NON B-LACTAM • TABLETS COATED AND UNCOATED • CAPSULES (HARD GELATIN) • ORAL LIQUIDS • CREAMS AND OINTMENT • SVP INJECTION SOLUTIONS (IN AMPOULES AND VIALS)	NOT RETAINED	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/1999

391	NDA/MAL/HDP/1756	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APICROM 2%	SODIUM CROMOGLYCATE	2%W/V	AMMAN PHARMACEUTICALS INDUSTRIES .-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	N/A	GMP EXPIRED ON 28/09/2023 FOR NON-BETA LACTAM: STERILE EYE DROPS (ASEPTICALLY PREPARED) STERILE EYE OINTMENTS (ASEPTICALLY PREPARED) NON-STERILE NASAL DROPS NON-STERILE METERED DOSE NASAL SPRAYS OINTMENTS, CREAMS & LOTIONS	RETAINED	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005

392	NDA/MAL/HDP/1758	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APICORT	PREDNISOLONE ACETATE	0.12%W/V	AMMAN PHARMACEUTICALS INDUSTRIES .-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	N/A	GMP EXPIRED ON 28/09/2023 FOR NON-BETA LACTAM: STERILE EYE DROPS (ASEPTICALLY PREPARED) STERILE EYE OINTMENTS (ASEPTICALLY PREPARED) NON-STERILE NASAL DROPS NON-STERILE METERED DOSE NASAL SPRAYS OINTMENTS, CREAMS & LOTIONS	RETAINED	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005
393	NDA/MAL/HDP/1759	SHAIGAN PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	AMLOPIN	AMLODIPINE	5MG	N/A	SHAIGAN PHARMACEUTICALS (PVT) LTD14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN	N/A	NOT RETAINED	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	07/01/2004

394	NDA/MAL/HDP/1760	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEODEX	NEOMYCIN +DEXAMETHASONE	0.5%W/V + 0.1%W/V	AMMAN PHARMACEUTICALS INDUSTRIES-AMMAN PHARMACEUTICAL INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	N/A	GMP EXPIRED ON 28/09/2023 FOR NON-BETA LACTAM: STERILE EYE DROPS (ASEPTICALLY PREPARED) STERILE EYE OINTMENTS (ASEPTICALLY PREPARED) NON-STERILE NASAL DROPS NON-STERILE METERED DOSE NASAL SPRAYS OINTMENTS, CREAMS & LOTIONS	RETAINED	JORDAN	OTIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005

395	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	N/A	GMP EXPIRED ON 28/09/2023 FOR NON-BETA LACTAM: STERILE EYE DROPS (ASEPTICALLY PREPARED) STERILE EYE OINTMENTS (ASEPTICALLY PREPARED) NON-STERILE NASAL DROPS NON-STERILE METERED DOSE NASAL SPRAYS OINTMENTS, CREAMS & LOTIONS	RETAINED	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005
396	NDA/MAL/HDP/1765	UMEDICA LABORATORIES PVT LTD	VITACARE LIMITED	RILIF PLUS	ACECLOFENAC + PARACETAMOL	100MG + 500MG	N/A	UMEDICA LABORATORIES PVT LTDPLOT NO. 221, 2ND PHASE, GIDC, VAPI 396195, GUJARAT. INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2012

397	NDA/MAL/HDP/1767	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES -	WIDE SPECTRUM ENTERPRISES (U) LIMITED	PROSTETROL	ALFUZOSIN HYDROCHLORIDE	10MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS FOR INTERNAL USE TABLETS (COATED AND UNCOATED) HARD GELATIN CAPSULES ORAL POWDER FOR SUSPENSION OINTMENTS, CREAMS AND GELS	NOT RETAINED	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2013
398	NDA/MAL/HDP/1768	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	ULTIVA INJECTION 2MG	REMIFENTANIL	2MG	GLAXOSMITHKLINE MANUFACTURING SPA ,.,-STRADA PROVINCIALE ASOLANA, 90-43056, S.POLO DI TORRILE (PARMA)	N/A	GMP FOR ASOLANA EXPIRED ON THE 30/10/2021 FOR NON-BETA LACTAM SMALL VOLUME PARENTERAL SOLUTIONS (ASEPTICALLY FILLED AND TERMINALLY STERILISED IN AMPOULES AND VIALS)	RETAINED	ITALY	PARENTERAL ORDINARY DRY VIALS	1.0X5.0 VIAL CARTON	01/07/1999

399	NDA/MAL/HDP/1778	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCONCIL 500MG CAPSULES	AMOXYCILLIN TRIHYDRATE	500MG	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	N/A	GMP EXPIRED ON 28/9/2023 FOR BETA LACTAM (PENICILLIN): ORAL DRY POWDERS FOR SUSPENSION HARD GELATIN CAPSULES TABLETS SVP POWDERS (VIALS), NON-BETA LACTAM: ORAL DRY POWDERS (HUMAN & VETERINARY) HARD GELATIN CAPSULES TABLETS ORAL LIQUIDS ORAL POWDERS IN SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED) CREAMS, OINTMENTS, GELS, SUPPOSITORIES, PESSARIES & OVULES	NOT RETAINED	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/1998
400	NDA/MAL/HDP/1786	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGONAC TABLETS (THANE)	DICLOFENAC	50MG	N/A	AGOG PHARMA LTDPLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X1000.0 TABLET CONTAINER, 10.0X10.0 TABLET BLISTER	01/07/2001

401	NDA/MAL/HDP/1802	AFRICURE PHARMACEUTICALS (INDIA) PRIVATELIMITED	ROYAL PHARMA 2011 LIMITED	DOXYRONE-100	DOXYCYCLINE	100MG	N/A	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA.	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1X10X10 CAPSULE Blister	01/07/2010
402	NDA/MAL/HDP/1804	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	LISTRIL	LISINOPRIL	5MG	N/A	TORRENT PHARMACEUTICAL LTDAHMEDABAD-MEHSANA HIGHWAY,TALUKA-KADI,DIST.MEHSANA ,INDRAD-382721	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2001
403	NDA/MAL/HDP/1805	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	JANUMET	SITAGLIPTIN + METFORMIN HYDROCHLORIDE	50MG + 1000MG	AESICA QUEESNBOROUGH LTD .- NORTH ROAD, QUEENBOROUGH KENT ME 11 5EL	N/A	APPLICATION FOR GMP RE-INSPECTION DOES NOT CONTAIN THE TABLET LINE. IT INCLUDES HORMONAL TABLETS	RETAINED	UNITED KINGDOM	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X14.0 TABLET BLISTER	01/07/2014
404	NDA/MAL/HDP/1811	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	DUOVIR TABLETS	ZIDOVUDINE+ LAMIVUDINE	300MG + 150MG	CIPLA LTD--- PLOT NO. 143 AND L-144A VERNA IND. ESTATE SALCETTE	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED - PLOT 1-7 1ST RING ROAD, LUZIRA, KAMPALA	GMP EXPIRED	RETAINED	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X6.0X10.0 TABLET BLISTER,1.0X60.0 TABLET BOTTLE	01/07/2001

405	NDA/MAL/HDP/1820	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	AZICIN-250	AZITHROMYCIN	250MG	ALLY PHARMA OPTIONS PVT-J-Z MIDC, TARAPUR INDUSTRIAL AREA, BOISAR-401506,DIST.THANE, MARAHASHTRA IN	EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	GMP EXPIRED ON THE 9/6/2018 FOR • TABLETS • HARD GELATIN CAPSULES • DRY SYRUP • ORAL LIQUID • EXTERNAL CREAMS AND OINTMENTS	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	01/07/2009
406	NDA/MAL/HDP/1840	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	OVA-MIT	CLOMIPHENE	50MG	N/A	REMEDICA LIMITED AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2011
407	NDA/MAL/HDP/1847	MICRO LABS	MALIX PHARMA (U) LIMITED	MOXILEB-250 CAPSULE	AMOXICILLIN	250MG	N/A	LEBEN LABORATORIES PVT. LTD.PLOT NO. L-4, PHASE –III, M.I.D.C, AKOLA, 444104, MAHARASHTRA, INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER, 1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0X10.0 CAPSULE BLISTER	01/07/2007

408	NDA/MAL/ HDP/1853	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	AERIUS ORAL SOLUTION	DESLORATADINE	0.5MG/ML	SCHERING-PLOUGH LABO N.V-- INDUSTRIE PARK 30, ZONE A 2220 HEIST-OP-DEN-BERG MSD (PTY) LTD-LOCATED AT 117 16TH ROAD	N/A	NAME OF FACILITY (SCHERING PLOUGH) CHANGED TO ORGANON HEIST BV, APPLICATION REQUIRED TO APPLY FOR VARIATION FOR CHANGE OF NAME; MSD FACILITY NOT APPROVED FOR THIS LINE	RETAINED	SOUTH AFRICA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE,1.0X150.0 ML BOTTLE	01/07/2007

409	NDA/MAL/HDP/1863	AMOUN PHARMACEUTICALS COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ORACURE GEL	LIDOCAINE HCL+CETYL PYRIDINUM CHLORIDE	2 GM+0.1 GM	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	N/A	GMP EXPIRED ON THE 29/9/2023 FOR NON-BETA LACTAM: HARD GELATIN CAPSULES SOFT GELATIN CAPSULES TABLETS (COATED & UNCOATED) DRY POWDERS FOR SUSPENSION POWDERS PACKED IN SACHETS SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED LIQUIDS) SMALL VOLUME PARENTERAL – (ASEPTICALLY PREPARED POWDERS) EYE DROPS (ASEPTICALLY PREPARED) ORAL LIQUIDS NON-STERILE NASAL DROPS EXTERNAL SEMI-SOLIDS (CREAMS & GELS)	RETAINED	EGYPT	ORAL TOPICAL GELS AND SOLS	1.0X15.0 G TUBE	01/07/2004

410	NDA/MAL/HDP/1864	NORVATIS PHARMA AG-SWITZERLAND	LABOREX UGANDA LIMITED	PATANOL	OLOPATADINE HYDROCHLORIDE	0.1%W/V	ALCON COUVREUR NVRIJKSWEG 14, B-2870 PUURS BELGIUM	N/A	GMP EXPIRED ON 08/12/2023 FOR Non-Beta Lactam: Semi-solids (Aseptically prepared) Small Volume Liquids (Aseptically prepared) Small Volume Liquids (Terminally Sterilized)	RETAINED	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML VIAL	01/07/2009
411	NDA/MAL/HDP/1865	FDC LTD	AIVEEN (U) LIMITED	MYCODERM-C POWDER	CLOTRIMAZOLE	1%W/W	FDC LIMITED - B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD-431 136	N/A	FACILITY NOT APPROVED FOR THIS LINE	RETAINED	INDIA	TOPICAL EXTERNAL POWDERS	1.0X75.0 G CONTAINER	01/07/2014
412	NDA/MAL/HDP/1867	RENE PHARMACY(R) LTD..	RENE PHARMACY LTD	LEVATEX TABLETS	LEVAMISOLE HYDROCHLORIDE	40MG	N/A	CYANO PHARMA(P)115-C IND ESTATE POLOGROUND, INDORE 452015	Small Volume Liquids (Terminally Sterilized)	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	500.0 TABLET CONTAINER, 1.0X10.0X3.0 TABLET BLISTER	01/07/1997
413	NDA/MAL/HDP/1873	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	JANUMET	SITAGLIPTIN + METFORMIN HYDROCHLORIDE	50MG + 850MG	AESICA QUEESNBOROUGH LTD .- NORTH ROAD, QUEENBOROUGH KENT ME 11 5EL	N/A	APPLICATION FOR GMP RE-INSPECTION DOES NOT CONTAIN THE TABLET LINE. IT INCLUDES HORMONAL TABLETS	RETAINED	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER	01/07/2014

414	NDA/MAL/HDP/1905	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	OXYTOCIN INJECTION	OXYTOCIN	10I.U/ML	ZHEJIANG RUIXIN PHARMACEUTICAL CO. LTD-KAIFA ROAD, LISHUI, ZHEJIANG P.R OF CHINA KIVIPHARM CO. LTD-NO.5 HANGTIAN STREET DONGSHAN HIGH-TECH INDUSTRIAL DEVELOPMENT ZONE, SHALINGZI TOWN ZHANGJIAKOU CITY, HEBEI PROVINCE	N/A	FAILED GMP ON THE 12/08/2019 FOR NON-BETA LACTAM: TABLET, CAPSULES, SMALL VOLUME LIQUIDS. HORMONES: SMALL VOLUME LIQUIDS. BETA LACTAM (CEPHALOSPORIN): TABLETS, GMP OF KIVIPHARM EXPIRED ON THE 25TH/09/2023 FOR NON BETA-LACTAM: SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED PACKED IN AMPOULES)	NOT RETAINED	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE,1.0X100.0X1.0 ML AMPOULE	01/07/2007
415	NDA/MAL/HDP/1921	SHAIGAN PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ANTIMIN	LORATIDINE	10MG	N/A	SHAIGAN PHARMACEUTICALS (PVT) LTD14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN	N/A	NOT RETAINED	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2005

416	NDA/MAL/HDP/1922	IPCA LABORATORIES	MEDVIN PHARMA LIMITED	AZIFAST-500	AZITHROMYCIN	500MG	IPCA LABORATORIES LTD, PLOT NO. T-139PLOT NO. T-139, MIDC, INDUSTRIAL ESTATE, TARAPUR, BOISOR, DIST-PALGHAR, THANE 401506, MAHARASHTRA. IPCA LABORAT	N/A	GMP EXPIRED ON 21/12/2023 FOR Non-Beta Lactam: Tablets (Coated & Uncoated) AND GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: TABLETS ORAL LIQUIDS SVP LIQUIDS IN VIALS AND AMPOULES (ASEPTIC FILLING AND TERMINALLY STERILIZED)	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X3.0 TABLET BLISTER	01/07/2007
417	NDA/MAL/HDP/1929	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORVA 40	ATORVASTATIN	40MG	CADILA HEALTH CARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAI	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2012

418	NDA/MAL/HDP/1932	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	CANDISTAT CREAM	CLOTRIMAZOLE	1%W/W	ELYS CHEMICAL INDUSTRIES LIMITED-ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	RETAINED	KENYA	ORAL TOPICAL CREAMS	1.0X20.0 G TUBE	01/07/2001
419	NDA/MAL/HDP/1936	GLAXO SMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PIRITON EXPECTORANT	CHLORPHENIRAMINE MALEATE + AMMONIUM CHLORIDE	MULTINGREDIENT	N/A	GLAXO WELLCOME (KENYA) LTDKENYA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997

420	NDA/MAL/HDP/1948	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	ZITHROMAX	AZITHROMYCIN DIHYDRATE	500MG	PFIZER LABORATORIES (PTY) LTD;--SOUTH AFRICA	HAUPT PHARMA LATINA S.R.L LATINA-SS 156KM 47,600-04100,BORGO SAN,MICHELE	GMP EXPIRED ON THE 17/10/2008 FOR NBL TABS, NBL HG CAPS, NBL SOLUBLE POWDERS PACKED IN SACKETS, NBL DRY POWDERS, NBL SOLUTIONS,SYRUPS N SUSPENSIONS, NBL LOTIONS, CREAMS N OINTEMENTS, SUPPOSITORIES	RETAINED	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER,1.0X2.0 TABLET BLISTER	01/07/1998
421	NDA/MAL/HDP/1961	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	MUILTIZEBEX	VITAMIN A + CHOLECALCIFEROL + THIAMINE + RIBOFLAVINE + PYRIDOXINE + NICOTINAMIDE	2500 IU + 200IU + 1MG +1MG + 0.5MG +15MG	N/A	TRIVENI FORMULATIONS LIMITED -PLOT NO 52-54,62-64 ALEAP INDUSTRIAL ESTATE SURAMPALLI (V) VIJAYAWADA A.P	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2014

422	NDA/MAL/HDP/1962	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	NIMBEX	CISATRACURIUM BESYLATE	2MG/ML	GLAXOSMITHKLINE S.P.A - STRADA PROVINCIALE ASOLANA 9	N/A	GMP FOR ASOLANA EXPIRED ON THE 30/10/2021 FOR NON-BETA LACTAM SMALL VOLUME PARENTERAL SOLUTIONS (ASEPTICALLY FILLED AND TERMINALLY STERILISED IN AMPOULES AND VIALS)	RETAINED	ITALY	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL,1.0X2.5 ML VIAL	01/07/1997
423	NDA/MAL/HDP/1969	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN SR 75MG	DICLOFENAC SODIUM	75MG	NOVARTIS PHARMA SPA, TORRE ANNUNZI	N/A	GMP EXPIRED ON THE 30/7/2023 FOR NBL TABLETS	RETAINED	ITALY	ORAL SOLID RETARD TABLETS	1.0X30.0 TABLET CONTAINER	01/07/1997
424	NDA/MAL/HDP/1994	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	PANUM 40	PANTOPRAZOLE	40MG	N/A	J.B. CHEMICALS AND PHARMACEUTICALS LTD .128/1, GIDC, ANKLESHWAR 393 002, GUJARAT	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007

425	NDA/MAL/ HDP/2011	HETERO LABS LTD	AIVEEN (U) LIMITED	GIAGRA 50	SILDENAFIL CITRATE	50MG	N/A	HETERO LABS LTD. UNIT (V) .S.N0.439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER,1.0X 10.0X1.0X4. 0 TABLET BLISTER	01/07/2013

426	NDA/MAL/ HDP/2021	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	PREGVIT ZINC	MULTIVITAMIN/MINERALS	MULT-INGREDIENT	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	N/A	GMP EXPIRED ON 28/9/2023 FOR BETA LACTAM (PENICILLIN): ORAL DRY POWDERS FOR SUSPENSION HARD GELATIN CAPSULES TABLETS SVP POWDERS (VIALS), NON-BETA LACTAM: ORAL DRY POWDERS (HUMAN & VETERINARY) HARD GELATIN CAPSULES TABLETS ORAL LIQUIDS ORAL POWDERS IN SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED) CREAMS, OINTMENTS, GELS, SUPPOSITORIES, PESSARIES & OVULES	NOT RETAINED	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X12.0X2.0 CAPSULE BLISTER	01/07/2000

427	NDA/MAL/HDP/2028	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	SELANZ - SR	LANSOPRAZOLE	30MG	THE SEARLE COMPANY LIMITED-F-319, S.I.T.E KARACHI 75530 - PAKISTAN	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, ORAL LIQUIDS FOR INTERNAL USE	RETAINED	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X7.0 CAPSULE BLISTER	01/07/2005
428	NDA/MAL/HDP/2031	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOZID TABLETS	ISONIAZID	100MG	N/A	AGOG PHARMA LTDPLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER	01/07/2004
429	NDA/MAL/HDP/2043	COSMOS LTD	ASTRA PHARMA (U) LIMITED	DIASTOP TABLETS	ATTAPULGITE / ALUMINIUM HYDROXIDE	N/A	N/A	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 41433, NAIROBI	N/A	NOT RETAINED	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X25.0X4.0 TABLET STRIP	01/07/1998

430	NDA/MAL/HDP/2045	ELDA INTERNATIONAL DMCC	REDDYS PHARMA LIMITED	BUPICAN	BUPIVACAINE	0.5% W/V	CLARIS INJECTABLES LIMITED--- CHACHARWADI VASANA 382 213 AHMEDABAD GUJARAT	N/A	GMP EXPIRED ON THE 17/11/2020 FOR • SMALL VOLUME PARENTERALS (VIALS AND AMPUOLES) • SMALL VOLUME PARENTERALS (EMULSIONS AND AQUEOUS SOLUTIONS IN GLASS BOTTLES)	NOT RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL	01/07/2006
431	NDA/MAL/HDP/2049	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	KEFSTAR-500	CEFUROXIME AXETIL	500MG	N/A	SANCE LABORATORIES PVT LTDVI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET STRIP,1.0X1.0X10.0 TABLET BLISTER	01/07/2005

432	NDA/MAL/HDP/2062	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	MUCOLYN PAEDIATRIC SYRUP	DEXTROMETHORPHAN HYDROBROMIDE BP + CHLORPHENIRAMINE MALEATE BP + AMMONIUM CHLORIDE BP + PSEUDOEPHEDRINE HYDROCHLORIDE BP	(5MG + 2MG + 50MG + 10MG)/5ML	SHELYS PHAMACEUTICALS LTD .- NEW BAGAMOYO RD, MWENGE, PLOT 696, DAR ES SALAAM	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO LR 209/6534 MOGADISHU ROAD	GMP EXPIRED ON THE 28/11/2019 FOR • TABLETS • HARD GELATIN CAPSULES. • ORAL LIQUIDS. • DRY POWDER FOR ORAL SUSPENSION • ORS • CREAMS AND OINTMENTS.	RETAINED	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	01/07/2006
433	NDA/MAL/HDP/2066	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	METHOTREXATE	METHOTREXATE	2.5MG	N/A	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
434	NDA/MAL/HDP/2078	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	ALCLOX SYRUP	CLOXACILLIN SODIUM	125MG/5ML	N/A	LEBEN LAB PVT LTDL4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2007
435	NDA/MAL/HDP/2097	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	ALCLOX	CLOXACILLIN	250MG	N/A	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER, 1.0X10.0X10.0 CAPSULE BLISTER	01/07/2011

436	NDA/MAL/HDP/2122	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYMOL	PARACETAMOL	120MG/5ML	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	NOT RETAINED	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X 100.0 ML BOTTLE	01/07/1997
437	NDA/MAL/HDP/2123	VHB MEDI SCIENCES LTD	NORVIK ENTERPRISES LIMITED	PLATFIRST	CISPLASTIN	1MG/ML	N/A	VHB MEDI SCIENCES LTDPLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1X50 ML Vial	\N
438	NDA/MAL/HDP/2124	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYMOX	AMOXYCILLIN	125MG/5ML	N/A	ELYS CHEMICAL INDUSTRIES LTDROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	N/A	NOT RETAINED	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

439	NDA/MAL/HDP/2128	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	TRANSAMIN INJECTION 500MG	TRANEXAMIC ACID	500MG/5ML	N/A	HILTON PHARMA (PVT) LTDPLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	N/A	NOT RETAINED	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X10.0X5.0 ML AMPOULE	01/07/2005
440	NDA/MAL/HDP/2135	VHB MEDI SCIENCES LTD	NORVIK ENTERPRISES LIMITED	IVIXONE	CEFTRIAXONE	1G	N/A	VHB MEDI SCIENCES LTDPLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1X1 G Vial, 1X1 G Vial	\N
441	NDA/MAL/HDP/2143	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	GRISEOFIL	GRISEOFULVIN	500MG	N/A	FOURRTS INDIA LABORATORIES PVT. LIMITEDVANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1X10X10 TABLET Blister	01/07/2005

442	NDA/MAL/HDP/2144	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPICOTIL	TENOXICAM	20MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	PARENTERAL ORDINARY VIALS	1.0X3.0 VIAL CARTON + 1*3*2ML WFI AMPOULE	01/07/2014

443	NDA/MAL/HDP/2156	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	NIRPID 10 INTRAVENOUS FAT EMULSION	SOYA OIL	10%W/V	N/A	ACULIFE HEALTHCARE PVT. LTDVILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2011
444	NDA/MAL/HDP/2158	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	NIRPID	INTRAVENOUS FAT EMULSION	20%W/V	N/A	ACULIFE HEALTHCARE PVT. LTDVILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2010
445	NDA/MAL/HDP/2161	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CYCLOVAX CREAM	ACICLOVIR	5%W/W	N/A	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	N/A	NOT RETAINED	CYPRUS	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE	01/07/1997

446	NDA/MAL/HDP/2164	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYCORT	HYDROCORTISONE	1%W/W	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	NOT RETAINED	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997
447	NDA/MAL/HDP/2165	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	TRAMAREN	TRAMADOL HYDROCHLORIDE	50MG	N/A	RENE INDUSTRIES LTDPLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	N/A	NOT RETAINED	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2014
448	NDA/MAL/HDP/2167	BAYER AG	SURGIPHARM (U) LIMITED	MYCOSPOR SOLUTION	BIFONAZOLE	10MG	BAYER PHARMA AG-D-51368 LEVERKU	N/A	FACILITY NOT APPROVED FOR THIS LINE	RETAINED	GERMANY	TOPICAL EXTERNAL LIQUIDS	1.0X15.0 ML BOTTLE,1.0X50.0 ML BOTTLE	01/07/1997

449	NDA/MAL/HDP/2178	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL CEFUROXIME-250	CEFUROXIME AXETIL	250MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	N/A	GMP EXPIRED ON THE 28/9/2023 FOR NON-BETA LACTAM: TABLETS COATED & UNCOATED HARD GELATIN CAPSULES ORAL LIQUIDS SVP LIQUIDS AND POWDER STERILE GELS , (BETA LACTAM) CEPHALOSPORIN: HARD GELATIN CAPSULES DRY POWDER FOR ORAL SUSPENSION SVP POWDER , CORTICOSTEROIDS: OINTMENTS AND CREAMS	RETAINED	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/2008

450	NDA/MAL/ HDP/2183	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	OCID I.V.	OMEPRAZOLE	40MG/VIAL	CADILA HEALTHCARE LTD. - PLOT NO. 417, 419 & 420, SARKHEJ-BAVLA N.H. NO. 8A, MORAIYA, TAL: SANAND, DIST. AHMEDABAD	N/A	FACILITY NOT APPROVED FOR THIS LINE; NAME OF FACILITY CHANGED TO ZYDUS LIFESCINECES, APPLICANT REQUIRED TO APPLY FOR A VARIATION	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X40.0 MG VIAL + 1*10ML AMPOULE OF WFI	01/07/2007

451	NDA/MAL/HDP/2186	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL DIPHENHYDRAMINE PAEDIATRIC SYRUP	DIPHENHYDRAMINE HYDROCHLORIDE + AMMONIUM CHLORIDE	7MG+67.5 MG/5ML	KOTRA PHARMA-BHD 1, JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA, MALAYSIA	N/A	GMP EXPIRED ON THE 28/9/2023 FOR NON-BETA LACTAM: TABLETS COATED & UNCOATED HARD GELATIN CAPSULES ORAL LIQUIDS SVP LIQUIDS AND POWDER STERILE GELS , (BETA LACTAM) CEPHALOSPORIN: HARD GELATIN CAPSULES DRY POWDER FOR ORAL SUSPENSION SVP POWDER , CORTICOSTEROIDS: OINTMENTS AND CREAMS	RETAINED	MALAYSIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2008
452	NDA/MAL/HDP/2188	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	PREDNISOLONE	PREDNISOLONE	5MG	N/A	CIPLA LTD .PLOT NO. S-103 TO S-105, S-107 TO S-112, L-147 TO L-1147-1, VERNA ELECTRONIC CITY GOA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER	01/07/2010

453	NDA/MAL/HDP/2189	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	N/A	GMP EXPIRED ON THE 28/9/2023 FOR NON-BETA LACTAM: TABLETS COATED & UNCOATED HARD GELATIN CAPSULES ORAL LIQUIDS SVP LIQUIDS AND POWDER STERILE GELS , (BETA LACTAM) CEPHALOSPORIN: HARD GELATIN CAPSULES DRY POWDER FOR ORAL SUSPENSION SVP POWDER , CORTICOSTEROIDS: OINTMENTS AND CREAMS	RETAINED	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X5.0 G TUBE	01/07/2008
454	NDA/MAL/HDP/2193	CIPLA LTD..	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLOX-500	CIPROFLOXACIN	500MG	N/A	CIPLA LIMITED.PLOT NO. L-139, S-103 & M-62, VERNA INDUSTRIAL ESTATE, VERNA SALCETTE, GOA, PIN 403722	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER	01/07/2007

455	NDA/MAL/HDP/2203	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	MYCORIL 100 VAGINAL TABLETS	CLOTRIMAZOLE	100MG	N/A	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	CYPRUS	VAGINAL TABLETS	1.0X2.0X3.0 PESSARY STRIP	01/07/1998
456	NDA/MAL/HDP/2208	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL CEPHALEXIN	CEPHALEXIN MONOHYDRATE	500MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	N/A	GMP EXPIRED ON THE 28/9/2023 FOR NON-BETA LACTAM: TABLETS COATED & UNCOATED HARD GELATIN CAPSULES ORAL LIQUIDS SVP LIQUIDS AND POWDER STERILE GELS , (BETA LACTAM) CEPHALOSPORIN: HARD GELATIN CAPSULES DRY POWDER FOR ORAL SUSPENSION SVP POWDER , CORTICOSTEROIDS: OINTMENTS AND CREAMS	RETAINED	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2010

457	NDA/MAL/HDP/2216	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	METOCLOPRAMIDE	METOCLOPRAMIDE	5MG/ML	NINGBO DAHONGYING PHARMACEUTICAL CO.LTDNO. 396 MINGZHU ROAD, HI-TECH PARK, NINGBO CITY ZHEJIANG	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: TABLETS, CAPSULES, SVP LIQUIDS	RETAINED	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE	01/07/2005
458	NDA/MAL/HDP/2217	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AMINOPHYLLINE	AMINOPHYLLINE	20MG	NINGBO DAHONGYING PHARMACEUTICAL CO.LTDNO. 396 MINGZHU ROAD, HI-TECH PARK, NINGBO CITY ZHEJIANG PROVINCE, CHINA	N/A	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: TABLETS, CAPSULES, SVP LIQUIDS; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X50.0X10.0 ML AMPOULE	01/07/2005
459	NDA/MAL/HDP/2218	LEBEN LABORATORIES LTD	MALIX PHARMA (U) LIMITED	ZINECTIL-100	CHLORPROMAZINE	100MG	N/A	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 10.0X10.0 TABLET BLISTER	01/07/2008

460	NDA/MAL/HDP/2220	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	AMLODAC 5	AMLODIPINE BESYLATE	5MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET STRIP,1.0X3.0X10.0 TABLET BLISTER	01/07/2003
461	NDA/MAL/HDP/2224	VOGEN LABORATORIES LTD	BUFFALO HEALTH CARE LTD	DURAMOX 500	AMOXICILLIN	500MG	VOGEN LABORATORIES LTD70, M.HERACLEOUS STR. AYIOS ATHANASIOS INDUSTRI	N/A	GMP EXPIRED ON 08/12/2023 FOR Penicillin: Hard Gelatin Capsules	RETAINED	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER,1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013
462	NDA/MAL/HDP/2236	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	TEGRETOL 200	CARBAMAZEPINE	200MG	NOVARTIS FARMA S.P.A.-VIA PROVINCIALE SCHITO 131,	N/A	GMP EXPIRED ON THE 30/7/2023 FOR NBL TABLETS	RETAINED	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/1997
463	NDA/MAL/HDP/2239	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	TEGRETOL SYRUP	CARBAMAZEPINE	20MG/ML	DELPHARMA HUNINGUE S.A.S-26, RUE DE LA CHAPELLE, 68330 HUNINGUE, FRANCE	N/A	GMP EXPIRED ON 19/10/2023 FOR NON-BETA LACTAM: SUPPOSITORIES, LIQUIDS FOR EXTERNAL USE, LIQUIDS FOR INTERNAL USE, SEMI SOLIDS	RETAINED	FRANCE	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X250.0 ML BOTTLE	01/07/2006

464	NDA/MAL/HDP/2242	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CYCLOVAX 200 TABLETS	ACYCLOVIR	200MG	N/A	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/1997
465	NDA/MAL/HDP/2258	MYLAN LABORATORIES LIMITED (OTL)	KIMSY MEDS LTD	TENOFOVIR DISOPROXIL + LAMIVUDINE + EFAVIRENZ	TENOFOVIR DISOPROXIL + LAMIVUDINE + EFAVIRENZ	300MG/300MG/600MG	N/A	QUESTA CARE LIMITEDPLOT NO 209/7184 HOMABAY RD TERMINUS GATE NO-19, INDUSTRIAL AREA NAIROBI, KENYA. MYLAN LABORATORIES LTD-F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD - PLOT NO. H-12 & H-13 MIDCWALUJ INDUSTRIAL AREA AURANGABAD 431136 MAHARASTRA GREEN STONE LIMITEDPLOT NO. 11,12&13 INDORE SPECIAL ECONOMIC ZONE	N/A	NOT RETAINED	INDIA KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET BOTTLE,1.0X1.0X30.0 TABLET BOTTLE	01/07/2009

466	NDA/MAL/HDP/2270	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	ZITHROCIN 500	AZITHROMYCIN	500MG	N/A	J.B. CHEMICALS AND PHARMACEUTICALS LTD .128/1, G.I.D.C. INDUSTRIAL AREA, ANKLESHWAR, GUJARAT 393002 INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	01/07/2006
467	NDA/MAL/HDP/2280	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	N/A	GMP EXPIRED ON 2/11/2023 NON-BETA LACTAM: EYE DROPS, EAR DROPS, EXTERNAL PREPARATIONS (CREAMS & OINTMENTS), EYE OINTMENTS, ORAL LIQUIDS	RETAINED	PAKISTAN	OPHTHALMIC DROPS	1.0X7.5 ML VIAL	01/07/1999
468	NDA/MAL/HDP/2293	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,	N/A	GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES	RETAINED	EGYPT	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2005

469	NDA/MAL/HDP/2295	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	ROZITTA 10	ROSUVASTATIN CALCIUM	10MG	N/A	DAR AI DAWANA UR PLANT,AMMAN,JORDAN	N/A	NOT RETAINED	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013
470	NDA/MAL/HDP/2299	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	ROZITTA 20	ROSUVASTATIN CALCIUM	20MG	N/A	DAR AI DAWANA UR PLANT,AMMAN,JORDAN	N/A	NOT RETAINED	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013
471	NDA/MAL/HDP/2312	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CLAVOMID 625	AMOXICILLIN + CLAVULANIC ACID	500 MG + 125 MG	N/A	REMEDICA LIMITED AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	2.0X10.0 TABLET BLISTER	01/07/2006
472	NDA/MAL/HDP/2313	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CLAVOMID 375	AMOXICILLIN + CLAVULANIC ACID	250 MG + 125 MG	N/A	REMEDICA LIMITED AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	2.0X10.0 TABLET BLISTER	01/07/2006

473	NDA/MAL/HDP/2315	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	N/A	GMP EXPIRED ON 20/11/2023 FOR BETA LACTAM (CEPHALOSPORIN): TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, DRY POWDER FOR ORAL SUSPENSION	RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X30.0 ML BOTTLE,1.0X 100.0 ML BOTTLE	01/07/2006

474	NDA/MAL/HDP/2322	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	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X1.0 CAPSULE STRIP	01/07/2007

475	NDA/MAL/HDP/2323	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ALPRIM	CO-TRIMOXAZOLE	240MG/5ML	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	NOT RETAINED	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X 100.0 ML BOTTLE,1.0X 5.0 L JERRYCAN	01/07/1997
476	NDA/MAL/HDP/2326	EMCURE PHARMACEUTICALS LTD -	HARLEYS UGANDA LIMITED	SYLATE-500	ETHAMSYLATE	500MG	N/A	EMCURE PHARMACEUTICALS LTDLANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X6.0 TABLET STRIP	01/07/2004

477	NDA/MAL/HDP/2330	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	COARTEM	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	NORVATIS SAGLIK GIDA VE TARIM URENLERI SAN, VE TIC-AC-YENISEHIR MAHALLESI IHLA VADISI SOKAK, NO.2, 34912 KURTKOY, INSTANBUL - TURKEY	NOVARTIS PHARMA AG-SCHAFFHAUSERSTRASSE 4332 STEIN SWITZERLAND	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS	RETAINED	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X24.0 TABLET BLISTER,1.0X30.0X24.0 TABLET BLISTER,1.0X30.0X6.0 TABLET BLISTER,1.0X36.0X6.0 TABLET BLISTER,1.0X3.0X8.0 TABLET BLISTER,1.0X30.0X12.0 TABLET BLISTER,1.0X30.0X18.0 TABLET BLISTER,1.0X4.0X6.0 TABLET	01/07/2005
478	NDA/MAL/HDP/2335	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOBEN TABLETS(THANE)	MEBENDAZOLE	100MG	N/A	AGOG PHARMA LTDPLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	10.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER, 1.0X100.0 TABLET CONTAINER, 1.0X250.0 TABLET CONTAINER, 1.0X1000.0 TABLET	01/07/2001

479	NDA/MAL/HDP/2337	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AUROXETIL-500	CEFUROXIMEAXETIL	500MG	N/A	AUROBINDO PHARMA LIMITED, FORMULATIONS UNIT-VI-R7AUROBINDO PHARMA LIMITED, FORMULATIONS UNIT-VI SY.NO.329/39 & 329/47 CHITKUL(V) PATANCHERU MANDAL, SANGA REDDY DISTTELANGANA502307	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2007
480	NDA/MAL/HDP/2339	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	KOACT-375	AMOXICILLIN + CLAVULANATE POTASSIUM	250 MG + 125 MG	N/A	AUROBINDO PHARMA LTD, UNIT XII,.SURVEY NO 314, BACHUPALLY VILLAGE, QUTHUBULLAPAR, R.R DISTRICT .A. PRADESH	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X5.0 TABLET BLISTER,1.0X20.0X5.0 TABLET BLISTER	01/07/2007
481	NDA/MAL/HDP/2342	AUROBINDO PHARMA LTD UNIT VII	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	KOACT-625	AMOXICILLIN + CLAVULANATE POTASSIUM	500 MG + 125 MG	N/A	AUROBINDO PHARMA LIMITED, UNIT IIISURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELENGANA (STATE)	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X5.0 TABLET BLISTER	01/07/2007

482	NDA/MAL/HDP/2356	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	QUININE	QUININE DIHYDROCHLORIDE	600MG/2ML	NINGBO DAHONGYING PHARMACEUTICAL CO.LTDNO. 396 MINGZHU ROAD, HI-TECH PARK, NINGBO CITY ZHEJIANG	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N-119, N-113 MIDC TARAPUR BOISAR DIST. THANE 401506 MAHARASHTRA	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: TABLETS, CAPSULES, SVP LIQUIDS	RETAINED	CHINA INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2005
483	NDA/MAL/HDP/2359	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	ASPIREM 75	ASPIRIN	75MG	N/A	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X2.0X28.0 TABLET BLISTER	01/07/2007
484	NDA/MAL/HDP/2360	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	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	RETAINED	KENYA	VAGINAL TABLETS	1.0X14.0 PESSARY PACK,5.0X3.0 PESSARY STRIP,1.0X100.0 PESSARY CONTAINER	01/07/2002

485	NDA/MAL/HDP/2361	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CLAREM 500	CLARITHROMYCIN	500MG	N/A	REMEDICA LTDAHARNON STREET, LIMASSOL INDUSTRIAL ESTATE, 3056 LIMASSOL	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2007
486	NDA/MAL/HDP/2363	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	GENTAMICIN SULPHATE	GENTAMICIN SULPHATE	80MG/2ML	NINGBO DAHONGYING PHARMACEUTICAL CO.LTDNO. 396 MINGZHU ROAD, HI-TECH PARK, NINGBO CITY ZHEJIANG	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: TABLETS, CAPSULES, SVP LIQUIDS	RETAINED	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE,1.0X10.0X10.0X2.0 ML AMPOULE	01/07/2005
487	NDA/MAL/HDP/2381	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED	ROYAL PHARMA 2011 LIMITED	SIMTRIM-480 TABLETS	CO-TRIMOXAZOLE	480MG	N/A	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITEDPLOT 9-12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR-401404. INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997

488	NDA/MAL/HDP/2389	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	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	RETAINED	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2007
489	NDA/MAL/HDP/2394	MERCK SHARP & DOHME BV.	SURGIPHARM (U) LIMITED	STOCRIN	EFAVIRENZ	600MG	MERCK SHARP & DOHME B.V-WAARDENWEG 392031 BN, HAARLEM	ZHEJIANG HUAHAI PHARMACEUTICAL CO. LTD-XUNQIAO, LINHAI, ZHEJIANG PROVINCE 317024 PEOPLES' REPUBLIC OF CHINA	GMP EXPIRED ON THE 10/04/2021 FOR NON BETA LACTAM; • TABLETS (PRIMARY AND SECONDARY PACKAGING) • ORAL LIQUIDS (SECONDARY PACKAGING)	RETAINED	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2004

490	NDA/MAL/HDP/2423	MEDLEY PHARMACEUTICALS	EUROPA HEALTHCARE (U) LTD	ATORIN	ATORVASTATIN	10MG	N/A	MEDLEY PHARMACEUTICALS LTD,PLOT 18 & 19 SURVEY NO 378/7 & 379/ 2&3 ZARI CAUSEWAY ROAD KACHIGAM	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014
491	NDA/MAL/HDP/2431	ZYDUS LIFESCIENCES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	FORMONIDE 200	BUDESONIDE + FORMOTEROL FUMARATE	200MCG/6MCG	CADILA HEALTHCARE LTD--SARKHEJ-PLOT 417,419, 420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL:	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X1.0 CANNISTER CARTON	01/07/2007
492	NDA/MAL/HDP/2432	CADILA HEALTH CARE LTD	ABACUS PHARMA (AFRICA) LIMITED	FORMONIDE 100	BUDESONIDE + FORMOTEROL FUMARATE	100MCG+6MCG	CADILA HEALTHCARE LTD--SARKHEJ-PLOT 417,419, 420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL:	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER	01/07/2007

493	NDA/MAL/HDP/2434	STRIDES PHARMA SCIENCE LIMITED	DELMAW ENTERPRISES LIMITED	SOLCER	OMEPRAZOLE	40MG	STRIDES ARCOLAB LTD - BILEKAHALLI OPP IIM BANNER GHATTA ROAD BANGALORE 560076 INDIA	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	GMP EXPIRED ON THE 9/11/2012 STERILE PRODUCTS - STERILE DILUENT FRO OMEPRAZOLE STERILE POWDER FOR INJECTION. QUANTUM LIFE SCIENCES - CEPHALOSPORIN SVP LINE BL - SVP POWDERS, CAPSULES, TABLETS	RETAINED	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	01/07/2009
494	NDA/MAL/HDP/2436	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	COFORM-AX	AMBROXOL /SULBUTAMOL / GUAIFENESIN	15/ 1MG/ 50MG	N/A	AJANTA PHARMA LTD.B-4-5-6 MIDC IND AREA, PARTHEN 431125, MAHARASHTRA INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2011
495	NDA/MAL/HDP/2451	ACINO PHARMA AG	LABOREX UGANDA LIMITED	OLFEN -75 SR PROLONGED - BRELEASE TABLETS	DICLOFENAC SODIUM	75 MG	ACINO PHARMA AG- DORNACHERSTRASSE 114, CH-4147 AESCH	N/A	GMP EXPIRED ON THE 12/11/2022 FOR NON-BETA LACTAM: TABLETS HARD GELATIN CAPSULES	RETAINED	SWITZERLAND	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2004

496	NDA/MAL/HDP/2455	ACINO PHARMA AG	LABOREX UGANDA LIMITED	ARTEQUIN 600/750 LACTAB	ARTESUNATE + MEFLOQUINE	200 MG + 250 MG	ACINO PHARMA AG-DORNACHERSTRASSE 114, CH-4147 AESCH	N/A	GMP EXPIRED ON THE 12/11/2022 FOR NON-BETA LACTAM: TABLETS HARD GELATIN CAPSULES; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER	01/07/2004
497	NDA/MAL/HDP/2461	UMEDICA LABORATORIES PVT LTD	VITACARE LIMITED	UMERAN SR - 100	DICLOFENAC	100MG	N/A	UMEDICA LABORATORIES PVT, VAPIPLOT 221, GIDC II, VAPI-396195, INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
498	NDA/MAL/HDP/2467	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	NOKLOT	CLOPIDOGREL	75MG	CADILA HEALTHCARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO.203-213, KUNDAI	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2003

499	NDA/MAL/HDP/2479	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANCEPH-250 CAP	CEPHALEXIN	250MG	N/A	SANCE LABORATORIES PVT. LTD.VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2012
500	NDA/MAL/HDP/2489	VITACARE LIMITED	VITACARE LIMITED	UMETAC-150	RANITIDINE	150MG	N/A	UMEDICA LABORATORIES PVT LTDPLOT NO. 221, 2ND PHASE, GIDC, VAPI 396195, GUJARAT. INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2006
501	NDA/MAL/HDP/2496	MACLEODS PDHARMACEUTICALS LT	VITACARE LIMITED	ZETIVAS 20	ATORVASTATIN/EZETIMIBE	20MG/10MG	N/A	MACLEODS PHARMACEUTICALS LTD PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008
502	NDA/MAL/HDP/2498	MACLEODS PDHARMACEUTICALS LT	VITACARE LIMITED	ZETIVAS 10	ATORVASTATIN/EZETIMIBE	10MG/10MG	N/A	MACLEODS PHARMACEUTICALS LTD PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008

503	NDA/MAL/HDP/2500	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	CHLORAMPHENICOL SODIUM SUCCINATE INJECTION BP	CHLORAMPHENICOL SODIUM SUCCINATE	1G	N/A	MACLEODS PHARMACEUTICALS LTD PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA.	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2007
504	NDA/MAL/HDP/2506	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	NADOXIN	NADIFLOXACIN	1%W/W	N/A	WOCKHARDT LTD VILLAGE KUNJHAL P.O BAROTIWALA DIST SOLAN HIMACHAL PRADESH	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE,1.0X20.0 G TUBE	01/07/2011
505	NDA/MAL/HDP/2508	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	HYOSCINE	HYOSCINE	20MG/ML	NINGBO DAHONG YING PHARMACEUTICAL CO LTDNO.3986 MINZHU ROAD NINGBO CITY ZHEJIANG	N/A	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: TABLETS, CAPSULES, SVP LIQUIDS; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2011

506	NDA/MAL/HDP/2511	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	ULTIVA INJECTION 5MG	REMIFENTANIL	5MG	GLAXOSMITHKLINE MANUFACTURING SPA ,.,-STRADA PROVINCIALE ASOLANA, 90-43056, S.POLO DI TORRILE (PARMA)	N/A	GMP FOR ASOLANA EXPIRED ON THE 30/10/2021 FOR NON-BETA LACTAM SMALL VOLUME PARENTERAL SOLUTIONS (ASEPTICALLY FILLED AND TERMINALLY STERILISED IN AMPOULES AND VIALS)	RETAINED	ITALY	PARENTERAL ORDINARY DRY VIALS	1.0X5.0 VIAL CARTON	01/07/1999
507	NDA/MAL/HDP/2512	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	DICLOFENAC SODIUM INJECTABLE SOLUTION	DICLOFENAC SODIUM	25MG/ML	ZHEJIANG RUIXIN PHARMACEUTICAL CO. LTD-KAIFA ROAD, LISHUI, ZHEJIANG P.R OF CHINA	WUHAN FUXING BIOPHARMACEUTICAL CO., LTD-NO.9, FUXING ROAD, HANCUAN ECONOMIC & DEVELOPMENT DISTRICT, HUBEI PROVINCE	FAILED GMP ON THE 12/08/2019 FOR NON-BETA LACTAM: TABLET, CAPSULES, SMALL VOLUME LIQUIDS. HORMONES: SMALL VOLUME LIQUIDS. BETA LACTAM (CEPHALOSPORIN): TABLETS	RETAINED	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X3.0 ML AMPOULE,1.0X10.0X3.0 ML AMPOULE	01/07/2009
508	NDA/MAL/HDP/2516	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	UNIAMP DRY SUSPENSION	AMPICILLIN	125MG/5ML	N/A	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

509	NDA/MAL/HDP/2524	MEDLEY PHARMACEUTICALS LTD	EUROPA HEALTHCARE (U) LTD	PRIMODIL-5	AMLODIPINE BESYLATE	5MG	N/A	MEDLEY PHARMACEUTICALS LTDPLOT NO 18 & 19, SURVEY NO. 378/7& 8,379/2&3 ZARI ?AUSEWAY ROAD,, KACHIGAM, DAMAN-396 210	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
510	NDA/MAL/HDP/2529	B & O PHARM ZAC	TRIDEM PHARMA UGANDA LIMITED	G-CEFTRIA	CEFTRIAXONE	1G	GUILIN PHARMA CEUTICAL CO LTD-NO.43 QILIDIAN ROAD GUILIN 541004 GUANGXI CHINA NATIONAL MEDICINES, GUORUI PHARMA CEUTICAL CO., LTD-CAOYANG EAST ROAD, HUAINAN ECONOMICAL AND TECHNOL	N/A	FACILITY NOT APPROVED TO MANUFACTURE BETA LACTAMS AND GMP EXPIRED ON 29/12/2023 FOR Non-Beta Lactam: Small volume parenteral solutions Small volume parenteral powders, Beta lactam (Cephalosporins): Small volume parenteral solutions Small volume parenteral powders	RETAINED	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

511	NDA/MAL/HDP/2545	NORVATIS PHARMA AG-SWITZERLAND	LABOREX UGANDA LIMITED	TOBREX	TOBRAMYCIN	0.3%W/V	ALCON COUVREUR NVRIJKSWEG 14, B-2870 PUURS BELGIUM	N/A	GMP EXPIRED ON 08/12/2023 FOR Non-Beta Lactam: Semi-solids (Aseptically prepared) Small Volume Liquids (Aseptically prepared) Small Volume Liquids (Terminally Sterilized)	RETAINED	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/1997
512	NDA/MAL/HDP/2556	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	TRUVADA	EMTRICITABINE/TENOFOVIR	200MG/300MG	ASPEN PHARMACARE-7 FAIRCLOUGH ROAD KORSTEN PORT ELIZABETH, 6020 SOUTH AFRICA	PATHEON INC-ADDRESS: 2100 SYNTEX COURT, MISSISSAUGA, ONTARIO L5N 7K9 COUNTRY: CANADA TAKEDA GMBH-16515 ORANIENBURG GERMANY	GMP EXPIRED ON THE 22/3/2015 FOR I. TABLETS II. CAPSULES (HARD GELATIN)	RETAINED	CANADA GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2005
513	NDA/MAL/HDP/2557	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	EPSITRON 25 TABLETS	CAPTOPRIL	25MG	N/A	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1999
514	NDA/MAL/HDP/2561	PHARMATHEN LTD	GOODMAN INTERNATIONAL LTD	LANOMYCIN	AMIKACIN SULPHATE	500MG	PHARMATHEN S.A-6,DERVENAKION STR,PALLINI,AHICA GREECE	N/A	FACILITY NOT APPROVED FOR THE MANUFACTURE OF THE PRODUCT LINE (SMALL VOLUME PARENTERAL LIQUIDS)	RETAINED	GREECE	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE	01/07/1997

515	NDA/MAL/HDP/2565	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	TRAMAZAC INJECTION	TRAMADOL HYDROCHLORIDE	50MG/ML	CADILA HEALTHCARE LTD--SARKHEJ-PLOT 417,419, 420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL:	FARBE FIRMAPLOT NO. 1508, GIDC ANKLESHWAR - 393002, GUJARAT INDIA	FACILITY NOT APPROVED TO MANUFACTURE PRODUCT LINE; NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	PARENTERAL ORDINARY AMPOULES	, 1X5X2 ML Ampoule, 1X2 ML Vial	\N
516	NDA/MAL/HDP/2567	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CIPROBID-500	CIPROFLOXACIN	500MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	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	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	10.0X10.0 TABLET BLISTER	01/07/1997

517	NDA/MAL/HDP/2571	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CO-METHER	ARTEMETHER + LUMEFANTRINE	180 MG + 1080 MG	N/A	AGOG PHARMA LTDPLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X60.0 ML BOTTLE,1.0X 30.0 ML BOTTLE	01/07/2010
518	NDA/MAL/HDP/2572	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	DERINIDE 100 INHALER	BUDESONIDE	100 MCG/METERED INHALATION	CADILA HEALTHCARE LTDPLOT 203-213, KUNDAIM INDUSTRIAL ESTATE, GOA	N/A	FACILITY IS NOT LICENSED TO MANUFACTURE THE PRODUCT LINE; A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	OTHER SYSTEMIC GASES FOR INHALATION	1X200 Metered Dose Cannister,	01/07/2005

519	NDA/MAL/HDP/2573	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	DERINIDE 200 INHALER	BUDESONIDE	200MCG/INHALATION	CADILA HEALTHCARE LTDPLOT 203-213, KUNDAIM INDUSTRIAL ESTATE, GOA	N/A	FACILITY IS NOT LICENSED TO MANUFACTURE THE PRODUCT LINE; A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	OTHER SYSTEMIC GASES FOR INHALATION	1X200 Metered Dose Cannister,	01/07/2005
520	NDA/MAL/HDP/2579	ACINO PHARMA AG	LABOREX UGANDA LIMITED	ARTEQUIN 300/375 LACTAB	ARTESUNATE + MEFLOQUINE	300 MG + 375 MG	ACINO PHARMA AG-DORNACHERSTRASSE 114, CH-4147 AESCH	N/A	GMP EXPIRED ON THE 12/11/2022 FOR NON-BETA LACTAM: TABLETS HARD GELATIN CAPSULES; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER	01/07/2005

521	NDA/MAL/HDP/2589	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS LTD	CIFRAN OD TABLETS 1000MG	CIPROFLOXACIN	1000MG	SUN PHARMACEUTICAL INDUSTRIES LIMITEDSUN HOUSE, PLOT NO. 201 B/1 WESTERN EXPRESS HIGHWAY, GOREGA	N/A	FACILITY ADDRESS NOT FOUND	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1X10X10 TABLET Blister, 1X100X10 TABLET Blister	01/07/2005
522	NDA/MAL/HDP/2591	HEALTHCARE LTD.	HEALTHCARE LTD.	VITAGLOBIN SYRUP	MULTI-INGREDIENT	MULTI-INGREDIENT	AL FAZAL PHARMA INDUSTRIES (PVT) LTD-PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN	N/A	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS, HARD GELATIN CAPSULES, OINTMENTS/CREAMS/GELS;	RETAINED	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X90.0 ML BOTTLE,1.0X 250.0 ML BOTTLE	01/07/2001
523	NDA/MAL/HDP/2595	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	ZEPILEN	CEFAZOLIN	1000MG	MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X1.0 G VIAL	01/07/2009

524	NDA/MAL/HDP/2601	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	AXETINE 750MG	CEFUROXIME	750MG	MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X750.0 MG VIAL	01/07/2009
525	NDA/MAL/HDP/2602	: ALKEM LABORATORIES LIMITEDv	ABACUS PHARMA (AFRICA) LIMITED	CLAVAMBID	AMOXICILLIN + CLAVULANIC ACID	200 MG + 28.5 MG/ 5 ML	ALKEM LABORATORIES LTD--PLOT NO. 167/1, MAHATMA GANDHI UDYONG NAGAR, AMALIYA, DABHEL, DAMAN, 396210 INDIA.	INDCHEMIE HEALTH SPECIALTIES PVT. LTD-(UNIT 3 BETA LACTAM BLOCK) VILLAGE: THANA, TEHSIL: BADDI, DISTRICT: SOLAN HIMACHAL PRADESH -173205 INDIA	GMP FOR ALKEM EXPIRED ON THE 29/11/2019 FOR HARD GELATIN CAPSULES (NBL, CEPHALOSPORIN & PENICILLIN) TABLETS. (NBL & CEPHALOSPORIN) POWDERS FOR ORAL SUSPENSION (CEPHALOSPORIN) POWDERS FOR ORAL SUSPENSION, (PENICILLIN) POWDERS FOR INJECTION AND TABLETS.(PENICILLIN)	RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE,1.0X70.0 ML BOTTLE	01/07/2010

526	NDA/MAL/HDP/2610	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	ATROPINE	ATROPINE	1MG/ML	NINGBO DAHONGYING PHARMACEUTICALS LTD NO. 396 MIN	N/A	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: TABLETS, CAPSULES, SVP LIQUIDS	NOT RETAINED	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2009
527	NDA/MAL/HDP/2617	BLUE CROSS LABORATORIES LIMITED	STAR PHARMACEUTICALS LTD	BLUDROX TABLETS DISPERSABLE	CEFADROXIL	250MG	BLUE CROSS LABORATORIES LIMITEDA-12 MIDC AMBAD-NASHIK-422010 MAHARASHTRA STATE, INDIA	N/A	FACILITY NOT LICENSED TO MANUFACTURE BETA LACTAMS; GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, SMALL VOLUME LIQUIDS	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET STRIP	01/07/2001
528	NDA/MAL/HDP/2641	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	AXETINE 250MG	CEFUROXIME AXETIL	250MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY,FACTORY C-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIALAREA 4101 AGIOS	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET STRIP	01/07/2014

529	NDA/MAL/HDP/2642	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MEDOXANUM	CEFTRIAXONE	1G	MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 10 ML AMPOULE WFI	01/07/2016
530	NDA/MAL/HDP/2645	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANZIDIME 1000	CEFTAZIDIME	1000MG	N/A	SANCE LABORATORIES PVT LTDVI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL	01/07/2010
531	NDA/MAL/HDP/2674	CADILA PHARMACEUTICALS LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	STPASE	STREPTOKINASE	1,500,000IU	N/A	LA-MED HEALTHCARE PVT LTD1389 TRASAD ROAD, DHOLKA, AHMEDABAD, GUJARAT INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	01/07/2009
532	NDA/MAL/HDP/2688	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AMOXYN-250	AMOXICILLIN	250MG	REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD	N/A	FACILITY ADDRESS CHANGED TO NO.1. APPLICANT REQUIRED TO APPLY FOR A VARIATION	RETAINED	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0X10.0 CAPSULE BLISTER	01/07/2011

533	NDA/MAL/HDP/2698	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	AZICIN-500	AZITHROMYCIN	500MG	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR-401506, DIST.THANE, MARAHASHTRA, INDIA	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	FAILED GMP ON THE 14/5/2019 FOR NON BETA-LACTAM: TABLETS (COATED AND UNCOATED), EXTERNAL PREPARATIONS (CREAMS AND OINTMENTS), HARD GELATIN CAPSULES, DRY POWDER FOR ORAL SUSPENSION, ORAL LIQUIDS	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	01/07/2009
534	NDA/MAL/HDP/2699	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	CARVIL 12.5	CARVEDILOL	12.5 MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2005
535	NDA/MAL/HDP/2702	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EUGLIM 2	GLIMEPIRIDE	2MG	CADILA HEALTH CARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAI	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2004

536	NDA/MAL/HDP/2704	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	PRIMACORT-100	HYDROCORTISONE SODIUM SUCCINATE	100MG	MACLEODS PHARMACEUTICALS LTD-MAHIM ROAD, NEAR KULDEEP NAGAR	N/A	GMP EXPIRED	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X100.0 MG VIAL	01/07/2005
537	NDA/MAL/HDP/2706	SOLVAY PHARMACEUTICALS BV	HARLEYS UGANDA LIMITED	DUSPATALIN	MEBEVERINE HCL	135MG	SOLVAY PHARMACEUTICALS PV-VEERVEG 12 8121 AA 0187 NETHERLAND	N/A	FACILITY NAME CHANGED TO ABBOTT BIOLOGICALS B.V., APPLICANT REQUIRED TO APPLY FOR VARIATION	RETAINED	NETHERLANDS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X5.0 TABLET BLISTER	01/07/2008
538	NDA/MAL/HDP/2718	SHAIGAN PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	GYNOMIN	Z	Z	N/A	SHAIGAN PHARMACEUTICALS (PVT) LIMITED14 KM ADYALA RD, RAWALPINDI, PAKISTAN	N/A	NOT RETAINED	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	01/07/1997

539	NDA/MAL/HDP/2719	SEDICO PHARMACEUTICAL CO.	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LORASED	LORATADINE	10MG	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT	N/A	GMP EXPIRED ON THE 28/09/2023 FOR NON-BETA LACTAM: ORAL VETERINARY POWDERS TABLETS POWDERS FOR ORAL SUSPENSION HARD GELATIN CAPSULES ORAL LIQUIDS OINTMENTS, CREAMS & GELS SUPPOSITORIES STERILE LIQUIDS IN AMPOULES POWDER SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED IN PLASTIC AMPOULE) SMALL VOLUME LYOPHILIZED POWDER (ASEPTICALLY PREPARED) SOFT GELATIN CAPSULES , BIOLOGICALS (SVP): RECOMBINANT INSULIN	RETAINED	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET STRIP	01/07/2016

540	NDA/MAL/HDP/2720	SEDICO PHARMACEUTICAL CO.	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FLUCAMOX 250MG POWDER FOR ORAL SUSPENSION	AMOXICILLIN +FLUCLOXACILLIN	125MG/5ML+125MG/5ML	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT	N/A	GMP EXPIRED ON THE 28/09/2023 FOR NON-BETA LACTAM: ORAL VETERINARY POWDERS TABLETS POWDERS FOR ORAL SUSPENSION HARD GELATIN CAPSULES ORAL LIQUIDS OINTMENTS, CREAMS & GELS SUPPOSITORIES STERILE LIQUIDS IN AMPOULES POWDER SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED IN PLASTIC AMPOULE) SMALL VOLUME LYOPHILIZED POWDER (ASEPTICALLY PREPARED) SOFT GELATIN CAPSULES , BIOLOGICALS (SVP): RECOMBINANT INSULIN	RETAINED	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X80.0 ML BOTTLE	01/07/2007
541	NDA/MAL/HDP/2723	TABROS PHARMA	HEALTHCARE LTD.	DURAGESIC TABLET	PARACETAMOL + ORPHENADRINE	450MG+35MG	TABROS PHARMA L-20/B SECTOR 22 FB INDUSTRIAL AREA KARACHI	N/A	GMP EXPIRED ON 08/12/2023 FOR Non- Beta Lactam: Tablets	RETAINED	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997

542	NDA/MAL/HDP/2725	ASTRA PHARMA (U) LTD	ASTRA PHARMA (U) LIMITED	STREPTOMYCIN SULPHATE FOR INJECTION	STREPTOMYCIN SULPHATE	1GM	N/A	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	Hard Gelatin Capsules	NOT RETAINED	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X5.0X1.0X10.0 VIAL CARTON	01/07/2011
543	NDA/MAL/HDP/2742	AMANTA HEALTHCARE LTD	PHARMA VILLE LIMITED	STERILIZED WATER FOR INJECTION BP	STERILIZED WATER FOR INJECTION BP	MULTI-INGREDIENT	N/A	AMANTA HEALTHCARE LIMITED (FORMERLY KNOWN AS MARCK BIOSCIENCES LTD)PLOT NO. 876, N.H. NO. 8, VILLAGE - HARIYALA, DIST - KHEDA 387411, GUJARAT	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X10.0X5.0X10.0 ML BOTTLE	01/07/2016
544	NDA/MAL/HDP/2751	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	FLUDAC CAPSULES	FLUOXETINE HCL	20MG	N/A	CADILA PHARMACEUTICALS LIMITED1389 DHOLKA 387810 DISTRCT AHMEDABAD GUJARAT STATE	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X20.0 CAPSULE BLISTER	01/07/1997

545	NDA/MAL/HDP/2763	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	CANDISTAT	CLOTRIMAZOLE	100MG	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	RETAINED	KENYA	VAGINAL SUPPOSITORIES	1.0X2.0X3.0 PESSARY STRIP	01/07/1997
546	NDA/MAL/HDP/2774	ACINO PHARMA AG -	LABOREX UGANDA LIMITED	BACTIFLOX NEO 500	CIPROFLOXACIN	500MG	ACINO PHARMA AG.-DORNACHERSTRASSE 114, CH-4147 AESCH, SWITZERLAND	ACINO PHARMA AG-BIRSWEG 2, 4253, LIESBERG - SWITZERLAND	GMP EXPIRED ON THE 12/11/2022 FOR NON-BETA LACTAM: TABLETS, HARD GELATIN CAPSULES	RETAINED	SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2005

547	NDA/MAL/HDP/2783	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN SUPPOSITORIES 25MG	DICLOFENAC SODIUM	25MG	DELPHARM HUNINGUE S.A.S-SITE INDUSTRIAL HUNINGUE26, RUE DE LA CHAPELLE, F-68330, HUNING	N/A	GMP EXPIRED ON 19/10/2023 FOR NON-BETA LACTAM: SUPPOSITORIES, LIQUIDS FOR EXTERNAL USE, LIQUIDS FOR INTERNAL USE, SEMI SOLIDS	RETAINED	FRANCE	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X10.0 SUPPOSITORY STRIP	01/07/2006
548	NDA/MAL/HDP/2790	UNICHEM LABORATORIES LIMITEDv	EUROPA HEALTHCARE (U) LTD	TG-TOR 20	ATORVASTATIN	20MG	N/A	UNICHEM LABORATORIES LIMITED UNIT IIVILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2003
549	NDA/MAL/HDP/2792	UNICHEM LABORATORIES LIMITEDv	EUROPA HEALTHCARE (U) LTD	TG-TOR 10	ATORVASTATIN	10MG	N/A	UNICHEM LABORATORIES LIMITED UNIT IIVILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2003

550	NDA/MAL/HDP/2793	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	VIREAD	TENOFOVIR DISOPROXIL FUMARATE	300MG	ASPEN PHARMA CARE-7 FAIRCLOUGH ROAD KORSTEN PORT ELIZABETH, 6020 SOUTH AFRICA	TAKEDA GMBH,PLANT ORANIENBURG-LEHNITZSTRASSE 70-98,16515,ORANIENBURG-GERMANY PATHEON YM INC. TORONTO-TORONTO, CANADA	GMP EXPIRED ON THE 22/3/2015 FOR I. TABLETS II. CAPSULES (HARD GELATIN); NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	GERMANY CANADA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X30.0 TABLET BOTTLE	01/07/2004
551	NDA/MAL/HDP/2805	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	NIFELAT 20R TABLETS	NIFEDIPINE	20MG	N/A	REMEDICA LIMITED AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/1997
552	NDA/MAL/HDP/2806	RENE INDUSTRIES LIMITED	RENE PHARMACY LTD	PHENOBARBITONE TABLETS	PHENOBARBITONE	30MG	N/A	CYANO PHARMA(P)115-C IND ESTATE POLOGROUND, INDORE 452015	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER	01/07/1997
553	NDA/MAL/HDP/2816	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CATENOL-100 TABLETS	ATENOLOL	100MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER	01/07/1997

554	NDA/MAL/HDP/2818	TRIVENI FORMULATIONS LIMITED	SUPER MEDIC LTD	TRICIP	CIPROFLOXACIN	500MG	N/A	TRIVENI FORMULATION LTDPLOT NO.52,53,54,63,62,64, ALEAP INDUSTRIAL ESTATE SURAMPALI, AP-INDIA – 521212	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
555	NDA/MAL/HDP/2830	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	QUINIMIX MIXTURE	QUININE HYDROCHLORIDE	100MG/5ML	N/A	MEDIPHARM INDUSTRIES (E.A) LTDPLOT 65, KAKAJJO ROAD (BWEYOGERERE)	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	UGANDA	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE	01/07/2003

556	NDA/MAL/HDP/2846	SINO AFRICA MEDICINES AND HEALTH LTD	SINO AFRICA MEDICINES & HEALTH LTD	BENZATHINE BENZYL PENICILLIN FOR INJECTION	BENZATHINE BENZYL PENICILLIN	2400000 I.U	SHIJIAZHUANG PHARMA GROUP, ZHOUGNUO, PHARMACEUTICAL-N0188 GONGNONG ROAD, SHIJIAZHUANG CITY HEBEI PROVINCE, PEOPLE'S REP. CHINA	N/A	GMP EXPIRED, APPLICANT REQUIRED TO APPLY FOR VARIATION TO UPDATE MANUFACTURER DETAILS TO CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) COMPANY LIMITED-NO. 88 YANGZI ROAD, ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, SHIJIAZHUANG, HEBEI, PEOPLE'S REPUBLIC OF CHINA, WORKSHOP 406 AND 407	NOT RETAINED	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 VIAL CARTON,1.0X50.0 VIAL CARTON	01/07/2009
557	NDA/MAL/HDP/2848	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	DIPROGENTA OINTMENT	BETAMETHASONE /GENTAMICIN SULPHATE	0.5MG/G+1.0MG/G	SCHERING-PLOUGH LABONV-INDUSTRIE PARK 30, B-220 HEIST-OP-DEN-BERG, BELGIUM	N/A	NAME OF FACILITY (SCHERING PLOUGH) CHANGED TO ORGANON HEIST BV, APPLICATION REQUIRED TO APPLY FOR VARIATION FOR CHANGE OF NAME	RETAINED	BELGIUM	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE,1.0X30.0 G TUBE	01/07/2001

558	NDA/MAL/HDP/2868	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	LOSACAR 50	LOSARTAN POTASSIUM	50MG	CADILA HEALTH CARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAI	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X10.0X7.0 TABLET BLISTER	01/07/2003
559	NDA/MAL/HDP/2877	AMANTA HEALTHCARE LTD	PHARMA VILLE LIMITED	CANDICAN	FLUCONAZOLE	0.2%W/V	N/A	AMANTA HEALTHCARE LIMITED (FORMERLY KNOWN AS MARCK BIOSCIENCES LTD)PLOT NO. 876, N.H. NO. 8, VILLAGE - HARIYALA, DIST - KHEDA 387411, GUJARAT	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2005

560	NDA/MAL/HDP/2878	PHARCO PHARMACEUTICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCOCIN CREAM	GENTAMYCIN SULPHATE	0.1%W/W	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	N/A	GMP EXPIRED ON 28/9/2023 FOR BETA LACTAM (PENICILLIN): ORAL DRY POWDERS FOR SUSPENSION HARD GELATIN CAPSULES TABLETS SVP POWDERS (VIALS), NON-BETA LACTAM: ORAL DRY POWDERS (HUMAN & VETERINARY) HARD GELATIN CAPSULES TABLETS ORAL LIQUIDS ORAL POWDERS IN SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED) CREAMS, OINTMENTS, GELS, SUPPOSITORIES, PESSARIES & OVULES	NOT RETAINED	EGYPT	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2000

561	NDA/MAL/HDP/2879	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	OFLIN-200	OFLOXACIN	200MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAI	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X20.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER,10.0X1.0X10.0 TABLET BLISTER	01/07/2004
562	NDA/MAL/HDP/2880	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CARBIMAZOLE 5	CARBIMAZOLE	5MG	N/A	REMEDICA LIMITED,LIMASSOL INDUSTRIAL ESTATE, AHARNON ST, P.O. BOX 51706,3508 LIMASSOL	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010
563	NDA/MAL/HDP/2888	VHB MEDI SCIENCES LTD	NORVIK ENTERPRISES LIMITED	SUCCICORT	HYDROCORTISONE SODIUM SUCCINATE	100MG/VIAL	N/A	VHB MEDI SCIENCES LTDPLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	, 1X100 MG Vial	\N
564	NDA/MAL/HDP/2890	KPI INDUSTRIES(1996) LTED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	BETASOL N	BETAMETHASONE+NEOMYCIN	1MG/G+5MG/G	N/A	KPI INDUSTRIES (1996) LTDPLOT NO.M444B STRETCHER RD, NTINDA, KAMPALA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2005

565	NDA/MAL/HDP/2894	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MUCOGEL SUSPENSION	DRIED ALUMINIUM HYDROXIDE + MAGNESSIUM HYDROXIDE + OXETHAZAINE	8G/100ML + 2G/100ML + 0.2 G/100ML	EGYPIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO EIPICO10TH OF RAMADAN CITY-FIRST INDUSTRIAL AREA - EGYPT	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X125.0 ML BOTTLE	01/07/2005

566	NDA/MAL/HDP/2900	MICRO LABS LTD	LABOREX UGANDA LIMITED	GRAMOCEF-O-200	CEFIXIME	200MG	MICRO LABS LIMITED, BOMMASANDRA PLOT NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560	N/A	GMP EXPIRED ON 20/11/2023 FOR BETA LACTAM (CEPHALOSPORIN): TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, DRY POWDER FOR ORAL SUSPENSION	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/2005
567	NDA/MAL/HDP/2903	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	ABACAVIR SULPHATE TABLETS	ABACAVIR SULFATE	300MG	N/A	STRIDES ARCOLAB LIMITED 36/7 SURAGAJAKKANAHALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2009

568	NDA/MAL/HDP/2911	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL LORATADINE	LORATADINE	10MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	N/A	GMP EXPIRED ON THE 28/9/2023 FOR NON-BETA LACTAM: TABLETS COATED & UNCOATED HARD GELATIN CAPSULES ORAL LIQUIDS SVP LIQUIDS AND POWDER STERILE GELS , (BETA LACTAM) CEPHALOSPORIN: HARD GELATIN CAPSULES DRY POWDER FOR ORAL SUSPENSION SVP POWDER , CORTICOSTEROIDS: OINTMENTS AND CREAMS	RETAINED	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010
569	NDA/MAL/HDP/2912	FDC LTD	AIVEEN (U) LIMITED	MYCODERM	SALICYLIC ACID + BENZOIC ACID	3%W/W + 6%W/W	FDC LIMITED - B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD-431 136	N/A	FACILITY NOT APPROVED FOR THIS LINE	RETAINED	INDIA	TOPICAL EXTERNAL POWDERS	1.0X100.0 G CONTAINER	01/07/2007

570	NDA/MAL/HDP/2919	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ODIMONT 5	MONTELUKAST	5MG	CADILA HEALTHCARE LTD--SARKHEJ-PLOT 417,419, 420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL:	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
571	NDA/MAL/HDP/2923	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	COLD PLUS SYRUP	PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + CHLORPHENIRAMINE MALEATE	125MG + 2.5MG + 2.5MG/5ML	N/A	CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, 119 MIDC TARAPUR BOISAR DIST THANE 4011 506	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2014
572	NDA/MAL/HDP/2941	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORVA 20	ATORVASTATIN	20MG	CADILA HEALTH CARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAI	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X5.0X7.0 TABLET BLISTER	01/07/2005

573	NDA/MAL/HDP/2945	MEDLEY PHARMACEUTICALS LTD	EUROPA HEALTHCARE (U) LTD	ONCET	CETIRIZINE DIHYDROCHLORIDE	10MG	N/A	MEDLEY PHARMACEUTICALS LTDPLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
574	NDA/MAL/HDP/2950	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	XALATAN	LATANOPROST	0.005%W/V	N/A	PFIZER MANUFACTURING NV/NA, RIJKSWEG 12 2870, PUURS	N/A	NOT RETAINED	BELGIUM	OPHTHALMIC DROPS	1.0X2.5 ML BOTTLE	01/07/1998
575	NDA/MAL/HDP/2955	SHAIGAN PHARMACEUTICALS (PVT) LTD	HARLEYS UGANDA LIMITED	CLOZOX	CLOTRIMAZOLE	2%W/W	N/A	SHAIGAN PHARMACEUTICALS (PVT) LTD14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	PAKISTAN	VAGINAL CREAMS	1.0X1.0X35.0 G TUBE + TWO APPLICATORS	01/07/2005
576	NDA/MAL/HDP/2963	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	AZIWOK 500	AZITHROMYCIN	500MG	N/A	WOCKHARDT LIMITEDPLOT 57 VILLAGE KUNJHAL, JHAMAJRI, BAROTIWALA, BADDI, TEHSIL-NALAGARH, DISTRICT SOLAN, 174103 HIMACHAL PRADESH, INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X6.0 TABLET BLISTER	01/07/2014

577	NDA/MAL/HDP/2972	SHAIGAN PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ANTIMIN SYRUP	LORATIDINE	5MG/ML	N/A	SHAIGAN PHARMACEUTICALS (PVT) LTD14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN	N/A	NOT RETAINED	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE	01/07/2005
578	NDA/MAL/HDP/2974	NORVATIS PHARMA AG-SWITZERLAND	LABOREX UGANDA LIMITED	TRAVATAN	TRAVOPROST	4µG/ML	ALCON COUVREUR NVRIJKSWEG 14, B-2870 PUURS BELGIUM	N/A	GMP EXPIRED ON 08/12/2023 FOR Non-Beta Lactam: Semi-solids (Aseptically prepared) Small Volume Liquids (Aseptically prepared) Small Volume Liquids (Terminally Sterilized)	RETAINED	BELGIUM	OPHTHALMIC DROPS	1.0X2.5 ML VIAL	01/07/2009
579	NDA/MAL/HDP/2981	SHAIGAN PHARMACEUTICALS (PVT) LTD	HARLEYS UGANDA LIMITED	STAMIN	CETIRIZINE DIHYDROCHLORIDE	1MG/ML	N/A	SHAIGAN PHARMACEUTICALS (PVT) LTD14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	PAKISTAN	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X60.0 ML BOTTLE	01/07/2005

580	NDA/MAL/HDP/2990	MICRO LABS LTD	LABOREX UGANDA LIMITED	PULMOCEF-500	CEFUROXIME AXETIL USP	500MG	MICRO LABS LTD-NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099	N/A	GMP EXPIRED ON 20/11/2023 FOR BETA LACTAM (CEPHALOSPORIN): TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, DRY POWDER FOR ORAL SUSPENSION	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X3.0X4.0 TABLET BLISTER	01/07/2004
581	NDA/MAL/HDP/2992	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	HAVRIX1440	HEPATITIS A ANTIGEN(HM 175 STRAIN)	NLT 1440 ELISA UNITS OF VIRAL ANTIGENS(HM 175 STRAIN)	N/A	GLAXOSMITHKLINE BIOLOGICALSRUE DE L' LNSTITUT 89-1330 RIXENSART	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL (1 DOSE)	01/07/1997
582	NDA/MAL/HDP/3002	LEBEN LABORATORIES LTD	MALIX PHARMA (U) LIMITED	KELVIN	PARACETAMOL	500MG	N/A	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2011
583	NDA/MAL/HDP/3008	VHB MEDI SCIENCES LTD	NORVIK ENTERPRISES LIMITED	BLEOSOL	BLEOMYCIN	15 UNITS	N/A	VHB MEDI SCIENCES LTDPLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1X5 ML Vial	\N

584	NDA/MAL/HDP/3015	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	PENEGRA-50 TABLETS	SILDENAFIL	50MG	CADILA HEALTHCARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO.203-213, KUNDAI	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER,1.0X20.0X4.0 TABLET BLISTER	01/07/2001
585	NDA/MAL/HDP/3017	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	LIDOCAINE INJECTION	LIDOCAINE HYDROCHLORIDE	20MG/ML	ZHEJIANG RUIXIN PHARMACEUTICALS CO LTD-KAIFA ROAD TIANNING IDOUS ZONE LISHUI CITY	SANJAR PHARMA LLP HIMATNAGAR-VIJOPUR HIGHWAY, DEDHROTA HIMATNAGAR 383 220, GUJARAT INDIA	FAILED GMP ON THE 12/08/2019 FOR NON-BETA LACTAM: TABLET, CAPSULES, SMALL VOLUME LIQUIDS. HORMONES: SMALL VOLUME LIQUIDS. BETA LACTAM (CEPHALOSPORIN): TABLETS	RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1.0X25.0X20.0 ML VIAL,1.0X30.0 ML VIAL	01/07/2008
586	NDA/MAL/HDP/3019	MJ BIOPHARM PVT LTD	VITACARE LIMITED	BIOSULIN 30/70	INSULIN SOLUBLE + INSULIN ISOPHANE	30 I.U + 70 I.U	N/A	MJ BIOPHARM PRT LTDL-7 MIDC INDUSTRIAL AREA, TALOJA, NARI MUMBAI MAHARASHTRA	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	01/07/2008

587	NDA/MAL/ HDP/3020	M.J BIOPHARM PVT LTD	VITACARE LIMITED	BIOSULIN N	INSULIN ISOPHANE	100 I.U/ML	N/A	M.J .BIOPHARML7, M.I.D.C INDUSTRIAL AREA TALOJA, NAVI MUMBAI MAHARAHTRA	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL	01/07/2008

588	NDA/MAL/HDP/3026	KOTRA PHARMA (M) SDN BHD	ABACUS PHARMA (AFRICA) LIMITED	AXCEL DETROMETHORPHAN-15 SYRUP	DEXTROMETHORPHAN HYDROBROMIDE	15MG/5ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	N/A	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED; GMP EXPIRED ON THE 28/9/2023 FOR NON-BETA LACTAM: TABLETS COATED & UNCOATED HARD GELATIN CAPSULES ORAL LIQUIDS SVP LIQUIDS AND POWDER STERILE GELS , (BETA LACTAM) CEPHALOSPORIN: HARD GELATIN CAPSULES DRY POWDER FOR ORAL SUSPENSION SVP POWDER , CORTICOSTEROIDS: OINTMENTS AND CREAMS	RETAINED	MALAYSIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2008

589	NDA/MAL/HDP/3030	MJ BIOPHARM PVT LTD	VITACARE LIMITED	BIOSULIN R	INSULIN SOLUBLE	100 IU/ML	N/A	M.J BIOPHARM PVT LTD -L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL	01/07/2008
590	NDA/MAL/HDP/3042	PFIZER LABS LTD	LABOREX UGANDA LIMITED	NEUROTIN	GABAPENTIN	300MG	N/A	PFIZER MANUFACTURING DEUTSCHLAND (PMD) GMBHPHYSICAL ADDRESS: MOOSWALDALLEE 1D – 79090 FREIBURG	N/A	NOT RETAINED	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2014
591	NDA/MAL/HDP/3044	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	PIRICAM-20 CAPSULES	PIROXICAM	20MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER,2.0X10.0 CAPSULE BLISTER	01/07/1997
592	NDA/MAL/HDP/3060	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	KETOS TABLET	KETOCONAZOLE USP	200 MG	N/A	AGOG PHARMA LIMITEDPLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA	MARKETING AUTHORIZATION FOR ORAL KETOCONAZOLE HAS BEEN WITHDRAWN; 18TH AUTHORITY RESOLUTION DATED 20/2/2023	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	07/07/2007

593	NDA/MAL/HDP/3068	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	OPTACHLOR EYE DROPS	CHLORAMPHENICOL	0.5%W/V	REMINGTON PHARMACEUTICAL INDUS. PVT LTD, 117 ALLAM	N/A	GMP EXPIRED ON 2/11/2023 NON-BETA LACTAM: EYE DROPS, EAR DROPS, EXTERNAL PREPARATIONS (CREAMS & OINTMENTS), EYE OINTMENTS, ORAL LIQUIDS	RETAINED	PAKISTAN	OPHTHALMIC DROPS	1.0X10.0 ML VIAL	01/07/1999
594	NDA/MAL/HDP/3073	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CARDINOL TABLET	ATENOLOL	50MG	N/A	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	N/A	NOT RETAINED	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	2.0X14.0 TABLET STRIP	01/07/1997

595	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.	N/A	GMP EXPIRED ON THE 29/9/2023 FOR NON-BETA LACTAM: HARD GELATIN CAPSULES SOFT GELATIN CAPSULES TABLETS (COATED & UNCOATED) DRY POWDERS FOR SUSPENSION POWDERS PACKED IN SACHETS SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED LIQUIDS) SMALL VOLUME PARENTERAL – (ASEPTICALLY PREPARED POWDERS) EYE DROPS (ASEPTICALLY PREPARED) ORAL LIQUIDS NON-STERILE NASAL DROPS EXTERNAL SEMI-SOLIDS (CREAMS & GELS)	RETAINED	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2004
596	NDA/MAL/HDP/3102	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	EPANUTIN READY MIXED	PHENYTOIN SODIUM	50MG/ML	ACTAVIS ITALY S.P.A-VIALE PASTEUR, 10 20014 NERVIANO(MILAN)	N/A	SITE ADDRESS NOT FOUND	NOT RETAINED	ITALY	PARENTERAL ORDINARY AMPOULES	1.0X5.0X5.0 ML AMPOULE	01/07/1997

597	NDA/MAL/HDP/3105	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DEPIN-E RETARD	NIFEDIPINE	20MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/1997
598	NDA/MAL/HDP/3108	IPCA LABORATOIES LTD	MEDVIN PHARMA LIMITED	ZERODOL	ACECLOFENAC	100MG	IPCA LABORATORIES LTD, PLOT NO. T-139PLOT NO. T-139, MIDC, INDUSTRIAL ESTATE, TARAPUR, BOISOR, DIST-PALGHAR, THANE 401506, MAHARASHTRA. IPCA LABORAT	N/A	GMP EXPIRED ON 21/12/2023 FOR Non-Beta Lactam: Tablets (Coated & Uncoated) AND GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: TABLETS ORAL LIQUIDS SVP LIQUIDS IN VIALS AND AMPOULES (ASEPTIC FILLING AND TERMINALLY STERILIZED)	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2005

599	NDA/MAL/HDP/3140	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	ULTIVA INJECTION 1MG	REMIFENTANIL	1 MG	GLAXOSMITHKLINE MANUFACTURING SPA ,.,-STRADA PROVINCIALE ASOLANA , 90-43056, S.POLO DI TORRILE (PARMA)	N/A	GMP FOR ASOLANA EXPIRED ON THE 30/10/2021 FOR NON-BETA LACTAM SMALL VOLUME PARENTERAL SOLUTIONS (ASEPTICALLY FILLED AND TERMINALLY STERILISED IN AMPOULES AND VIALS)	RETAINED	ITALY	PARENTERAL ORDINARY VIALS	1.0X5.0 VIAL CARTON	01/07/1999
600	NDA/MAL/HDP/3150	VHB MEDI SCIENCES LTD	NORVIK ENTERPRISES LIMITED	MTX-VHB	METHOTREXATE	50MG/2ML	N/A	VHB MEDI SCIENCES LTDPLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	PARENTERAL ORDINARY VIALS	, 1X2 ML Vial	\N
601	NDA/MAL/HDP/3158	MJ BIOPHARM PVT LTD	VITACARE LIMITED	GLIBEX-5	GLIBENCLAMIDE	5MG	N/A	M.J BIOPHARM PVT LTD -L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2012

602	NDA/MAL/HDP/3163	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, HUNING	N/A	GMP EXPIRED ON 19/10/2023 FOR NON-BETA LACTAM: SUPPOSITORIES, LIQUIDS FOR EXTERNAL USE, LIQUIDS FOR INTERNAL USE, SEMI SOLIDS	RETAINED	FRANCE	RECTAL SYSTEMIC ADULT SUPPOSITORIES	1.0X1.0X10.0 SUPPOSITORY STRIP	01/07/2006
603	NDA/MAL/HDP/3167	MJ BIOPHARM PVT LTD	KIMSY MEDS LTD	MONAN-0.5G	MEROPENEM	0.5G	N/A	M.J BIOPHARM PVT LTD -L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X0.5 G VIAL	01/07/2010
604	NDA/MAL/HDP/3173	MEDOPHARM PRIVATE LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	MEDOCILLIN 250	AMPICILLIN	250MG	N/A	MEDOPHARM PVT LTD NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY-603203 TAMIL NADU	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	07/01/2010
605	NDA/MAL/HDP/3175	M.J.BIOPHARM PVT LTD	VITACARE LIMITED	SPACOVIN	DROTAVERINE	40MG	N/A	M.J. BIOPHARM PVT. LTDL-7, M.I.D.C. , TALOJA, DISTRICT RAIGAD - 410 208 NAVI MUMBAI, INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2012

606	NDA/MAL/HDP/3176	AFRICURE PHARMACEUTICALS (INDIA) PRIVATELIMITED	AFRICURE PHARMACEUTICALS U LIMITED	DOXYRONE-100	DOXYCYCLINE HYDROCHLORIDE	100	N/A	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CONTAINER, 1.0X10.0X10.0 CAPSULE BLISTER	01/07/2005
607	NDA/MAL/HDP/3182	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	TADACIP 20	TADALAFIL	20MG	N/A	CIPLA LTDCIPLA LTD PLOT NO L-139,VERNA IND ESTATE, VERNA GOA INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	01/07/2005
608	NDA/MAL/HDP/3184	M.J BOPHARM PUT LTD	KIMSY MEDS LTD	MONAN	MEROPENEM	1G	N/A	M.J BIOPHARM PUT LTD L-7 MIDC INDUSTRIOL DIST GAIDED TOLOJA	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2008
609	NDA/MAL/HDP/3197	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	TRIAM-DENK 40 INJECTION	TRIAMCINOLONE ACETONIDE	40 MG/ML	DENK PHARMA, GOLLSTR.,-1-D-845529 TITTMONING GERMAN	FISIOPHARMA S.R.L.-NUCLEOO INDUSTRIALE, 84020, PALOMONTE (SA) - ITALY	FACILITY NOT APPROVED TO MANUFACTURE PARENTERALS	RETAINED	ITALY	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2004

610	NDA/MAL/HDP/3198	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPEN-125	PHENOXYMETHYL PENICILLIN POTASSIUM	125MG/ML	N/A	MILAN LABORATORIES (INDIA) PVT LTDPLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTRA-410209,INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X1.0X100.0 ML BOTTLE	01/07/2011
611	NDA/MAL/HDP/3205	EAGLEVET UGANDA LIMITED	MEDVIN PHARMA LIMITED	AZIFAST-250	AZITHROMYCIN	250MG	IPCA LABORATORIES LTD,PLOT NO. T-139 - SEJAVTA, RATLAM-457 002 (M.P.) INDIA	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: TABLETS ORAL LIQUIDS SVP LIQUIDS IN VIALS AND AMPOULES (ASEPTIC FILLING AND TERMINALLY STERILIZED)	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X6.0 TABLET BLISTER	01/07/2007
612	NDA/MAL/HDP/3206	HEALTHCARE LTD.	HEALTHCARE LTD.	POSTINOR 2	LEVONORGESTREL	0.75MG	N/A	GEDEON RICHTER PLC1103 BUDAPEST GYOMROI UT 19-21	N/A	NOT RETAINED	HUNGARY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X2.0 TABLET BLISTER	01/07/2010
613	NDA/MAL/HDP/3208	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	NIRFOL 1%	PROPOFOL	1%W/V	N/A	ACULIFE HEALTHCARE PVT. LTDVILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0X1.0X20.0 ML VIAL,1.0X10.0X50.0 ML VIAL	01/07/2010

614	NDA/MAL/HDP/3221	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	OPTADEX-N EYE DROPS	DEXAMETHASONE/NEOMYCIN	1MG/3MG	REMINGTON PHARMACEUTICAL INDUS. PVT LTD, 117 ALLAM	N/A	GMP EXPIRED ON 2/11/2023 NON-BETA LACTAM: EYE DROPS, EAR DROPS, EXTERNAL PREPARATIONS (CREAMS & OINTMENTS), EYE OINTMENTS, ORAL LIQUIDS	RETAINED	PAKISTAN	OPHTHALMIC DROPS	1.0X5.0 ML VIAL	01/07/1999
615	NDA/MAL/HDP/3229	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	CIFLO	CIPRFLOXACIN	500MG	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	NOT RETAINED	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER	01/07/2003

616	NDA/MAL/HDP/3232	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	L-TRIM	SULFAMETHOXAZOLE + TRIMETHOPRIM	400MG + 80MG	N/A	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER	01/07/2016
617	NDA/MAL/HDP/3233	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	WHITFIELD'S OINTMENT BP	BENZOIC ACID + SALICYLIC ACID	0.06G+0.03G	N/A	NEM LABORATORIES PVT LTDPLOT NO. 133 KRISHNA IND. ESTATE, VASAI E,DIST PALGHAR-401210, MAHARASHTRA STATE	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE	01/07/1997
618	NDA/MAL/HDP/3244	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	UMICILLIN	AMPICILLIN	250MG	N/A	UNI MEDICOLABS. 2122 PHARMACITY SELAQUI DEHRADUN 248197	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2015

619	NDA/MAL/HDP/3245	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NYSTATIN ORAL DROPS	NYSTATIN	100,000 I.U/ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	ORAL TOPICAL DROPS	1.0X30.0 ML BOTTLE	01/07/2013

620	NDA/MAL/HDP/3249	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	LOSACAR-H	LOSARTAN POTASSIUM + HYDROCHLOROTHIAZIDE	50MG + 12.5MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2004
621	NDA/MAL/HDP/3251	SCHERING N.V.SA...	SURGIPHARM (U) LIMITED	UROGRAFIN	DIATRIZOIC ACID	76%W/V	SCHERING N.V, SA-SPAIN	N/A	FACILITY NOT FOUND	RETAINED	SPAIN	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X20.0 ML VIAL	01/07/1997
622	NDA/MAL/HDP/3265	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AMOXICILLIN	AMOXICILLIN TRIHYDRATE	250MG	M/S SCOTT-EDIL PHARMACIA LTD - 56 EPIP, PHASE-I, JHARMAJRI	CSPC ZHONGNUO PHARMACEUTICALS (SHIJIAZHUANG) CO. LTD-SHIJIAZHUANG CITY	FACILITY NOT APPROVED TO MANUFACTURE BETA LACTAMS	NOT RETAINED	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER, 10.0X10.0 CAPSULE BLISTER	01/07/2010
623	NDA/MAL/HDP/3278	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	TOPIDIC 2% OINTMENT	SODIUM FUSIDATE	20MG/G	N/A	PHARMA INTERNATIONAL CO.AMMAN JORDAN PLANT AL-QARTAL MARKETING DEPARTMENT ALBUJAH COMPLEX, ALJUBAIHA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	JORDAN	TOPICAL EXTERNAL OINTMENTS	, 1X15 G Tube	01/07/2007

624	NDA/MAL/HDP/3296	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	LOPINAVIR / RITONAVIR	LOPINAVIR / RITONAVIR	100MG / 25MG	N/A	MYLAN LABORATORIES LTD-F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET CONTAINER, 1.0X60.0 TABLET CONTAINER	01/07/2011
625	NDA/MAL/HDP/3299	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	METODINE-DF SUSPENSION	METRONIDAZOLE/DILOXANIDE FUROATE	200MG/250MG	SEARLE PAKISTAN LIMITED-PLOT 35KM, MULTAN ROAD, LAHORE - PAKISTAN	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, ORAL LIQUIDS FOR INTERNAL USE	NOT RETAINED	PAKISTAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE	01/07/2004
626	NDA/MAL/HDP/3301	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	TRANSAMIN CAPSULES 250	TRANEXAMIC ACID	250MG	N/A	HILTON PHARMA (PVT) LTDPLOT 13, SECTOR 15, KORANGI INDUSTRIAL AREA,KARACHI, PAKISTAN.	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2000

627	NDA/MAL/HDP/3307	FREDUN PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	TINIFRED TABLETS	TINIDAZOLE	500MG	N/A	FREDUN PHARMACEUTICALS LIMITED,14,15,16 - ZORABIAN INDUSTRIAL COMPLEX, VEOOR, PALGHAR (E), THANE	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X4.0 TABLET BLISTER	01/07/1999
628	NDA/MAL/HDP/3309	UMEDICA LABORATORIES PVT LTD	VITACARE LIMITED	CLORIFORT VAGINAL TABLETS	CLOTRIMAZOLE	100MG	N/A	UMEDICA LABORATORIES PVT LTDPLOT NO. 221, 2ND PHASE, GIDC, VAPI 396195, GUJARAT. INDIA.	N/A	NOT RETAINED	INDIA	VAGINAL TABLETS	1.0X6.0 PESSARY STRIP	01/07/2002
629	NDA/MAL/HDP/3322	AUROBINDOM PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	NEVIRAPINE	NEVIRAPINE	50MG	N/A	AUROBINDO PHARMA LTD, UNIT III SURVEY NO. 313, 314 BACHUPALLY (VILLAGE) QUTHUBULLAPUR (MANDAL) RR DISTRICT HYDERABAD ANDHRA PRADESH 500090	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2012

630	NDA/MAL/HDP/3331	NORVATIS PHARMA AG-SWITZERLAND	LABOREX UGANDA LIMITED	BETOPTIC	BETAXOLOL	O.5%W/V	ALCON COUVREUR NVRIJKSWEG 14, B-2870 PUURS BELGIUM	N/A	GMP EXPIRED ON 08/12/2023 FOR Non-Beta Lactam: Semi-solids (Aseptically prepared) Small Volume Liquids (Aseptically prepared) Small Volume Liquids (Terminally Sterilized)	NOT RETAINED	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML VIAL	01/07/1997
631	NDA/MAL/HDP/3356	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYCEL-100 CAPSULES	CELECOXIB	100MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER	01/07/2001
632	NDA/MAL/HDP/3368	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	VIAGRA 50MG	SILDENAFIL	50MG	N/A	PFIZER PGM AMBROISE ZONE INDUSTRIELLE 29 ROUTE DES INDUSTRIES 37530 POCE SUR CISSE	N/A	NOT RETAINED	FRANCE	ORAL SOLID ORDINARY TABLETS	1.0X12.0 TABLET BLISTER,1.0X8.0 TABLET BLISTER,1.0X4.0 TABLET BLISTER	01/07/1998

633	NDA/MAL/HDP/3379	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIFASI	HUMAN CHORIONIC GONADOTROPIN	5000I.U	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	NOT RETAINED	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X2.0 AMPOULE CARTON	01/07/2011

634	NDA/MAL/HDP/3389	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	CLARINASE REPE TABS	LORATADINE + PSEUDOEPHEDRINE	5MG + 120MG	SCHERING PLOUGH LABO N.V,-INDUSTRY PARK 30, 2220 HEIST OPDENBERG BELGIUM	N/A	NAME OF FACILITY (SCHERING PLOUGH) CHANGED TO ORGANON HEIST BV, APPLICATION REQUIRED TO APPLY FOR VARIATION FOR CHANGE OF NAME	NOT RETAINED	BELGIUM	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2009
635	NDA/MAL/HDP/3390	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	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	NOT RETAINED	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X5.0 ML JERRYCAN	01/07/1997

636	NDA/MAL/HDP/3394	AMANTA HEALTHCARE LTD	PHARMA VILLE LIMITED	MAGNESIUM SULPHATE	MAGNESIUM SULPHATE	50%W/V	N/A	AMANTA HEALTHCARE LIMITED (FORMERLY KNOWN AS MARCK BIOSCIENCES LTD)PLOT NO. 876, N.H. NO. 8, VILLAGE - HARIYALA, DIST - KHEDA 387411, GUJARAT	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X50.0X10.0 ML AMPOULE	01/07/2010
637	NDA/MAL/HDP/3400	ACINO PHARMA AG	LABOREX UGANDA LIMITED	OLFEN GEL	DICLOFENAC SODIUM	1%W/W	ACINO PHARMA AG-DORNACHERSTRASSE 114, CH-4147 AESCH	SOFARIMEX INDUSTRIA QUIMIRA E FARMACEUTICA SAAV. DAS INDUSTRIAS - ALTO DO COLARIDE, 2735-213 AGUALVA CACEM ACINO PHARMA AGDORNACHERSTRASSE 114, CH-4147 AESCH	GMP EXPIRED ON THE 12/11/2022 FOR NON-BETA LACTAM: TABLETS, HARD GELATIN CAPSULES; FACILITY WAS NOT APPROVED FOR THIS LINE	RETAINED	PORTUGAL	TOPICAL EXTERNAL GELS AND SOLS	1.0X50.0 G TUBE,1.0X20.0 G TUBE	01/07/1997
638	NDA/MAL/HDP/3419	MEDIPHARM (EA) LTD	MEDIPHARM INDUSTRIES (E.A) LTD	PIRITEX BABY COUGH LINCTUS	COUGH LINCTUS WITH DILUTE ACETIC ACID	0.42ML/5ML	N/A	MEDIPHARM INDUSTRIES (E.A) LTDPLOT 65, KAKAJJO ROAD, BWEYOGERERE	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2006

639	NDA/MAL/HDP/3423	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	AMOXICLAV-DENK 1000/125	AMOXICILLIN TRIHYDTATE + POTASSIUM CLAVULANATE	1000 MG + 125 MG	PENCEF PHARMA GMBHBRITENBACH STR ASSE 13 D-13509 BERLIN	N/A	GMP EXPIRED ON 29/12/2023 FOR Beta Lactam (Human): Tablets Oral Powders for Oral Suspension Hard Gelatin Capsules	RETAINED	GERMANY	ORAL LIQUID ORDINARY UNIT DOSE POWDERS	1.0X12.0X3.0 G SACHET,1.0X8.0X3.0 G SACHET	01/07/2011
640	NDA/MAL/HDP/3428	MEDI PHARMA IDUSTRIES E.A LTD	MEDIPHARM INDUSTRIES (E.A) LTD	ORALYTE CO-PACK	MULTI INGREDIENT	MULTI INGREDIENT	N/A	MEDI PHARMA INDUSTRIES E.A LTDPLOT 65 KAKAJJO ROAD BWEYOGERERE	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	UGANDA	ORAL SOLID ORDINARY OTHER SPECIAL FORMS	1.0X2.0X20.5 G SACHET + 1*60.0 ML BOTTLE	01/07/2013

641	NDA/MAL/HDP/3431	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	NAZOL-200	KETOCONAZOLE	200MG	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR-401506, DIST.THANE, MARAHASHTRA, INDIA	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	MARKETING AUTHORIZATION FOR ORAL KETOCONAZOLE HAS BEEN WITHDRAWN; 18TH AUTHORITY RESOLUTION DATED 20/2/2023; MAXHEAL FAILED GMP ON THE 14/5/2019 FOR NON BETA-LACTAM: TABLETS (COATED AND UNCOATED), EXTERNAL PREPARATIONS (CREAMS AND OINTMENTS), HARD GELATIN CAPSULES, DRY POWDER FOR ORAL SUSPENSION, ORAL LIQUIDS	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
642	NDA/MAL/HDP/3433	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	CO-DIOVAN 80/12.5	VALSARTAN + HYDROCHLOROTHIAZIDE	80 MG +12.5 MG	NOVARTIS PHARMA SPA,-TORRE ANNUNZIATA ITALY	NOVARTIS PHARMA STEIN AG.-SCHAFFHAUSER STRASSE 4332, STEIN - SWITZERLAND	GMP EXPIRED ON THE 30/7/2023 FOR NBL TABLETS	RETAINED	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2006

643	NDA/MAL/HDP/3434	BETA HEALTHCARE INTERNATIONAL LIMITED	BETA HEALTHCARE UGANDA LIMITED	SEPTRIN	CO-TRIMOXAZOLE	480MG	N/A	GLAXO WELLCOME EGYPT CO. S.A.ECAIRO BETA HEALTHCARE INTERNATIONAL LTD PLOT NO. LR 209/6554, MOGADISHU ROAD INDUSTRIAL AREA, NAIROBI KENYA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	EGYPT KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0 TABLET CARTON,1.0 X50.0 TABLET CARTON,1.0 X10.0X10.0 TABLET BLISTER,1.0X 2.0X10.0 TABLET BLISTER	01/07/1997
644	NDA/MAL/HDP/3435	UNIVERSAL CORPORATION LTD	PHARMA VILLE LIMITED	CLOTRINE	CLOTRIMAZOLE	1%W/W	N/A	UNIVERSAL CORPORATION LTDKIKUYU NAIROBI KENYA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	01/07/2007
645	NDA/MAL/HDP/3437	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	REMYCIN 100 CAPSULES	DOXYCYCLINE HYDROCHLORIDE	100MG	N/A	REMEDICA LIMITED AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1997
646	NDA/MAL/HDP/3442	PIRAMAL HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	HAEMACCEL	POLYGELINE	3.5%W/V	PIRAMAL ENTERPRISES LTD, INDIA-DIGWAL VILLAGE KOHIR MENDAL MEDAK DISTRICT, ANDHRA	N/A	FACILITY NOT APPROVED FOR THE MANUFACTURE OF THE PRODUCT LINE	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2005

647	NDA/MAL/HDP/3450	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	TRAMADEX 50	TRAMADOL	50MG	N/A	DELORBIS PHARMACEUTICALS LTD17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2009
648	NDA/MAL/HDP/3456	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES -	WIDE SPECTRUM ENTERPRISES (U) LIMITED	PREGAVALEX 150MG	PREGABALIN	150MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS FOR INTERNAL USE TABLETS (COATED AND UNCOATED) HARD GELATIN CAPSULES ORAL POWDER FOR SUSPENSION OINTMENTS, CREAMS AND GELS	NOT RETAINED	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2013

649	NDA/MAL/HDP/3459	AMOUN PHARMACEUTICALS COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ENEMAX	HYPERTONIC SOLUTION OF SODIUM PHOSPHATES	6GM AND 16GM/100 ML	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY CAIRO EGYPT	N/A	GMP EXPIRED ON THE 29/9/2023 FOR NON-BETA LACTAM: HARD GELATIN CAPSULES SOFT GELATIN CAPSULES TABLETS (COATED & UNCOATED) DRY POWDERS FOR SUSPENSION POWDERS PACKED IN SACHETS SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED LIQUIDS) SMALL VOLUME PARENTERAL – (ASEPTICALLY PREPARED POWDERS) EYE DROPS (ASEPTICALLY PREPARED) ORAL LIQUIDS NON-STERILE NASAL DROPS EXTERNAL SEMI-SOLIDS (CREAMS & GELS)	NOT RETAINED	EGYPT	RECTAL SYSTEMIC ENEMA LIQUIDS	1.0X120.0 ML BOTTLE	01/07/1997

650	NDA/MAL/HDP/3461	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ZIDOVUDINE	ZIDOVUDINE	300MG	N/A	MYLAN LABORATORIES LTD .F/4 & F/12, MALEGAON MIDC, SINNAR, NASHIK-422 113, MAHARASHTRA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2008
651	NDA/MAL/HDP/3473	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TRIXONE	CEFTRIAXONE	1G	REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	P.R & INJECT CARE PARENTERALS PVT LTD-PLOT 130, SILVASSA ROAD,G.I.D.C,VAPI-396195,GUJARAT,INDIA ZEISS PHARMA LIMITED-IGC,SIDCO, PHASE II, SAMBA, JAMMU - 184121,(J&K)	FACILITY ADDRESS OF REYOUNG CHANGED TO NO.1. APPLICANT REQUIRED TO APPLY FOR A VARIATION;	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL,1.0X10.0X1.0 G VIAL	01/07/2016
652	NDA/MAL/HDP/3480	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	HYOSPAN	HYOSCINE BUTYL BROMIDE	10MG	N/A	CIPLA LTD MIDC PATALGANGA MS 410 220 INDIA MFG LIC: 845	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2009

653	NDA/MAL/HDP/3482	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCLOX-250	CLOXACILLIN	250MG	N/A	MILAN LABORATORIES (INDIA) PVT LTDPLOT NOS 63, 67 & 87, JAWAHAR CO-OP. INDUSTRIAL ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2011
654	NDA/MAL/HDP/3495	BELL SONS & CO.(DRUGGISTS) LTD	ECHO PHARMACY (U) LIMITED	MENTHODEX COUGH MIXTURE	MULTIINGREDIENT	N/A	BELL SONS & CO (DRUGGISTS) LTD-SLAIDBURN CRES CHESHIRE HOUSE/GORSEY LA	N/A	GMP EXPIRED ON THE 8/11/2020 FOR POWDERS FOR ORAL SUSPENSION CREAMS/OINTMENTS/LOTIONS ORAL LIQUIDS; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	UNITED KINGDOM	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE	01/07/2001
655	NDA/MAL/HDP/3500	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	GIZLAN 300	IRBESARTAN	300MG	N/A	DAR AI DAWANA UR PLANT,AMMAN,JORDAN	N/A	NOT RETAINED	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014

656	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	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	NOT RETAINED	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X100.0 MG VIAL + 1*2ML AMPOULE OF WFI	01/07/2010

657	NDA/MAL/HDP/3519	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	TENOFOVIR DISOPROXIL FUMARATE	TENOFOVIR DISOPROXIL FUMARATE	300MG	STRIDES ARCOLAB LIMITED - 36/7 SURAGAJAKKANA HALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106	N/A	FACILITY NAME CHANGED TO STRIDES PHARMA SCIENCE LIMITED; APPLICANT REQUIRED TO APPLY FOR VARIATION FOR CHANGE OF NAME	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2010
658	NDA/MAL/HDP/3526	CYANO PHARMA(P)	RENE PHARMACY LTD	PROMETHAZINE TABLETS	PROMETHAZINE HYDROCHLORIDE	25MG	N/A	CYANO PHARMA(P)115-C IND ESTATE POLO GROUND INDORE	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER	01/07/2001
659	NDA/MAL/HDP/3528	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	LONART-DISPERSABLE	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	N/A	BLISS GVS PHARMA LIMITEDNO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X6.0 TABLET BLISTER,1.0X2.0X6.0 TABLET BLISTER	01/07/2013

660	NDA/MAL/HDP/3533	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	LEVOZIN	LEVOCETIRIZINE	5MG	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR-401506, DIST.THANE, MARAHASHTRA, INDIA	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	MAXHEAL FAILED GMP ON THE 14/5/2019 FOR NON BETA-LACTAM: TABLETS (COATED AND UNCOATED), EXTERNAL PREPARATIONS (CREAMS AND OINTMENTS), HARD GELATIN CAPSULES, DRY POWDER FOR ORAL SUSPENSION, ORAL LIQUIDS	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008
661	NDA/MAL/HDP/3538	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	APLEV	LEVOCETIRIZINE DIHYDROCHLORIDE	5	N/A	AJANTA PHARMA LTD31-0, M.I.D.C. CHIKALTHANA, CHIKALTHANA, AURANGABAD, MAHARASHTRA STATE, INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2008

662	NDA/MAL/HDP/3540	EAGLEVET UGANDA LIMITED	MEDVIN PHARMA LIMITED	CLOPACT-75	CLOPIDOGREL	75 MG	IPCA LABORATORIESLIMITED-IPCA LABORATORIES LTD P.O SEJANTA DISTRICT RATLAM 457002 INDIA	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: TABLETS ORAL LIQUIDS SVP LIQUIDS IN VIALS AND AMPOULES (ASEPTIC FILLING AND TERMINALLY STERILIZED)	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008
663	NDA/MAL/HDP/3568	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	MYCOSPOR CREAM	BIFONAZOLE	1%W/W	BAYER PHARMA AG - 51368 LEVERKU	N/A	FACILITY NOT APPROVED FOR THIS LINE	NOT RETAINED	GERMANY	TOPICAL EXTERNAL CREAMS	1.0X50.0 G TUBE,1.0X15.0 G TUBE	01/07/1997
664	NDA/MAL/HDP/3569	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CARBADAC-200	CARBAMAZEPINE	200MG	CADILA HEALTH CARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAI	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997

665	NDA/MAL/HDP/3577	ASTRA PHARMA (U) LTD	ASTRA PHARMA (U) LIMITED	METOCLOPRAMIDE	METOCLOPRAMIDE	5MG/ML	ZHEJIANG RUIXIN PHARMACEUTICAL CO. LTD-KAIFA ROAD, LISHUI, ZHEJIANG P.R OF CHINA	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	FAILED GMP ON THE 12/08/2019 FOR NON-BETA LACTAM: TABLET, CAPSULES, SMALL VOLUME LIQUIDS. HORMONES: SMALL VOLUME LIQUIDS. BETA LACTAM (CEPHALOSPORIN): TABLETS	RETAINED	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE,1.0X10.0X10.0X2.0 ML AMPOULE	01/07/2009
666	NDA/MAL/HDP/3578	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CINNARON 25	CINNARIZINE	25MG	N/A	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2005
667	NDA/MAL/HDP/3582	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	SULPHADIMIDINE	SULPHADIMIDINE	500MG	N/A	RENE INDUSTRIES LTD680,KAMULI,KIREKA KAMPALA,UGANDA	N/A	NOT RETAINED	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2009
668	NDA/MAL/HDP/3590	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	ALFOXAN 500 FC TABLETS	MEFENAMIC ACID	500MG	N/A	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2004

669	NDA/MAL/HDP/3593	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DROX 500	CEFADROXIL	500MG	N/A	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	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER,1.0X 10.0X10.0 CAPSULE BLISTER	01/07/2007
670	NDA/MAL/HDP/3597	DAFRA PHARMA LTD	MULTIPHAR UGANDA LIMITED	ARTESIANE 20 PAEDIATRIC	ARTEMETHER	20MG/ML	N/A	ANFARM HELLAS S.A.61ST KM. NATIONAL ROAD, ATHENS-LAMIA, 320 09 SCHIMATARI VIOTIAS - GREECE	N/A	NOT RETAINED	GREECE	PARENTERAL ORDINARY I M AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2001

671	NDA/MAL/ HDP/3603	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	VUMTREX SYRUP	LEVAMISOLE	40MG/5ML	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	NOT RETAINED	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X30.0 ML BOTTLE	01/07/2003

672	NDA/MAL/HDP/3604	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	AC-FENAC	ACECLOFENAC	100MG	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR-401506, DIST.THANE, MARAHASHTRA, INDIA	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	MAXHEAL FAILED GMP ON THE 14/5/2019 FOR NON BETA-LACTAM: TABLETS (COATED AND UNCOATED), EXTERNAL PREPARATIONS (CREAMS AND OINTMENTS), HARD GELATIN CAPSULES, DRY POWDER FOR ORAL SUSPENSION, ORAL LIQUIDS	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008

673	NDA/MAL/HDP/3605	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	STOMACID	CPD MAGNESIUM TRISILICATE	MULTIINGRIDIENT	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	NOT RETAINED	KENYA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X25.0X4.0 TABLET BLISTER	01/07/1997
674	NDA/MAL/HDP/3608	SHAIGAN PHARMACEUTICALS (PVT) LTD	HARLEYS UGANDA LIMITED	MESAN	NICLOSAMIDE	500MG	N/A	SHAIGAN PHARMACEUTICALS (PVT) LIMITED14 KM ADYALA RD, RAWALPINDI, PAKISTAN	N/A	NOT RETAINED	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	01/07/1997

675	NDA/MAL/HDP/3609	AMOUN PHARMACEUTICALS COMPANY	BOOTS PHARMACEUTICALS LIMITED	ANTINAL	NIFUROXAZIDE	200MG	AMOUN PHARMACEUTICALS COMPANY1ST INDUSTRIAL ZONE EL OBOUR CITY CAIRO EGYPT	N/A	GMP EXPIRED ON THE 29/9/2023 FOR NON-BETA LACTAM: HARD GELATIN CAPSULES SOFT GELATIN CAPSULES TABLETS (COATED & UNCOATED) DRY POWDERS FOR SUSPENSION POWDERS PACKED IN SACHETS SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED LIQUIDS) SMALL VOLUME PARENTERAL – (ASEPTICALLY PREPARED POWDERS) EYE DROPS (ASEPTICALLY PREPARED) ORAL LIQUIDS NON-STERILE NASAL DROPS EXTERNAL SEMI-SOLIDS (CREAMS & GELS)	NOT RETAINED	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X12.0 CAPSULE BLISTER,1.0X12.0 CAPSULE BLISTER	01/07/1997

676	NDA/MAL/HDP/3611	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	COLDRIL SYRUP	PARACETAMOL + CHLORPHENIRAMINE + PSEUDOEPHEDRINE	120MG+1MG+10MG	SHELYS PHARMACEUTICALS LTD,-NEW BAGAMOYO ROAD, MWENGE, PLOT NO 696,BLOCK NO 32, P.O.BOX 3016, DAR ES SALAAM	BETA HEALTHCARE INTERNATIONAL LIMITED-PLOT NUMBER LR 209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA ROAD INDUSTRIAL AREA, P.O.BOX 42569-00100 NAIROBI,KENYA	GMP EXPIRED ON THE 28/11/2019 FOR • TABLETS • HARD GELATIN CAPSULES. • ORAL LIQUIDS. • DRY POWDER FOR ORAL SUSPENSION • ORS • CREAMS AND OINTMENTS.	RETAINED	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2000
677	NDA/MAL/HDP/3620	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	HALOXEN 10 TABLETS	HALOPERIDOL BP	10MG	N/A	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER	01/07/2004
678	NDA/MAL/HDP/3645	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	NEUROBEX	THIAMINE + RIBOFLAVIN + PYRIDOXINE + CYANOCOBALAMIN+ FOLIC ACID	250MG + 15MG + 200MG + 250MG + 500MCG	N/A	TRIVENI FORMULATIONS LTD .PLOT NO. 52, 53,54 ALEAP INDUSTRIAL ESTATE SURAMPALLI VILLAGE GANNAVARAM MANDAL KRISHNA (DT) A.P	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2014

679	NDA/MAL/HDP/3650	AMOUN PHARMACEUTICALS COMPANY	BOOTS PHARMACEUTICALS LIMITED	ANTINAL	NIFUROXAZIDE	220MG/5ML	AMOUN PHARMACEUTICALS COMPANY1ST INDUSTRIAL ZONE EL OBOUR CITY, CAIRO EGYPT	N/A	GMP EXPIRED ON THE 29/9/2023 FOR NON-BETA LACTAM: HARD GELATIN CAPSULES SOFT GELATIN CAPSULES TABLETS (COATED & UNCOATED) DRY POWDERS FOR SUSPENSION POWDERS PACKED IN SACHETS SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED LIQUIDS) SMALL VOLUME PARENTERAL – (ASEPTICALLY PREPARED POWDERS) EYE DROPS (ASEPTICALLY PREPARED) ORAL LIQUIDS NON-STERILE NASAL DROPS EXTERNAL SEMI-SOLIDS (CREAMS & GELS)	NOT RETAINED	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2011

680	NDA/MAL/HDP/3656	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	LUMERAX	ARTEMETHER / LUMEFANTRINE	80MG/480 MG	IPCA LABORATORIES LTD,- SEJAVTA, RATLAM 457-002 REG.OFF. 48 KANDIVLI IND.ESTATE MUMBAI 400067	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: TABLETS ORAL LIQUIDS SVP LIQUIDS IN VIALS AND AMPOULES (ASEPTIC FILLING AND TERMINALLY STERILIZED)	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X6.0 TABLET BLISTER	01/07/2011
681	NDA/MAL/HDP/3663	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	AMLODAC 10	AMLODIPINE BESYLATE	10MG	CADILA HEALTHCARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO.203-213, KUNDAI	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET STRIP,1.0X3.0X10.0 TABLET BLISTER	01/07/2003

682	NDA/MAL/HDP/3673	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	PROMETHAZINE INJECTABLE SOLUTION	PROMETHAZINE HCL	25MG/ML	ZHEJIANG RUIXIN PHARMACEUTICAL CO. LTD-KAIFA ROAD, LISHUI, ZHEJIANG P.R OF CHINA	WUHAN FUXING BIOPHARMACEUTICAL CO., LTD-NO.9, FUXING ROAD, HANCUAN ECONOMIC & DEVELOPMENT DISTRICT, HUBEI PROVINCE	FAILED GMP ON THE 12/08/2019 FOR NON-BETA LACTAM: TABLET, CAPSULES, SMALL VOLUME LIQUIDS. HORMONES: SMALL VOLUME LIQUIDS. BETA LACTAM (CEPHALOSPORIN): TABLETS	RETAINED	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE,1.0X10.0X2.0 ML AMPOULE	01/07/2010
683	NDA/MAL/HDP/3684	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	I-PILL	LEVONORGESTREL	1.5MG	N/A	CIPLA LTD.- PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X1.0 TABLET BLISTER	01/07/2009
684	NDA/MAL/HDP/3690	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	INTUSSED SYRUP	DEXTROMETHORPHAN HBR BP +EPHEDRINE HCL BP 8MG+PROMETHAZINE HCL BP	8MG+8MG+4MG, PER 5ML.	N/A	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/1997

685	NDA/MAL/HDP/3693	JASSEN-CILAG (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	IMODIUM	LOPERAMIDE HCL	2MG	SPECPHARM HOLDINGS- 15TH ROAD HALFWAY HOUSE	N/A	FACILITY NOT APPROVED FOR THE MANUFACTURE OF THIS PRODUCT LINE; APPLICATION FOR RE-INSPECTION DOES NOT INCLUDE THE PRODUCT LINE	NOT RETAINED	SOUTH AFRICA	ORAL SOLID ORDINARY CAPSULES	1.0X6.0 CAPSULE BLISTER	01/07/1997
686	NDA/MAL/HDP/3694	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	LORIDIN RAPITAB	LORATADINE	10MG	CADILAN HEALTH CARE LTD ,,;KUNDAIN INDUSTRIAL ESTATE PONDA GOA	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2002
687	NDA/MAL/HDP/3697	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	APRAZOLE-20	OMEPRAZOLE	20 MG	N/A	AJANTA PHARMA LTD .B-4//5/6, MIDC INDUSTRIALAREA, PAITHAN-431 128, AURANGBAD	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE STRIP,1.0X10.0X10.0 CAPSULE STRIP	01/07/2005

688	NDA/MAL/HDP/3699	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SINOPRIL 5MG TABLETS	LISINOPRIL	5MG	GLOBAL NAPI PHARMACEUTICALS -2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	N/A	GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES	RETAINED	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2005
689	NDA/MAL/HDP/3704	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	PENEGRA 100	SILDENAFIL	100MG	CADILA HEALTHCARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO.203-213, KUNDAI	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER,1.0X20.0X4.0 TABLET BLISTER	01/07/2002

690	NDA/MAL/HDP/3705	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SORAL 20MG CAPSULES	TENOXICAM	20MG	GLOBAL NAPI PHARMACEUTICALS -2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	N/A	GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES	RETAINED	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER,1.0X2.0X10.0 CAPSULE BLISTER	01/07/2005
691	NDA/MAL/HDP/3739	CADILA HEALTH CARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ALDREN	ALENDRONATE	70MG	CADILA HEALTHCARE LIMITED KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	, 1X4 TABLET Blister	01/07/2011
692	NDA/MAL/HDP/3743	CADILA HEALTH CARE LTD	ABACUS PHARMA (AFRICA) LIMITED	CARVIL 3.125	CARVEDILOL	3.125 MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2006

693	NDA/MAL/HDP/3752	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PAINOTAB	PARACETAMOL + CAFFEINE	650MG + 30MG	N/A	COSMOS LIMITED-RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 41433, NAIORBI INDUSTRIAL AREA	N/A	NOT RETAINED	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2003
694	NDA/MAL/HDP/3763	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	NORVASC	AMLODIPINE	5MG	R-PHARM GERMANY GMBH - HEINRICH-MACH-STRASSE 35,89257,ILLERTISSEN,GERMANY	R-PHARM GERMANY GMBH HEINRICH-MACH-STRASSE 35,89257,ILLERTISSEN,GERMANY PFIZER PHARMACEUTICAL LLC ROAD 689 KM 1.9 VEGA BAJA PUERTO RICO 00693	GMP EXPIRED ON THE 25/8/2018	NOT RETAINED	USA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/1997

695	NDA/MAL/HDP/3765	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	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	RETAINED	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER	01/07/1997
696	NDA/MAL/HDP/3766	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	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	RETAINED	KENYA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997

697	NDA/MAL/HDP/3770	AMOUN PHARMACEUTICALS COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	XITHRONE	AZITHROMYCIN	500 MG	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY, CAIRO EGYPT	N/A	GMP EXPIRED ON THE 29/9/2023 FOR NON-BETA LACTAM: HARD GELATIN CAPSULES SOFT GELATIN CAPSULES TABLETS (COATED & UNCOATED) DRY POWDERS FOR SUSPENSION POWDERS PACKED IN SACHETS SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED LIQUIDS) SMALL VOLUME PARENTERAL – (ASEPTICALLY PREPARED POWDERS) EYE DROPS (ASEPTICALLY PREPARED) ORAL LIQUIDS NON-STERILE NASAL DROPS EXTERNAL SEMI-SOLIDS (CREAMS & GELS)	RETAINED	EGYPT	ORAL SOLID ORDINARY COATED TABLETS	1.0X1.0X5.0 TABLET BLISTER	01/07/2005

698	NDA/MAL/ HDP/3777	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	AMPOXIN 500	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	N/A	UNICHEM LABORATORIES LIMITED UNIT IIVILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL	01/07/1999

699	NDA/MAL/HDP/3778	AMOUN PHARMACEUTICALS COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	XITHRONE	AZITHROMYCIN	200MG/5ML	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY, CAIRO EGYPT	N/A	GMP EXPIRED ON THE 29/9/2023 FOR NON-BETA LACTAM: HARD GELATIN CAPSULES SOFT GELATIN CAPSULES TABLETS (COATED & UNCOATED) DRY POWDERS FOR SUSPENSION POWDERS PACKED IN SACHETS SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED LIQUIDS) SMALL VOLUME PARENTERAL – (ASEPTICALLY PREPARED POWDERS) EYE DROPS (ASEPTICALLY PREPARED) ORAL LIQUIDS NON-STERILE NASAL DROPS EXTERNAL SEMI-SOLIDS (CREAMS & GELS)	RETAINED	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X15.0 ML BOTTLE	01/07/2004

700	NDA/MAL/HDP/3781	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ALZENTAL	ALBENDAZOLE	20MG/ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X20.0 ML BOTTLE	01/07/2014

701	NDA/MAL/HDP/3797	ELDA INTERNATIONAL DMCC	REDDYS PHARMA LIMITED	PROVIVE 1%	PROPOFOL	10MG/ML	BAXTER PHARMACEUTICALS INDIA PRIVATE LIMITEDCHACHARWADI - VASANA, AHMEDABAD, IN 382213	N/A	GMP EXPIRED ON 14/12/2023 FOR Non-Beta Lactam: Small Volume Parenterals (vials and ampoules) Small Volume Parenterals (emulsions and aqueous solutions in glass bottles)	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X50.0 ML VIAL,1.0X20.0 ML VIAL	01/07/2002

702	NDA/MAL/HDP/3798	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEUROTON TABLET	MULTI-INGREDIENT	N/A	AMOUN PHARMACETICAL COMPANY-1ST INDUSTRIAL ZONE, EL OBOUR CITY, CAIRO, EGYPT	N/A	GMP EXPIRED ON THE 29/9/2023 FOR NON-BETA LACTAM: HARD GELATIN CAPSULES SOFT GELATIN CAPSULES TABLETS (COATED & UNCOATED) DRY POWDERS FOR SUSPENSION POWDERS PACKED IN SACHETS SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED LIQUIDS) SMALL VOLUME PARENTERAL – (ASEPTICALLY PREPARED POWDERS) EYE DROPS (ASEPTICALLY PREPARED) ORAL LIQUIDS NON-STERILE NASAL DROPS EXTERNAL SEMI-SOLIDS (CREAMS & GELS)	RETAINED	EGYPT	ORAL SOLID ORDINARY COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2004

703	NDA/MAL/HDP/3801	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	FUNGISTIN ORAL SUSPENSION	NYSTATIN	100000 IU/ML	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	RETAINED	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2002
704	NDA/MAL/HDP/3807	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	ARTEMETHER INJECTION	ARTEMETHER	80MG/ML	NINGBO DAHONGYING PHARMACEUTICAL SN0.396 MINZHU RD NINGBO CITY ZHEJIANG, CHINA	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: TABLETS, CAPSULES, SVP LIQUIDS	RETAINED	CHINA INDIA	PARENTERAL ORDINARY IM AMPOULES	1.0X6.0X1.0 ML AMPOULE	01/07/2008

705	NDA/MAL/HDP/3808	NORVATIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN SUPPOSITORIES 12.5MG	DICLOFENAC SODIUM	12.5MG	DELPHARM HUNINGUE S.A.S-SITE INDUSTRIAL HUNINGUE26, RUE DE LA CHAPELLE, F-68330, HUNING	N/A	GMP EXPIRED ON 19/10/2023 FOR NON-BETA LACTAM: SUPPOSITORIES, LIQUIDS FOR EXTERNAL USE, LIQUIDS FOR INTERNAL USE, SEMI SOLIDS	RETAINED	FRANCE	RECTAL SYSTEMIC PAEDIATRIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY STRIP	01/07/2006
706	NDA/MAL/HDP/3818	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	REPOITIN	RECOMBINANT HUMAN ERYTHROPOIETIN	2000 I.U/0.5ML	N/A	SERUM INSTITUTE OF INDIA LTD212/2 HADAPSAR, PUNE, 411028, INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X0.5 ML VIAL,1.0X0.5 ML PRE-FILLED SYRINGE	01/07/2012
707	NDA/MAL/HDP/3823	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	D-WORM ORAL SUSPENSION	ALBENDAZOLE	200MG/5ML	N/A	TORQUE PHARMACEUTICALS LTDISSAPUR P.O DAPPAR 140506	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	01/07/2009
708	NDA/MAL/HDP/3844	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN RETARD	DICLOFENAC SODIUM	100MG	NORVATIS FARMA SPA--VIA PROVINCIALE SCHITO, 131 1-80052	NOVARTIS PHARMA STEIN AG-SCHAFFHARVSERTRASSE CH-4332 STEIN SWITZERLAND.	GMP EXPIRED ON THE 30/7/2023 FOR NBL TABLETS	RETAINED	SWITZERL AND ITALY	ORAL SOLID RETARD TABLETS	1.0X30.0 TABLET CONTAINER	01/07/1997

709	NDA/MAL/HDP/3847	ROYAL PHARMA	ROYAL PHARMA 2011 LIMITED	FORTIFIED PROCAINE PENICILLIN	FORTIFIED PROCAINE PENICILLIN	4 MEGA UNIT	SHIJIAZHUANG PHARMA GROUP-ZHOUGNUO, PHARMACEUTICAL	N/A	GMP EXPIRED, APPLICANT REQUIRED TO APPLY FOR VARIATION TO UPDATE MANUFACTURER DETAILS TO CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) COMPANY LIMITED-NO. 88 YANGZI ROAD, ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, SHIJIAZHUANG, HEBEI, PEOPLE'S REPUBLIC OF CHINA, WORKSHOP 406 AND 407	RETAINED	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0 VIAL CARTON,1.0X10.0 VIAL CARTON	
710	NDA/MAL/HDP/3853	MISSION PHARMA A/S	JOINT MEDICAL STORE (UPMB - UCMB)	ZINC SULPHATE TABLET USP	ZINC SULPHATE	20MG	N/A	MEDICAMEN BIOTECH LTDSP-1192, A &B, PHASE –IV, INDUSTRIAL AREA BHIWADI -301019 DIST. ALWAR (RAJASTHAN)	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009

711	NDA/MAL/HDP/3872	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	ZYNCET SYRUP	CETIRIZINE HYDROCHLORIDE	5MG/5ML	UNICHEM LABORATORIES LTD---C31 & 32 INDUSTRIAL AREA	THE MADRAS PHARMACEUTICALS-137-B OLD MAHABALIPURAM ROAD KARAPAKKAM CHENNAI 600 096	FACILITY NOT APPROVED FOR THE MANUFACTURE OF THIS PRODUCT LINE	RETAINED	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE	01/07/2006
712	NDA/MAL/HDP/3879	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	METRIM SUSPENSION	CO-TRIMOXAZOLE	240MG/5ML	N/A	MEDIPHARM INDUSTRIES(EA) LTDPLOT 65 KAKAJJO ROAD BWEYOGERERE P.O.BOX 6218,KAMPALA,UGANDA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/1997
713	NDA/MAL/HDP/3882	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	PEDIVIT FORTE CAPSULES	MULTIINGREDIENT	N/A	J.B. CHEMICALS AND PHARMACEUTICALS LTD-J.B. CHEMICALS & PHARMACEUTICALS LTD, 215/216, GIDC, PANOLI	N/A	FACILITY HAS NOT BEEN INSPECTED FOR THE CAPSULE LINE	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	3.0X7.0 CAPSULE BLISTER,1.0X3.0X10.0 CAPSULE BLISTER	01/07/1997
714	NDA/MAL/HDP/3887	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	LYRICA 150MG	PREGABALIN	150 MG	N/A	PFIZER GMBH ARZEIMITELWORK MOSWALDA 1144 79090 FREUBURG	N/A	NOT RETAINED	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER	01/07/2007
715	NDA/MAL/HDP/3889	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	LYRICA 75MG	PREGABALIN	75 MG	N/A	PFIZER GMBH ARZEIMITELWORK MOSWALDA 1144 79090 FREUBURG	N/A	NOT RETAINED	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER	01/07/2007

716	NDA/MAL/HDP/3893	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	EPINEPHRINE INJECTION USP	EPINEPHRINE HCL	1MG/ML	NINGBO DAHONGYING PHARMACEUTICAL CO LTDNO 396, MINGZHU ROAD NINGBO CITY CHINA	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: TABLETS, CAPSULES, SVP LIQUIDS	RETAINED	CHINA INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2008
717	NDA/MAL/HDP/3901	BAYER SCHERING PHARMA FRANCE	SURGIPHARM (U) LIMITED	MICROGYNON ED FE	LEVONORGESTREL + ETHINYLESTRADIOL	0.15MG + 0.03MG	N/A	BAYER WEIMER GMBH DOBEREINERSTRASSE 20, D-99427 WEIMER 2.BAYER PHARMA AG 13342, BERLIN BAYER PHARMA AG 51368 LEVERKUSEN GERMANY	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	FRANCE	ORAL SOLID ORDINARY TABLETS	1.0X3.0X28.0 TABLET BLISTER	01/07/2011
718	NDA/MAL/HDP/3902	CADILA PHARMACEUTICALS LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	NODON	NEBIVOLOL	5MG	N/A	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X1.0X10.0 TABLET BLISTER	01/07/2011

719	NDA/MAL/HDP/3903	VIIV HEALTHCARE UK LTD-	UNITED HEALTHCARE DISTRIBUTORS LTD	CELSENTRI 300MG	MARAVIROC	300MG	GODECKE GMBH - MOOSWALDALLEE 179090, FREIBERG GERMANY	N/A	SITE NOT FOUND; EXISITING SITE IS PFIZER MANUFACTURING DEUTSCHLAND GMBH BETRIEBSSTATTE FREIBURG, MOOSWALDALLEE 1, D-79090 FREIBURG - GERMANY. CLIENT REQUIRED TO APPLY FOR VARIATION OF NAME OF FPP MANUFACTURER.	RETAINED	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0X6.0 TABLET BLISTER	01/07/2008
720	NDA/MAL/HDP/3916	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	METOCLOPRAMIDE HYDROCHLORIDE INJECTION	METOCLOPRAMIDE HYDROCHLORIDE	5MG/ML	KIVIPHARM CO. LTD-NO.5 HANGTIAN STREET DONGSHAN HIGH-TECH INDUSTRIAL DEVELOPMENT ZONE, SHALINGZI TOWN ZHANGJI	SCOTT-EDIL PHARMACIA LTD (UNIT I)-56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	GMP EXPIRED ON THE 25TH/09/2023 FOR NON BETA-LACTAM: SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED PACKED IN AMPOULES)	RETAINED	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE,1.0X10.0X10.0X2.0 ML AMPOULE	01/07/2016

721	NDA/MAL/HDP/3920	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	PHOTERICIN B	AMPHOTERICIN B	50MG	N/A	CIPLA LTDM-61, M-62 & M-63, VERNA INDUSTRIAL ESTATE VERNA GOA,INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0 MG VIAL	01/07/2011
722	NDA/MAL/HDP/3925	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CALCIUM GLUCONATE INJECTION	CALCIUM GLUCONATE	10 %W/V	NINGBO DAHONGYING PHARMACEUTICAL SN0.396 MINZHU RD NINGBO CITY ZHEJIANG, CHINA	N/A	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: TABLETS, CAPSULES, SVP LIQUIDS; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X50.0X10.0 ML AMPOULE	01/07/2009
723	NDA/MAL/HDP/3926	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	MIFUPEN TABLETS	ACETYLSALICYLIC ACID + CAFFEINE	350MG + 30MG	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	NOT RETAINED	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET STRIP	01/07/1997

724	NDA/MAL/HDP/3927	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL CEPHALEXIN 125	CEPHALEXIN MONOHYDRATE	125MG/5ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	N/A	GMP EXPIRED ON THE 28/9/2023 FOR NON-BETA LACTAM: TABLETS COATED & UNCOATED HARD GELATIN CAPSULES ORAL LIQUIDS SVP LIQUIDS AND POWDER STERILE GELS , (BETA LACTAM) CEPHALOSPORIN: HARD GELATIN CAPSULES DRY POWDER FOR ORAL SUSPENSION SVP POWDER , CORTICOSTEROIDS: OINTMENTS AND CREAMS	RETAINED	MALAYSIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X60.0 ML BOTTLE,1.0X 100.0 ML BOTTLE	01/07/2008

725	NDA/MAL/ HDP/3931	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 MAHALLESI IHLA VADISI SOKAK, NO 2	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS	RETAINED	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER	01/07/2014

726	NDA/MAL/HDP/3932	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIRAX TABLETS	CLIDINIUM BROMIDE + CHLORDIAZEPOXIDE	2.5MG + 5MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2008

727	NDA/MAL/HDP/3948	: ALKEM LABORATORIES LIMITEDv	ABACUS PHARMA (AFRICA) LIMITED	TAXIM-O	CEFIXIME	50MG/5ML	EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMA CITY SELAQUI DEHRADUN – 248011	ALKEM LABORATORIES LIMITED.-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205	FACILITY NOT APPROVED TO MANUFACTURE CEPHALOSPORIN ORAL POWDERS	RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2009
728	NDA/MAL/HDP/3950	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICALS LIMITED	STROM	TRAMADOL HYDROCHLORIDE	50MG/ML	LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR	LINCOLN PARENTERAL LTD11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: SMALL VOLUME PARENTERAL SOLUTIONS SMALL VOLUME PARENTERAL POWDERS ORAL LIQUIDS	RETAINED	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2014

729	NDA/MAL/HDP/3960	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	IBUPAR	PARACETAMOL/IBUPROFEN	325/400MG	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR-401506, DIST.THANE, MARAHASHTRA, INDIA	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	MAXHEAL FAILED GMP ON THE 14/5/2019 FOR NON BETA-LACTAM: TABLETS (COATED AND UNCOATED), EXTERNAL PREPARATIONS (CREAMS AND OINTMENTS), HARD GELATIN CAPSULES, DRY POWDER FOR ORAL SUSPENSION, ORAL LIQUIDS	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER	01/07/2008

730	NDA/MAL/ HDP/3969	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FAWAR FRUIT EFFERVESCENT GRANULES	SODIUM CARBONATE + TARTARIC ACID + CITRIC ACID	2.8G + 1.33G + 0.82G	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	N/A	GMP EXPIRED ON 28/9/2023 FOR BETA LACTAM (PENICILLIN): ORAL DRY POWDERS FOR SUSPENSION HARD GELATIN CAPSULES TABLETS SVP POWDERS (VIALS), NON-BETA LACTAM: ORAL DRY POWDERS (HUMAN & VETERINARY) HARD GELATIN CAPSULES TABLETS ORAL LIQUIDS ORAL POWDERS IN SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED) CREAMS, OINTMENTS, GELS, SUPPOSITORIES, PESSARIES & OVULES	RETAINED	EGYPT	ORAL LIQUID ORDINARY EFFERVESCENT POWDERS/GRANULES	1.0X6.5 G SACHET	01/07/2002

731	NDA/MAL/HDP/3973	IPCA LABORATORIES LIMITED	MEDVIN PHARMA LIMITED	LARITHER	ARTEMETHER	80MG/ML	IPCA LABORATORIES LTD,-SEJAVTA, RATLAM 457-002 REG.OFF. 48 KANDIVLI IND.ESTATE MUMBAI 400067	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: TABLETS ORAL LIQUIDS SVP LIQUIDS IN VIALS AND AMPOULES (ASEPTIC FILLING AND TERMINALLY STERILIZED)	NOT RETAINED	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE,1.0X8.0X1.0 ML AMPOULE	01/07/1999
732	NDA/MAL/HDP/3983	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	EXTRADOL	PARACETAMOL/CAFFEINE TABLETS	500MG/65 MG	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR-401506, DIST.THANE, MARAHASHTRA, INDIA	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	MAXHEAL FAILED GMP ON THE 14/5/2019 FOR NON BETA-LACTAM: TABLETS (COATED AND UNCOATED), EXTERNAL PREPARATIONS (CREAMS AND OINTMENTS), HARD GELATIN CAPSULES, DRY POWDER FOR ORAL SUSPENSION, ORAL LIQUIDS	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X50.0X2.0 TABLET BLISTER	01/07/2008

733	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,ELOBOUR CITY, CAIRO, EGYPT	N/A	GMP EXPIRED ON THE 29/9/2023 FOR NON-BETA LACTAM: HARD GELATIN CAPSULES SOFT GELATIN CAPSULES TABLETS (COATED & UNCOATED) DRY POWDERS FOR SUSPENSION POWDERS PACKED IN SACHETS SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED LIQUIDS) SMALL VOLUME PARENTERAL – (ASEPTICALLY PREPARED POWDERS) EYE DROPS (ASEPTICALLY PREPARED) ORAL LIQUIDS NON-STERILE NASAL DROPS EXTERNAL SEMI-SOLIDS (CREAMS & GELS)	RETAINED	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X125.0 ML BOTTLE	01/07/2008

734	NDA/MAL/HDP/4019	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	N/A	GMP EXPIRED ON THE 28/09/2023 FOR NON-BETA LACTAM: ORAL VETERINARY POWDERS TABLETS POWDERS FOR ORAL SUSPENSION HARD GELATIN CAPSULES ORAL LIQUIDS OINTMENTS, CREAMS & GELS SUPPOSITORIES STERILE LIQUIDS IN AMPOULES POWDER SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED IN PLASTIC AMPOULE) SMALL VOLUME LYOPHILIZED POWDER (ASEPTICALLY PREPARED) SOFT GELATIN CAPSULES , BIOLOGICALS (SVP): RECOMBINANT INSULIN	RETAINED	EGYPT	PARENTERAL ORDINARY VIALS	1.0X1.0 G VIAL	01/07/2007

735	NDA/MAL/HDP/4021	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	AZY-500	AZITHROMYCIN	500MG	N/A	ASTRA LIFE CARE (INDIA) PVT.LTDPLOT NO. 57/P, SARKHEJ-BAVLA HIGHWAY, POST RAJODA-382220, TALUKA BAVLA, AHMEDABAD INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER	01/07/2011

736	NDA/MAL/HDP/4024	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	N/A	GMP EXPIRED ON THE 28/09/2023 FOR NON-BETA LACTAM: ORAL VETERINARY POWDERS TABLETS POWDERS FOR ORAL SUSPENSION HARD GELATIN CAPSULES ORAL LIQUIDS OINTMENTS, CREAMS & GELS SUPPOSITORIES STERILE LIQUIDS IN AMPOULES POWDER SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED IN PLASTIC AMPOULE) SMALL VOLUME LYOPHILIZED POWDER (ASEPTICALLY PREPARED) SOFT GELATIN CAPSULES , BIOLOGICALS (SVP): RECOMBINANT INSULIN	RETAINED	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2007

737	NDA/MAL/HDP/4036	JULPHAR GULF PHARMACEUTICAL INDUSTRIES	OMASI MED LIMITED	ACECLOFAR	ACECLOFENAC	100MG	N/A	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)AIRPORT ROAD, DIGDAGA, P.O.BOX: 997, RAS AL KHAIMAH, U.A.E.	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	UNITED ARAB EMIRATES	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2013
738	NDA/MAL/HDP/4049	CADILA HEALTH CARE LTD	ABACUS PHARMA (AFRICA) LIMITED	LEVODAY 500	LEVOFLOXACIN HEMIHYDRATE	500MG	CADILA HEALTH CARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM GOA-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X2.0X5.0 TABLET BLISTER,1.0X20.0X5.0 TABLET BLISTER,1.0X6.0X2.0X5.0 TABLET BLISTER	01/07/2004
739	NDA/MAL/HDP/4057	MICRO LABS	MALIX PHARMA (U) LIMITED	LAMPY	AMPICILLIN	250MG	N/A	LEBEN LABORATORIES PVT. LTDPLOT NO. L-4, PHASE-III, MIDC, AKOLA– 444 104 (MS).	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE BLISTER,1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0X10.0 CAPSULE BLISTER	01/07/2011

740	NDA/MAL/HDP/4060	NORVATIS PHARMA AG-SWITZERLAND	LABOREX UGANDA LIMITED	TOBRADEX	TOBRAMYCIN/DEXAMETHASONE	0.3%W/V+0.1%W/V	ALCON COUVREUR NVRIJKSWEG 14, B-2870 PUURS BELGIUM	N/A	GMP EXPIRED ON 08/12/2023 FOR Non-Beta Lactam: Semi-solids (Aseptically prepared) Small Volume Liquids (Aseptically prepared) Small Volume Liquids (Terminally Sterilized)	RETAINED	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/1997
741	NDA/MAL/HDP/4066	UNIVERSAL CORPORATION LTD	DELMAW ENTERPRISES LIMITED	UNIBROL	AMINOSIDINE	125MG/ML	N/A	UNIVERSAL CORPORATION LTDKIKUYU NAIROBI KENYA	N/A	NOT RETAINED	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE	01/07/2011
742	NDA/MAL/HDP/4067	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CATENOL-50 TABLETS	ATENOLOL	50MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/1997
743	NDA/MAL/HDP/4074	UMEDICA LABORATORIES PVT LTD	VITACARE LIMITED	UMICORT-100	HYDROCORTISONE SODIUM SUCCINATE	100MG	N/A	UMEDICA LABORATORIES PVT, VAPIPLOT 221, GIDC II, VAPI-396195, INDIA	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X100.0 MG VIAL	01/07/2001

744	NDA/MAL/ HDP/4085	GLAXO WELLCOME (KENYA) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZINACEF	CEFUROXIME SODIUM	750MG	GLAXO WELLCOME - VERONA ITALY	N/A	GMP EXPIRED ON THE 31/01/2022 FOR CEPHALOSPORIN: SMALL VOLUME PARENTERALS;	RETAINED	ITALY	PARENTERAL ORDINARY DRY VIALS	1.0X750.0 MG VIAL	01/07/1997

745	NDA/MAL/HDP/4092	PRISMA PHARMACEUTICALS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	FLORANORM	SACCHAROMYCES BOULARDII	250MG	BHARAT BIOTECH INTERNATIONAL LTD-TURKPALLY SHAMEX 500 078 MYDERAHAD INDIA	N/A	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: SMALL VOLUME PARENTERAL LIQUIDS PACKED IN AMPOULES, PREFILLED SYRINGES AND VIALS SMALL VOLUME PARENTERALS (LYOPHILIZED) PACKED IN VIALS TOPICAL OINTMENTS ORAL POWDERS PACKED IN SACHETS RECOMBINANT HEPATITIS-B VACCINE THIOMEROSAL FREE HEPATITIS-B VACCINE, COMVAC 3 (DIPHTHERIA, TETANUS AND PERTUSSIS VACCINE) COMVAC 4 (DIPHTHERIA, TETANUS, PERTUSSIS AND	RETAINED	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X2.0X250.0 MG SACHET,1.0X10.0X250.0 MG SACHET	01/07/2010

746	NDA/MAL/HDP/4094	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	EFAVIRENZ	EFAVIRENZ	200MG	N/A	STRIDES PHARMA SCIENCE LIMITED (STRIDES SHASUN)KRS GARDENS, PLOT 36/7 SURAGAJKKANAHALLI, INDLAWADI CROSS, ANKAL TALUK, BANGALORE SOUTH - 562106, INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X90.0 TABLET CONTAINER	01/07/2007
747	NDA/MAL/HDP/4098	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	EFAVIRENZ TABLETS	EFAVIRENZ	600MG	STRIDES SHASUN LTD-N0. 36/7, SURAGAJ AKKHAN AHALLI, INDLAVA DI CROSS, ANEKAL TALUK, BANGAL ORE	N/A	FACILITY NAME CHANGED TO STRIDES PHARMA SCIENCE LIMITED; APPLICANT REQUIRED TO APPLY FOR VARIATION FOR CHANGE OF NAME	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2007
748	NDA/MAL/HDP/4100	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	NORETHISTERONE	NORETHISTERONE	5MG	N/A	REMEDICA LIMITED AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2007

749	NDA/MAL/HDP/4107	ABBOTT HEALTHCARE, SAS	HARLEYS UGANDA LIMITED	DUSPATALIN 200 MG	MEBEVERINE	200MG	MYLAN LABORATORIES SASROUTE DE BELLEVILLE, LIEU DIT MAILLARD, 01400 CHATILLON-SUR-	N/A	GMP EXPIRED ON 08/12/2023 FOR Non-Beta Lactam: Hard Gelatin Capsules Tablets	RETAINED	FRANCE	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2008
750	NDA/MAL/HDP/4112	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED	ROYAL PHARMA 2011 LIMITED	ERYTHRONE TABLETS 250MG	ERYTHROMYCIN	250MG	N/A	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITEDPLOT 9-12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR-401404. INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2005
751	NDA/MAL/HDP/4119	MEDIPAK LIMITED	HEALTHCARE LTD.	MEDITIM	TIMOLOL MALEATE	0.5% W/V	N/A	MEDIPAK LIMITED132/1 INDUSTRIAL AREA KOTLAKHPAT LAHORE	N/A	NOT RETAINED	PAKISTAN	OPHTHALMIC LIQUIDS	1.0X5.0 ML VIAL	01/07/2007
752	NDA/MAL/HDP/4125	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	PARACETAMOL SUSPENSION	PARACETAMOL	120MG/5ML	N/A	MEDIPHARM INDUSTRIES (E.A) LTDPLOT 65, KAKAJJO ROAD, BWEYOGERERE	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/1997

753	NDA/MAL/HDP/4127	SANOFI 410 THALES	LABOREX UGANDA LIMITED	EPILIM	SODIUM VALPROATE	200MG/5ML	UNITHER LIQUID MANUFACTURING INDUSTRIE - COLOMIERS 1-3 ALLE DE LA NESTEL DEN SIGAL 31770	N/A	GMP OF THE FACILITY EXPIRED ON THE 24/6/2023 FOR NON-BETA LACTAM: LIQUIDS FOR EXTERNAL USE, ORAL LIQUIDS, SUPPOSITORIES	RETAINED	FRANCE	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE,1.0X 300.0 ML BOTTLE	01/07/1998
754	NDA/MAL/HDP/4132	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYCEL 200	CELECOXIB	200MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2001

755	NDA/MAL/HDP/4149	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	TRACRIUM INJECTION	ATRACURIUM BESYLATE	10MG/ML	GLAXO SMITHKLINE MANUFACTURING S.P.A .- STARDA PROVINCIALE ASOLANA 90, 43056 SAN POLO DI TORRILE (PARMA) GLAXOSMITHKLINE SPA FLEMING - 2, 37135 PARMA	N/A	GMP FOR ASOLANA EXPIRED ON THE 30/10/2021 FOR NON-BETA LACTAM SMALL VOLUME PARENTERAL SOLUTIONS (ASEPTICALLY FILLED AND TERMINALLY STERILISED IN AMPOULES AND VIALS). FOR FLEMING; FACILITY NAME CHANGED TO ACS DOBFAR S.P.A; FACILITY AWAITS PHYSICAL INSPECTION OF THIS PRODUCT LINE.	RETAINED	ITALY	PARENTERAL ORDINARY AMPOULES	1.0X2.5 ML AMPOULE,1.0X5.0 ML AMPOULE,1.0X10.0 ML AMPOULE	01/07/2010

756	NDA/MAL/HDP/4165	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ZEFONE INJECTION	CEFTRIAXONE SODIUM	1G	REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG PROVINCE P.R. 256100	SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382-213,GUJARAT-INDIA INJECTCARE PARENTERALS PVT. LTD.-PLOT130 SILVASSA ROAD GIDC VAPI 396195 GUJARAT ZEISS PHARMACEUTICALS PVT LTD-72 EXPORT PROMOTION INDUSTRIAL PARK ,PHASE-1,JHARMAJRI, BADDI DIST:SOLAN H.P INDIA ZYDUS HEALTHCARE LIMITED-SURVEY NO. 49/3, 51/1, 51/2 RINGANWADA VILLAGE, DAMAN (U.T)	FACILITY ADDRESS CHANGED TO NO.1. APPLICANT REQUIRED TO APPLY FOR A VARIATION	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2001

757	NDA/MAL/HDP/4169	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	FLUCOZYD-200	FLUCONAZOLE	200MG	CADILA HEALTH CARE LTDSARKHEJ BAVLA N.H NO. 8A MORAIJA, TAL, SANARD, AHMEDA	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X7.0 CAPSULE BLISTER,1.0X5.0X4.0 CAPSULE BLISTER	01/07/2008
758	NDA/MAL/HDP/4170	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TRAMAZAC	TRAMADOL HYDROCHLORIDE	50MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2000

759	NDA/MAL/HDP/4173	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	NASONEX	MOMETASONE FUROATE MONOHYDRATE	0.05%W/V	MSD PTY LTD-117 16TH ROAD, HALFWAY HOUSE 1685 SCHERING PLOUGH LABO N.V,-INDUSTRY PARK 30, 2220 HEIST OPDENBERG BELGIUM	N/A	NAME OF FACILITY (SCHERING PLOUGH) CHANGED TO ORGANON HEIST BV, APPLICATION REQUIRED TO APPLY FOR VARIATION FOR CHANGE OF NAME; MSD FACILITY NOT APPROVED FOR THIS LINE; APPLICATION FOR GMP RE-INSPECTION DOES NOT INCLUDE THE PRODUCT LINE	RETAINED	BELGIUM SOUTH AFRICA	NASAL SYSTEMIC METERED-DOSE LIQUIDS	1.0X1.0X120.0 METERED DOSE CANNISTER	01/07/2009
760	NDA/MAL/HDP/4175	AUROBINDO PHARMA LTD UNIT VII	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	KOACT 156.25	AMOXYCILLIN TRIHYDRATE+ POTASSIUM CLAVUNALATE	156.25MG/5ML	N/A	AUROBINDO PHARMA LIMITED, UNIT IIISURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELENGANA (STATE)	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2007

761	NDA/MAL/HDP/4183	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CHLORPROMAZINE	CHLORPROMAZINE	25MG/ML	NINGBO DAHONGYING PHARMACEUTICAL CO LTDNO 396, MINGZHU ROAD NINGBO CITY CHINA	N/A	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: TABLETS, CAPSULES, SVP LIQUIDS; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2011
762	NDA/MAL/HDP/4275	F. HOFFMANN LA-ROCHE	LABOREX UGANDA LIMITED	AVASTIN 100MG/4ML	BEVACIZUMAB	100 MG/4ML	F. HOFFMANN LA-ROCHE-WURMISWEG CH-4303 KAISERAUGST	F.HOFFMANN-LA ROCHE LTD-GRENZACHERSTRASSE 124,CH- 4070 BASEL ROCHE DIAGNOSTICS GMBH-SANDHOFER STRASSE 116 D-68305 MANNHEIM GERMANY	GMP OF THE FACILITY EXPIRED ON THE 30/7 2023 FOR BIOTECHNOLOGY PRODUCTS: SVP LIQUIDS IN VIALS SVP LYOPHILISATES PREFILLED SYRINGES , CEPHALOSPORIN: SVP POWDERS IN VIALS	RETAINED	SWITZERLAND GERMANY	PARENTERAL ORDINARY VIALS	1.0X4.0 ML VIAL	01/07/2016
763	NDA/MAL/HDP/4279	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROTIM	TIMOLOL MALEATE	0.5% W/V	N/A	AUROLABNO. 1, SIVAGANGAI MAIN ROAD, VEERAPANJAN, MADURAI	N/A	NOT RETAINED	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2016

764	NDA/MAL/HDP/4284	F. HOFFMANN LA-ROCHE	LABOREX UGANDA LIMITED	AVASTIN 400MG/4ML	BEVACIZUMAB	400MG/4ML	F. HOFFMANN LA-ROCHE-WURMISWEG CH-4303 KAISERAUGST	F.HOFFMANN-LA ROCHE LTD-GRENZACHERSTRASSE 124,CH- 4070 BASEL ROCHE DIAGNOSTICS GMBH-SANDHOFER STRASSE 116 D-68305 MANNHEIM GERMANY	GMP OF THE FACILITY EXPIRED ON THE 30/7 2023 FOR BIOTECHNOLOGY PRODUCTS: SVP LIQUIDS IN VIALS SVP LYOPHILISATES PREFILLED SYRINGES , CEPHALOSPORIN: SVP POWDERS IN VIALS	RETAINED	SWITZERLAND GERMANY	PARENTERAL ORDINARY VIALS	1.0X16.0 ML VIAL	01/07/2016
765	NDA/MAL/HDP/4287	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANAXONE 1000	CEFTRIAXONE	1000MG	N/A	SANCE LABORATORIES PVT. LTD.VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL,1.0X50.0X10.0 ML VIAL	01/07/2010
766	NDA/MAL/HDP/4291	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	VITAMIN B COMPLEX INJECTION	VITAMIN B COMPLEX	10MG/2ML	NINGBO DAHONGYING PHARMACEUTICALS LTD NO. 396 MIN	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: TABLETS, CAPSULES, SVP LIQUIDS	RETAINED	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2008

767	NDA/MAL/HDP/4308	SINO AFRICA MEDICINES AND HEALTH LTD	SINO AFRICA MEDICINES & HEALTH LTD	BENZYL PENICILLIN SODIUM	BENZYLPENICILLIN SODIUM	1000000 I.U	N/A	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTDNO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSHOP 406 AND 407)	N/A	NOT RETAINED	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0 VIAL CARTON,1.0 X10.0 VIAL CARTON	01/07/2009
768	NDA/MAL/HDP/4312	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GONAL-F	FOLLITROPIN ALFA	75IU/IE	MERCK SERONO S.A. (MSA) - 1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND	MERCK SERONO S.P.A-VIA DELLE MAGNOLIE,15.70026 MODUGNO (BA).ITALY	GMP EXPIRED ON THE 24/09/2023 FOR BIOTECHNOLOGY PRODUCTS: SMALL VOLUME LIQUIDS, SVP LYOPHILISATES IN PRE-FILLED SYRINGES & CATRIDGES	RETAINED	ITALY	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1 PRE FILLED SYRINGE OF WFI	01/07/2016
769	NDA/MAL/HDP/4318	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	AKUGABALIN	PREGABALIN	75 MG	N/A	AKUMS DRUGS & PHARMACEUTICALS LTD19, 20,21 SECTOR 6A IIE SIDCUL RANIPUR HARIDWAR 249 403	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	07/01/2016

770	NDA/MAL/HDP/4333	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	CARVIBER G	CARVEDILOL USP	6.25MG	N/A	THE MADRAS PHARMACEUTICALS137-B,OLD MAHABALI PURAM ROAD,KARAPAKKAM ,CHENNAL INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
771	NDA/MAL/HDP/4340	ASTRA PHARMA (U) LTD	ASTRA PHARMA (U) LIMITED	VITAMIN B COMPLEX	VITAMIN B1 + VITAMIN B2 + SODIUM NICOTINAMIDE + VITAMIN B6 + D-PANTHENOL SODIUM	10MG + 1.37MG + 15MG + 1MG + 0.5MG	ZHEJIANG RUIXIN PHARMACEUTICAL CO., LTD--KAITEE ROAD, TIANNING INDUSTRIAL ZONE, LISHUI, ZHEJIANG, P.R.CHINA	WUHAN FUXING BIOLOGICAL PHARMACEUTICAL COMPANY LIMITED-NO. 9 FUXING ROAD HANCHUAN ECONOMIC DEVELOPMENT DISTRICT, HUBEI PROVINCE - CHINA	FAILED GMP ON THE 12/08/2019 FOR NON-BETA LACTAM: TABLET, CAPSULES, SMALL VOLUME LIQUIDS. HORMONES: SMALL VOLUME LIQUIDS. BETA LACTAM (CEPHALOSPORIN): TABLETS	RETAINED	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE,1.0X10.0X10.0X2.0 ML AMPOULE	01/07/2008
772	NDA/MAL/HDP/4344	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	LISTRIL-10	LISINOPRIL	10MG	N/A	TORRENT PHARMACEUTICAL LTDAHMEDABAD-MEHSANA HIGHWAY,TALUKA-KADI,DIST.MEHSANA ,INDRAD-382721	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2000

773	NDA/MAL/HDP/4369	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLUCAP	CHLORPHENAMINE MALEATE+PSEUDOEPHEDRINE HYDROCHLORIDE+PARACETAMOL	1.25MG+10MG+120MG	N/A	TIL HEALTH CAREPLOT 100,WEST,R-5,SOUTH;SRICITY SEZ,CHERIVI,IRUHULAM,PSOT,SATYAVEDU MANDAL,CHITOOR DISTRICT-ANDRA PRADESH-517588, INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997
774	NDA/MAL/HDP/4370	UNOSOURCE PHARMA LTD	MEDVIN PHARMA LIMITED	AKUMERO	MEROPENEM	1000 MG	AKUMS DRUGS & PHARMACEUTICALS LTD. - PLANT III, PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL, RANIPUR,	N/A	FACILITY NOT APPROVED FOR THE MANUFACTURE OF THIS PRODUCT LINE (CARBAPENEMS)	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	07/01/2016

775	NDA/MAL/HDP/4372	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	ABDOL-500	PARACETAMOL	500MG	JIANGSU PENGYAO PHARMACEUTICALS CO. LTD -NO. 10 CHAQUAN ROAD YIXING CITY JIANGSU PROVINCE	N/A	FAILED GMP ON THE 28/8/2018 FOR NON BETA LACTAM: • SVP-SOLUTIONS IN AMPOULES • TABLETS • HARD GELATIN CAPSULES; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X10.0X100.0 TABLET BLISTER	01/07/2013
776	NDA/MAL/HDP/4375	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	ZITHROMAX	AZITHROMYCIN DIHYDRATE	200MG/5ML	PFIZER LABORATORIES (PTY) LTD;--SOUTH AFRICA	HAUPT PHARMA LATINA S.R.L LATINA-SS 156KM 47,600-04100,BORGO SAN,MICHELE	GMP EXPIRED ON THE 17/10/2008 FOR NBL TABS, NBL HG CAPS, NBL SOLUBLE POWDERS PACKED IN SACKETS, NBL DRY POWDERS, NBL SOLUTIONS,SYRUPS N SUSPENSIONS, NBL LOTIONS, CREAMS N OINTEMENTS, SUPPOSITORIES	RETAINED	ITALY	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X30.0 ML BOTTLE,1.0X15.0 ML BOTTLE	01/07/1997

777	NDA/MAL/HDP/4377	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	ORALYTE	ANHYDROUS GLUCOSE + SODIUM CHLORIDE + TRISODIUM CITRATE DIHYDRATE + POTASSIUM CHLORIDE	13.5MG + 2.6MG + 2.9MG + 1.5MG	N/A	MEDIPHARM INDUSTRIES (E.A) LTDPLOT 65, KAKAJJO ROAD, BWEYOGERERE	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	UGANDA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X20.5 G SACHET,1.0X 10.25 G SACHET	01/07/2008
778	NDA/MAL/HDP/4383	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	ZEEMYCIN - 150	CLINDAMYCIN HYDROCHLORIDE BP	150MG	N/A	THE MADRAS PHARMACEUTICALS137-B,OLD MAHABALI PURAM ROAD,KARAPAKKAM ,CHENNAL INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10 .0 CAPSULE BLISTER	01/07/2016
779	NDA/MAL/HDP/4390	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROCOL	CHLORAMPHENICOL	0.5%W/V	N/A	AUROLABNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA	N/A	NOT RETAINED	INDIA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE	01/07/2016

780	NDA/MAL/HDP/4401	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	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	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

781	NDA/MAL/HDP/4407	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD	SURGIPHARM (U) LIMITED	SUXAMETHONIUM CHLORIDE-FRESENIUS	SUXAMETHONIUM CHLORIDE	100MG/2ML	N/A	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD √6 GIBAUD…ROAD KORSTEN, PORT ELIZABETH, SOUTH AFRICA.	N/A	NOT RETAINED	SOUTH AFRICA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2016

782	NDA/MAL/HDP/4413	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPICEPHIN	CEFTRIAXONE	1G	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL (+ 1 GLASS AMPOULE OF 10ML WFI)	01/07/2011
783	NDA/MAL/HDP/4415	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	CATAFLAM 50MG TABLETS	DICLOFENAC POTASSIUM	50MG	NOVARTIS PHARMA SPA,-TORRE ANNUNZI	NOVARTIS--URUNLERI INSTABUL TURKEY	GMP EXPIRED ON THE 30/7/2023 FOR NBL TABLETS	RETAINED	TURKEY	ORAL SOLID ORDINARY COATED TABLETS	10.0X10.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER	01/07/1997

784	NDA/MAL/HDP/4417	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPICEPHIN	CEFTRIAXONE SODIUM	500MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X0.5 G VIAL + 1*5 ML OF WFI GLASS AMPOULES	01/07/2014

785	NDA/MAL/HDP/4418	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	VALORAN	CEFOTAXIME	1000MG	MEDOCHEMIE LIMITED (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 VIAL CARTON	01/07/2009

786	NDA/MAL/HDP/4419	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIGONAL 75	HUMAN MENOPAUSAL GONADOTROPHIN	75IU/5ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL + 1 ML AMPOULE 0.9%W/V NACL	01/07/2010

787	NDA/MAL/HDP/4483	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	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	RETAINED	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE,1.0X 100.0 L BOTTLE	01/07/1997
788	NDA/MAL/HDP/4524	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	FLUCOZAL 150	FLUCONAZOLE	150MG	N/A	DELORBIS PHARMACEUTICALS LTD17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X1.0 CAPSULE BLISTER	01/07/2008

789	NDA/MAL/HDP/4530	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	TREDOL 100	ATENOLOL	100MG	N/A	DELORBIS PHARMACEUTICALS LTD17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2008
790	NDA/MAL/HDP/4531	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	TREDOL 50	ATENOLOL	50MG	N/A	DELORBIS PHARMACEUTICALS LTD17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2008
791	NDA/MAL/HDP/4532	DELOBORIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	VIRUCID 400	ACICLOVIR	400 MG	N/A	DELORBIS PHARMACEUTICALS LTD17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY OTHER TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008

792	NDA/MAL/HDP/4534	DELOBORIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	LORYTEC 10	LORATADINE	10MG	N/A	DELORBIS PHARMACEUTICALS LTD17 ATHINON STR., ERGATES INDUSTRIAL AREA, 2643 ERGATES, P.O. BOX 28629, 2081 LEFKOSIA, CYPRUS	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2007

793	NDA/MAL/HDP/4536	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	N/A	GMP EXPIRED ON THE 28/09/2023 FOR NON-BETA LACTAM: ORAL VETERINARY POWDERS TABLETS POWDERS FOR ORAL SUSPENSION HARD GELATIN CAPSULES ORAL LIQUIDS OINTMENTS, CREAMS & GELS SUPPOSITORIES STERILE LIQUIDS IN AMPOULES POWDER SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED IN PLASTIC AMPOULE) SMALL VOLUME LYOPHILIZED POWDER (ASEPTICALLY PREPARED) SOFT GELATIN CAPSULES , BIOLOGICALS (SVP): RECOMBINANT INSULIN	RETAINED	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X4.0 CAPSULE STRIP	01/07/2004

794	NDA/MAL/HDP/4540	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	VIPROLOX 500	CIPROFLOXACIN	500MG	N/A	DELORBIS PHARMACEUTICALS LTD17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2008
795	NDA/MAL/HDP/4542	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	CLERON 500	CLARITHROMYCIN	500MG	N/A	DELORBIS PHARMACEUTICALS LTD17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X14.0 TABLET BLISTER	01/07/2008
796	NDA/MAL/HDP/4544	COSMOS LTD	ASTRA PHARMA (U) LIMITED	SALBUT TABLET 4MG	SALBUTAMOL	4MG	N/A	COSMOS LIMITED-RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	N/A	NOT RETAINED	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER	01/07/2000

797	NDA/MAL/HDP/4545	CACHET PHAMACUITICALS PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	CACH-ART 20/120	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	N/A	CACHET PHARMACEUTICALS PVT LTDVILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X8.0 TABLET BLISTER	01/07/2010
798	NDA/MAL/HDP/4549	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	UNIXIL 500MG	AMOXYCILLIN TRIHYDRATE	500MG	N/A	REGAL PHARMACEUTICALS LTDBABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/1997

799	NDA/MAL/HDP/4556	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM 375	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	250MG + 125MG	ALKEM LABORATORIES LTD--PLOT NO. 167/1, MAHATMA GANDHI UDYONG NAGAR, AMALIYA, DABHEL, DAMAN, 396210 INDIA.	INDCHEMIE HEALTH SPECIALTIES PVT. LTD-(UNIT 3 BETA LACTAM BLOCK) VILLAGE: THANA, TEHSIL: BADDI, DISTRICT: SOLAN HIMACHAL PRADESH -173205 INDIA	GMP FOR ALKEM EXPIRED ON THE 29/11/2019 FOR HARD GELATIN CAPSULES (NBL, CEPHALOSPORIN & PENICILLIN) TABLETS. (NBL & CEPHALOSPORIN) POWDERS FOR ORAL SUSPENSION (CEPHALOSPORIN) POWDERS FOR ORAL SUSPENSION, (PENICILLIN) POWDERS FOR INJECTION AND TABLETS.(PENICILLIN)	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET STRIP	01/07/2005

800	NDA/MAL/HDP/4568	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM 625	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	500MG + 125MG	ALKEM LABORATORIES LTD--PLOT NO. 167/1, MAHATMA GANDHI UDYONG NAGAR, AMALIYA, DABHEL, DAMAN, 396210 INDIA.	INDCHEMIE HEALTH SPECIALTIES PVT. LTD-(UNIT 3 BETA LACTAM BLOCK) VILLAGE: THANA, TEHSIL: BADDI, DISTRICT: SOLAN HIMACHAL PRADESH -173205 INDIA	GMP FOR ALKEM EXPIRED ON THE 29/11/2019 FOR HARD GELATIN CAPSULES (NBL, CEPHALOSPORIN & PENICILLIN) TABLETS. (NBL & CEPHALOSPORIN) POWDERS FOR ORAL SUSPENSION (CEPHALOSPORIN) POWDERS FOR ORAL SUSPENSION, (PENICILLIN) POWDERS FOR INJECTION AND TABLETS.(PENICILLIN)	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET STRIP	01/07/2005

801	NDA/MAL/HDP/4581	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM 1000	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	875MG + 125MG	ALKEM LABORATORIES LTD--PLOT NO. 167/1, MAHATMA GANDHI UDYONG NAGAR, AMALIYA, DABHEL, DAMAN, 396210 INDIA.	INDCHEMIE HEALTH SPECIALTIES PVT. LTD-(UNIT 3 BETA LACTAM BLOCK) VILLAGE: THANA, TEHSIL: BADDI, DISTRICT: SOLAN HIMACHAL PRADESH -173205 INDIA	GMP FOR ALKEM EXPIRED ON THE 29/11/2019 FOR HARD GELATIN CAPSULES (NBL, CEPHALOSPORIN & PENICILLIN) TABLETS. (NBL & CEPHALOSPORIN) POWDERS FOR ORAL SUSPENSION (CEPHALOSPORIN) POWDERS FOR ORAL SUSPENSION, (PENICILLIN) POWDERS FOR INJECTION AND TABLETS.(PENICILLIN)	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET STRIP	01/07/2005
802	NDA/MAL/HDP/4594	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TINIBA-500 TABLETS	TINIDAZOLE	500MG	CADILA HEALTH CARE LIMITED-KUNDAIM INDUSTRIAL ESTATE, PONDA, GOA-403401	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0X4.0 TABLET BLISTER,1.0X25.0X4.0 TABLET BLISTER,1.0X5.0X5.0X4.0 TABLET BLISTER	01/07/1997

803	NDA/MAL/HDP/4603	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	HALOXEN - 5	HALOPERIDOL	5MG	N/A	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
804	NDA/MAL/HDP/4609	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYCORT	HYDROCORTISONE	1%W/W	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	RETAINED	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997
805	NDA/MAL/HDP/4615	NVS KENYA LTD	SURGIPHARM (U) LIMITED	TASIGNA 150	NILOTONIB HYDROCHLORIDE MONOHYDRATE	150MG	N/A	NOVARTIS PHARMA STEIN AGSCHAFFHARVSERTRASSE CH-4332 STEIN SWITZERLAND.	N/A	NOT RETAINED	SWITZERLAND	ORAL SOLID ORDINARY CAPSULES	1.0X7.0X4.0 CAPSULE BLISTER	01/07/2014

806	NDA/MAL/HDP/4621	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	CARVIL 6.25	CARVEDILOL	6.25MG	CADILA HEALTHCARE LTD--PLOT 203-213, KUNDAIM INDUSTRIAL ESTATE, GOA	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2006
807	NDA/MAL/HDP/4626	ACINO PHARMA AG -	LABOREX UGANDA LIMITED	GASEC-20	OMEPRAZOLE	20MG	N/A	ACINO PHARMA AGBIRSWEG 2, 4253, LIESBERG - SWITZERLAND	N/A	NOT RETAINED	SWITZERLAND	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X14.0 CAPSULE BOTTLE	01/07/2005
808	NDA/MAL/HDP/4633	AMANTA HEALTHCARE LTD	PHARMA VILLE LIMITED	METRONIDAZOLE INFUSION	METRONIDAZOLE	5MG/ML	N/A	AMANTA HEALTHCARE LIMITED (FORMERLY KNOWN AS MARCK BIOSCIENCES LTD)PLOT NO. 876, N.H. NO. 8, VILLAGE - HARIYALA, DIST - KHEDA 387411, GUJARAT	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2014
809	NDA/MAL/HDP/4636	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	ZOLARAM 0.5	ALPRAZOLAM	0.5MG	N/A	DELORBIS PHARMACEUTICALS LTD17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2009

810	NDA/MAL/HDP/4650	NORVATIS PHARMA AG-SWITZERLAND	LABOREX UGANDA LIMITED	DUOTRAV	TRAVOPROST + TIMOLOL MALEATE	40MG/ML + 5MG/ML	ALCON COUVREUR NVRIJKSWEG 14, B-2870 PUURS BELGIUM	N/A	GMP EXPIRED ON 08/12/2023 FOR Non-Beta Lactam: Semi-solids (Aseptically prepared) Small Volume Liquids (Aseptically prepared) Small Volume Liquids (Terminally Sterilized)	RETAINED	BELGIUM	OPHTHALMIC DROPS	1.0X1.0X2.5 ML VIAL	01/07/2010
811	NDA/MAL/HDP/4657	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	VOLAR 300MG	GABAPENTIN	300MG	N/A	DAR AL DAWADAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL-HUSSEIN STREET. AMMAN, JORDAN	Small Volume Liquids (Terminally Sterilized)	NOT RETAINED	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2013
812	NDA/MAL/HDP/4660	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	RISDONE 2MG	RISPERIDONE	2MG	N/A	DAR AL DAWADAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL-HUSSEIN STREET. AMMAN, JORDAN	N/A	NOT RETAINED	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2013

813	NDA/MAL/HDP/4663	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	LORATAN	LORATIDINE	5MG/5ML	N/A	DAR AL DAWADAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL-HUSSEIN STREET. AMMAN, JORDAN	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	JORDAN	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2013
814	NDA/MAL/HDP/4675	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	DICLOGESIC RETARD 100	DICLOFENAC SODIUM	100MG	N/A	DAR AL DAWADAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL-HUSSEIN STREET. AMMAN, JORDAN	N/A	NOT RETAINED	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X6.0 CAPSULE BLISTER	01/07/2013
815	NDA/MAL/HDP/4677	: ALKEM LABORATORIES LIMITEDv	ABACUS PHARMA (AFRICA) LIMITED	ZOCEF	CEFUROXIME	125MG/5ML	EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMA CITY SELAQUI DEHRADUN – 248011	ALKEM LABORATORIES LIMITED.-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205	FACILITY NOT APPROVED TO MANUFACTURE CEPHALOSPORIN ORAL POWDERS	RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X1.0X30.0 ML BOTTLE,1.0X70.0 ML BOTTLE	01/07/2011

816	NDA/MAL/HDP/4680	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANCEPHDS	CEPHALEXIN	125MG/5ML	N/A	SANCE LABORATORIES PVT. LTD.VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2011
817	NDA/MAL/HDP/4690	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYPEN	PHENOXYMETHYL PENICILLIN	250MG	N/A	ELYS CHEMICAL INDUSTRIES LTDROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	N/A	NOT RETAINED	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997
818	NDA/MAL/HDP/4693	ELYS CHEMICAL INDUSTRIES LTD	ELYS CHEMICALS INDUSTRIES UGANDA LTD	ELYVATE	BETAMETHASONE VALERATE	1%W/W	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	NOT RETAINED	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997

819	NDA/MAL/HDP/4708	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	MEDIFEN	IBUPROFEN	100MG/5ML	N/A	MEDIPHARM INDUSTRIES (E.A) LTDPLOT 65, KAKAJJO ROAD, BWEYOGERERE	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE	01/07/2006
820	NDA/MAL/HDP/4712	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	MEFINAL-500	MEFENAMIC ACID	500MG	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR-401506, DIST.THANE, MARAHASHTRA, INDIA	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	MAXHEAL FAILED GMP ON THE 14/5/2019 FOR NON BETA-LACTAM: TABLETS (COATED AND UNCOATED), EXTERNAL PREPARATIONS (CREAMS AND OINTMENTS), HARD GELATIN CAPSULES, DRY POWDER FOR ORAL SUSPENSION, ORAL LIQUIDS	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
821	NDA/MAL/HDP/4714	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CEPHOXIN 250MG/5ML	CEPHALEXIN	250MG/5ML	N/A	PHARCO-B INTERNATIONAL PHARMACEUTICALSBORG EL-ARAB 3D INDUSTRIAL ZONE, BLOCK 18 AREA, 10, 11, ALEXANDRIA EGYPT	N/A	NOT RETAINED	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1998

822	NDA/MAL/HDP/4727	STRIDES SHASUN LIMITED .	DELMAW ENTERPRISES LIMITED	MELONAX	MELOXICAM	15MG	N/A	STRIDES ARCOLAB LIMITED 36/7 SURAGAJAKKANAHALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2010
823	NDA/MAL/HDP/4738	NORVATIS PHARMA AG-SWITZERLAND	LABOREX UGANDA LIMITED	CILOXAN	CIPROFLOXACIN	0.3%W/V	ALCON COUVREUR NVRIJKSWEG 14, B-2870 PUURS BELGIUM	N/A	GMP EXPIRED ON 08/12/2023 FOR Non-Beta Lactam: Semi-solids (Aseptically prepared) Small Volume Liquids (Aseptically prepared) Small Volume Liquids (Terminally Sterilized)	RETAINED	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/1997
824	NDA/MAL/HDP/4739	SWISS PARENTERALS LTD	SHREEJI CARE LIMITED	MERO	MEROPENEM	1G	SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220	SWISS PARENTERALS LIMITED UNIT IIPLOT 402, 412-414, KERALA INDUSTRIAL ESTATE, GIDC, NEAR BAVLA, AHMEDABAD - 382220, GUJARAT - INDIA	Small Volume Liquids (Aseptically prepared)	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2011

825	NDA/MAL/HDP/4743	DAFRA PHARMA N.V/S.A	MULTIPHAR UGANDA LIMITED	MERONIA 1000	MEROPENEM	1000MG	ANFARM HELLAS S.A.-61ST KM. NATIONAL ROAD, ATHENS-LAMIA, 320 09 SCHIMATARI	N/A	FACILITY NOT APPROVED TO MANUFACTURE CARBAPENEMS	RETAINED	GREECE	PARENTERAL ORDINARY VIALS	1.0X1000.0 MG VIAL	01/07/2013

826	NDA/MAL/HDP/4745	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PIPZO	PIPERACILLIN + TAZOBACTAM	4.5G	ALKEM LABORATORIES LTD--PLOT NO. 167/1, MAHATMA GANDHI UDYONG NAGAR, AMALIYA, DABHEL, DAMAN, 396210 INDIA. EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMA CITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	ALKEM LABS LTD.-VILLAGE THANA, BADDI, THE NALAGARH, DIST SOLAN (HP) 173205	EAST AFRICAN OVERSEAS IS NOT APPROVED FOR PENICILLIN LINE; GMP FOR ALKEM EXPIRED ON THE 29/11/2019 FOR HARD GELATIN CAPSULES (NBL, CEPHALOSPORIN & PENICILLIN) TABLETS. (NBL & CEPHALOSPORIN) POWDERS FOR ORAL SUSPENSION (CEPHALOSPORIN) POWDERS FOR ORAL SUSPENSION, (PENICILLIN) POWDERS FOR INJECTION AND TABLETS.(PENICILLIN)	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X4.5G VIAL + STERILIZED WATER FOR INJECTION	01/07/2014
827	NDA/MAL/HDP/4747	RIVA PHARMA FREE ZONE	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ZITHRORIV	AZITHROMYCIN	200MG/5ML	N/A	RIVA PHARMA FREE ZONENASR CITY CAIRO EGYPT	N/A	NOT RETAINED	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X22.5 ML BOTTLE	01/07/2011

828	NDA/MAL/HDP/4752	PFIZER LABORATORIES LTD	LABOREX UGANDA LIMITED	ADRIBLASTINA RD	DOXORUBICIN HYDROCHLORIDE	10MG	PHARMACIA AND UPJOHN S.P.A ITALY-VIA COMMESCION MARINO DEL TRONTO(ASCOLI	N/A	FACILITY NOT GMP COMPLIANT	NOT RETAINED	ITALY	PARENTERAL ORDINARY OTHER VIALS	1.0X10.0 ML VIAL	01/07/1998
829	NDA/MAL/HDP/4767	MEDIPAK LIMITED	HEALTHCARE LTD.	CIPROFENA	CIPROFLAXACIN HYDROCHLORIDE	0.3%W/V	N/A	MEDIPAK LIMITED132/1 INDUSTRIAL AREA KOTLAKHPAT LAHORE	N/A	NOT RETAINED	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X5.0 ML VIAL	01/07/2006

830	NDA/MAL/HDP/4774	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FERROFOLVIT-Z	FERROUS SULPHATE+FOLIC ACID+ASCORBIC ACID+THIAMINE MONONITRATE+RIBOTLAVINE+PYRIDOXINE HCL+NICOTINAMIDE+ZINC	150MG+0.5MG+50MG+2MG+2MG+1MG+10MG+25MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X6.0 CAPSULE BLISTER	01/07/2014

831	NDA/MAL/HDP/4778	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CURISAFE	CEFADROXIL MONOHYDRATE	125MG/5ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX	N/A	FACILITY NOT APPROVED TO MANUFACTURE CEPHALOSPORINS	NOT RETAINED	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X60.0 ML BOTTLE	01/07/2000
832	NDA/MAL/HDP/4782	VHB MEDI SCIENCES LTD	NORVIK ENTERPRISES LIMITED	CYBIN PF	CYTARABINE	100MG/ML	N/A	VHB MEDI SCIENCES LTDPLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	PARENTERAL ORDINARY AMPOULES	, 1X2 ML Ampoule, 1X2 ML Vial	\N
833	NDA/MAL/HDP/4785	JASSEN-CILAG (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	DAKTACORT	MICONAZOLE NITRATE+HYDROCORTISONE	2%W/W+1%W/W	N/A	SPECPHARM HOLDINGS 15TH ROAD HALFWAY HOUSE	N/A	NOT RETAINED	SOUTH AFRICA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997
834	NDA/MAL/HDP/4787	JASSEN-CILAG (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	DAKTARIN	MICONAZOLE NITRATE	20MG/G	N/A	SPECPHARM HOLDINGS 15TH ROAD HALFWAY HOUSE	N/A	NOT RETAINED	SOUTH AFRICA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/1997

835	NDA/MAL/HDP/4791	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	DALACIN C	CLINDAMYCIN PALMITATE	75MG/5ML	PHARMACIA AND UPJOHN S.P.A-RIJKSWEG 12, B-2870 PUURS	N/A	FACILITY NAME CHANGED TO PFIZER MANUFACTURING BELGIUM NV. FACILITY NOT APPROVED FOR THE MANUFACTURE OF THIS PRODUCT LINE	RETAINED	BELGIUM	ORAL LIQUID ORDINARY OTHER POWDERS/GRANULES	1.0X80.0 ML BOTTLE	01/07/1997

836	NDA/MAL/HDP/4799	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CITROLIN SOLUTION	CETRIMIDE+LIDOCAINE	25MG+3MG	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	N/A	GMP EXPIRED ON 28/9/2023 FOR BETA LACTAM (PENICILLIN): ORAL DRY POWDERS FOR SUSPENSION HARD GELATIN CAPSULES TABLETS SVP POWDERS (VIALS), NON-BETA LACTAM: ORAL DRY POWDERS (HUMAN & VETERINARY) HARD GELATIN CAPSULES TABLETS ORAL LIQUIDS ORAL POWDERS IN SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED) CREAMS, OINTMENTS, GELS, SUPPOSITORIES, PESSARIES & OVULES	NOT RETAINED	EGYPT	ORAL TOPICAL LIQUIDS	1.0X120.0 ML BOTTLE	01/07/1998

837	NDA/MAL/HDP/4813	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOMETROL TABLETS (THANE)	METRONIDAZOLE	200MG	N/A	AGOG PHARMA LTDPLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER, 1.0X100.0 TABLET CONTAINER, 1.0X1000.0 TABLET CONTAINER, 10.0X10.0 TABLET BLISTER	01/07/1998
838	NDA/MAL/HDP/4841	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROMETRO FC	METRONIDAZOLE	200MG	N/A	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007
839	NDA/MAL/HDP/4851	SHAIGAN PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	CLOZOX V	CLOTRIMAZOLE	100MG	N/A	SHAIGAN PHARMACEUTICALS (PVT) LTD14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN	N/A	NOT RETAINED	PAKISTAN	VAGINAL TABLETS	1.0X1.0X6.0 TABLET BLISTER	07/10/2004

840	NDA/MAL/HDP/4887	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	FLUCOZAL	FLUCONAZOLE	200MG	N/A	DELORBIS PHARMACEUTICALS LTD17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/1997
841	NDA/MAL/HDP/4889	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	FLUCOZAL	FLUCONAZOLE	50MG	N/A	DELORBIS PHARMACEUTICALS LTD17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X14.0 CAPSULE BLISTER	01/07/1999
842	NDA/MAL/HDP/4890	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	FLUCOZAL	FLUCONAZOLE	100MG	N/A	DELORBIS PHARMACEUTICALS LTD17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/1997

843	NDA/MAL/HDP/4916	FREDUN PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	NEOPROFANE 200 TABLETS	IBUPROFEN	200MG	N/A	FREDUN PHARMACEUTICALS LTD14,15,16 ZORBIAN INDUSTRIAL COMPLEX VEOOR PALGHAR EAST INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	10.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER, 1.0X1000.0 TABLET CONTAINER	01/07/2001
844	NDA/MAL/HDP/4917	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL EVILINE FORTE SUSPENSION	MAGNESSIUM HYDROXIDE +ALUMINIUM HYDROXIDE+SIMETHICONE	400MG/5ML+400MG/5ML+40MG/5ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	N/A	GMP EXPIRED ON THE 28/9/2023 FOR NON-BETA LACTAM: TABLETS COATED & UNCOATED HARD GELATIN CAPSULES ORAL LIQUIDS SVP LIQUIDS AND POWDER STERILE GELS , (BETA LACTAM) CEPHALOSPORIN: HARD GELATIN CAPSULES DRY POWDER FOR ORAL SUSPENSION SVP POWDER , CORTICOSTEROIDS: OINTMENTS AND CREAMS	RETAINED	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X120.0 ML BOTTLE	01/07/2010

845	NDA/MAL/ HDP/4919	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL FUSIDIC ACID- B CREAM	FUSIDIC ACID+BETAM ETHASONE 17 VALERATE	2%,W/W,+ 0.1% W/W	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRI AL ESTATE, 75250 MELAKA MALYSIA	N/A	GMP EXPIRED ON THE 28/9/2023 FOR NON-BETA LACTAM: TABLETS COATED & UNCOATED HARD GELATIN CAPSULES ORAL LIQUIDS SVP LIQUIDS AND POWDER STERILE GELS , (BETA LACTAM) CEPHALOSPORI N: HARD GELATIN CAPSULES DRY POWDER FOR ORAL SUSPENSION SVP POWDER , CORTICOSTEROI DS: OINTMENTS AND CREAMS	RETAINED	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2008

846	NDA/MAL/HDP/4927	NORVATIS PHARMA AG-SWITZERLAND	LABOREX UGANDA LIMITED	AZOPT	BRINZOLAMIDE	10MG/ML	ALCON COUVREUR NVRIJKSWEG 14, B-2870 PUURS BELGIUM	N/A	GMP EXPIRED ON 08/12/2023 FOR Non-Beta Lactam: Semi-solids (Aseptically prepared) Small Volume Liquids (Aseptically prepared) Small Volume Liquids (Terminally Sterilized)	RETAINED	BELGIUM	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML BOTTLE	01/07/2009
847	NDA/MAL/HDP/4928	AFRICURE PHARMACEUTICALS (INDIA) LTD	AFRICURE PHARMACEUTICALS U LIMITED	FOLIC ACID TABLETS	FOLIC ACID	5MG	N/A	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITEDPLOT 9-12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR-401404. INDIA.	Small Volume Liquids (Aseptically prepared)	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET STRIP	01/07/1997
848	NDA/MAL/HDP/4934	FREDUN PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	FOLIFRED	FOLIC ACID	5MG	N/A	FREDUN PHARMACEUTICALS LTD14,15,16 ZORBIAN INDUSTRIAL COMPLEX VEOOR PALGHAR EAST INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997
849	NDA/MAL/HDP/4946	ESAPHARM SRL	BYAMAKA PHARMACEUTICAL COMPANY LTD	MOVATE	CLOBETASOL	0.05%W/W	N/A	ESAPHARMA SRLVIA DE GASPERI, 13-20066 MELZO (MILAN) ITALY	N/A	NOT RETAINED	ITALY	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	01/07/1999

850	NDA/MAL/HDP/4967	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	PIRITEX JUNIOR	MULTI-INGREDIENT	MULTI-INGREDIENT	N/A	MEDIPHARM INDUSTRIES (E.A) LTDPLOT 65, KAKAJJO ROAD, BWEYOGERERE	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X 100.0 ML BOTTLE	01/07/1998
851	NDA/MAL/HDP/4968	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	FRUSEMIDE INJECTION	FUROSEMIDE	10MG/ML	NINGBO DAHONG YING PHARMA CEUTICAL CO.LTDN O. 396 MINGZH U ROAD, HI-TECH PARK, NINGBO CITY ZHEJIANG	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: TABLETS, CAPSULES, SVP LIQUIDS	RETAINED	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2008
852	NDA/MAL/HDP/4970	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	PIRITEX DRY COUGH SYRUP	DIPHENHYDRAMINE HCL/ DEXTROMETHORPHAN HBR/ PSEUDOEPHEDRINE HCL	14MG+15MG+30MG/5ML	N/A	MEDIPHARM INDUSTRIES (E.A) LTDPLOT 65, KAKAJJO ROAD, BWEYOGERERE	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2006
853	NDA/MAL/HDP/4971	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED	AFRICURE PHARMACEUTICALS U LIMITED	FRUSEMIDE TABLETS	FUROSEMIDE	40MG	N/A	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITEDPLOT 9-12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR-401404. INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP,1.0X1000.0 TABLET CONTAINER	01/07/1997

854	NDA/MAL/HDP/4973	MERCK	UNITED HEALTHCARE DISTRIBUTORS LTD	PERGOVERIS	FOLLITROPIN ALFA/LUTROPIN ALFA	150 I.U/75 I.U	MERCK SERONO S.A. (MSA) - 1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND	N/A	GMP EXPIRED ON THE 24/09/2023 FOR BIOTECHNOLOGY PRODUCTS: SMALL VOLUME LIQUIDS, SVP LYOPHILISATES IN PRE-FILLED SYRINGES & CATRIDGES	RETAINED	SWITZERLAND	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 ML VIAL + 1*1ML VIAL OF WFI	01/07/2014
855	NDA/MAL/HDP/4975	FREDUN PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	FRUSINA TABLETS	FUROSEMIDE	40MG	N/A	FREDUN PHARMACEUTICALS LTD14,15,16 ZORBIAN INDUSTRIAL COMPLEX VEOOR PALGHAR EAST INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER, 1.0X1000.0 TABLET CONTAINER, 1.0X10.0 TABLET BLISTER	01/07/1997
856	NDA/MAL/HDP/4977	JULPHAR GULF PHARMACEUTICAL INDUSTRIES	OMASI MED LIMITED	FULICRON	FERROUS SULPHATE+FOLIC ACID	150MG+500MCG	N/A	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)AIRPORT ROAD, DIGDAGA, P.O.BOX: 997, RAS AL KHAIMAH, U.A.E.	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	UNITED ARAB EMIRATES	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

857	NDA/MAL/HDP/5001	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	GENTAMICIN INJECTION	GENTAMYCIN	80MG/2ML	ZHEJIANG RUIXIN PHARMACEUTICAL CO. LTD-KAIFA ROAD, LISHUI, ZHEJIANG P.R OF CHINA	WUHAN FUXING BIOPHARMACEUTICAL CO., LTD-NO.9, FUXING ROAD, HANCUAN ECONOMIC & DEVELOPMENT DISTRICT, HUBEI PROVINCE	FAILED GMP ON THE 12/08/2019 FOR NON-BETA LACTAM: TABLET, CAPSULES, SMALL VOLUME LIQUIDS. HORMONES: SMALL VOLUME LIQUIDS. BETA LACTAM (CEPHALOSPORIN): TABLETS	RETAINED	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE,1.0X10.0X2.0 ML AMPOULE	01/07/2007
858	NDA/MAL/HDP/5007	DELOBORIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	VIRUCID	ACYCLOVIR	200MG	N/A	DELORBIS PHARMACEUTICALS LTD17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X25.0 TABLET CONTAINER	01/07/1997

859	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)	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X20.0 TABLET BLISTER	01/07/2011

860	NDA/MAL/HDP/5021	BAYER SCHERING PHARMA FRANCE	SURGIPHARM (U) LIMITED	COMBINATION 3	ETHINYL ESTRADIOL+ LEVONORGESTREL+FERROUS FUMARATE	0.03MG+0.15MG+75MG	DELPHARMA SAS ZONE INDUSTRIELLE - DELPHARMA SAS ZONE INDUSTRIELLE DE ROUBAIX EST RUE DE TOUFFLERS BP 50070 59452 LYS	BAYER PHARMA AG - 13353 BERLIN GERMANY BAYER WEIMAR GMBH UND CO. KG,-WEIMAR DEBEREINERSTRASSE 20, 99427 WEIMAR GERMANY	GMP EXPIRED	RETAINED	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X100.0X28.0 TABLET BLISTER	01/07/2011
861	NDA/MAL/HDP/5028	THE MENTHOLATUM COMPANY LTD TWY	HARLEYS UGANDA LIMITED	DEEP HEAT SPRAY	MULTI-INGREDIENT	MULTI-INGREDIENT	THE MENTHOLATUM COMPANY LTD, TWYFORD,-1 REDWOOD AVENUE, PEEL PARK CAMPUS EAST	COLEP LAUPHEIM GMBH & CO KG-FOCKESTRASSE 12, 88471, LAUPHEIM	FACILITY NOT APPROVED FOR THIS LINE	RETAINED	GERMANY	TOPICAL EXTERNAL PRESSURISED AEROSOLS	1.0X150.0 ML CANNISTER	01/07/1997

862	NDA/MAL/HDP/5041	NORVATIS PHARMA AG-SWITZERLAND	LABOREX UGANDA LIMITED	MAXITROL	DEXAMETHASONE/NEOMYCIN/POLYMYXIN B	0.1%W/W +0.1%W/W +6000 I.U	ALCON COUVREUR NVRIJKSWEG 14, B-2870 PUURS BELGIUM	N/A	GMP EXPIRED ON 08/12/2023 FOR Non-Beta Lactam: Semi-solids (Aseptically prepared) Small Volume Liquids (Aseptically prepared) Small Volume Liquids (Terminally Sterilized)	RETAINED	BELGIUM	OPHTHALMIC OINTMENTS	1.0X3.5 G TUBE	01/07/1997
863	NDA/MAL/HDP/5043	NORVATIS PHARMA AG-SWITZERLAND	LABOREX UGANDA LIMITED	MAXITROL	DEXAMETHASONE/NEOMYCIN/POLYMYXIN B	0.1%W/W+ 3500I.U/ML +6000I.U/ML	ALCON COUVREUR NVRIJKSWEG 14, B-2870 PUURS BELGIUM	N/A	GMP EXPIRED ON 08/12/2023 FOR Non-Beta Lactam: Semi-solids (Aseptically prepared) Small Volume Liquids (Aseptically prepared) Small Volume Liquids (Terminally Sterilized)	RETAINED	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/1997
864	NDA/MAL/HDP/5046	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	GIZLAN PLUS 150/12.5	IRBESARTAN+ HYDROCHLOROTHIAZIDE	150MG+12.5MG	N/A	DAR AI DAWANA UR PLANT,AMMAN,JORDAN	N/A	NOT RETAINED	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013

865	NDA/MAL/HDP/5047	VHB MEDI SCIENCES LTD	NORVIK ENTERPRISES LIMITED	MAXINEM 500MG	MEROPENEM	500MG	VHB MEDI SCIENCES LTDPLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5	N/A	FACILITY IS NOT LICENSED TO MANUFACTURE CARBAPENEMS; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	, 1X500 MG Vial	\N
866	NDA/MAL/HDP/5048	VHB MEDI SCIENCES LTD	NORVIK ENTERPRISES LIMITED	MAXINEM 1G	MEROPENEM	1G	VHB MEDI SCIENCES LTDPLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5	N/A	FACILITY IS NOT LICENSED TO MANUFACTURE CARBAPENEMS; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	, 1X1 G Vial	\N
867	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	N/A	DAR AI DAWANA UR PLANT,AMMAN,JORDAN	N/A	NOT RETAINED	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013

868	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	N/A	GMP EXPIRED ON 08/12/2023 FOR Non-Beta Lactam: Semi-solids (Aseptically prepared) Small Volume Liquids (Aseptically prepared) Small Volume Liquids (Terminally Sterilized)	RETAINED	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/1997
869	NDA/MAL/HDP/5051	CADILA HEALTHCARE LIMITED SARKHEJ	ABACUS PHARMA (AFRICA) LIMITED	DERIHALER	SALBUTAMOL	100CMG/DOSE	CADILA HEALTHCARE LTD--SARKHEJ-PLOT 417,419, 420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL:	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER	01/07/2005
870	NDA/MAL/HDP/5068	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	DEXAMETHASONE SODIUM PHOSPHATE	DEXAMETHASONE SODIUM PHOSPHATE	8MG/2ML	NINGBO DAHONGYING PHARMACEUTICAL CO LTD.NO. 3986, HI-TECH PARK MINZHU ROAD, NINGBO CITY	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: TABLETS, CAPSULES, SVP LIQUIDS	RETAINED	CHINA INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2010

871	NDA/MAL/HDP/5074	CADILA HEALTH CARE LTD	ABACUS PHARMA (AFRICA) LIMITED	DEXONA INJECTION	DEXAMETHASONE DISODIUM PHOSPHATE	4MG/ML	CADILA HEALTH CARE LTD-SARKHEJ BAVLA N.H NO. 8A MORAIJA, TAL, SANARD, AHMEDAD	SAKAR HEALTH CARE PVT LTD-10/13 CHONGODAR SARKHEJ BAVLA ROAD DIST AHEMABAD 382213 GUJARATI	FACILITY NOT APPROVED FOR THIS LINE	RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1.0X6.0X2.0 ML VIAL,16.0X6.0X2.0 ML VIAL	01/07/1997
872	NDA/MAL/HDP/5075	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	DEXONA TABLETS	DEXAMETHASONE	0.5MG	CADILA HEALTHCARE LIMITED SARKHEJSARKHEJ-BAVLA N.H NO.8A, N.H NO.8A	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET STRIP	01/07/1997
873	NDA/MAL/HDP/5080	GENO PHARMACEUTICALS PVT LTD	HARLEYS UGANDA LIMITED	LOBAK	DICLOFENAC/PARACETAMOL/CHLORZOXAZONE	50MG/325MG/250MG	N/A	GENO PHARMACEUTICALS LTD-PHARMACEUTICAL COMPLEX, TIVIM INDUSTRIAL ESTATE, P.O. KARASWADA, MAPUSA, GOA 403526	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2011

874	NDA/MAL/HDP/5087	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DIABEN TABLETS	GLIBENCLAMIDE	5MG	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	N/A	GMP EXPIRED ON 28/9/2023 FOR BETA LACTAM (PENICILLIN): ORAL DRY POWDERS FOR SUSPENSION HARD GELATIN CAPSULES TABLETS SVP POWDERS (VIALS), NON-BETA LACTAM: ORAL DRY POWDERS (HUMAN & VETERINARY) HARD GELATIN CAPSULES TABLETS ORAL LIQUIDS ORAL POWDERS IN SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED) CREAMS, OINTMENTS, GELS, SUPPOSITORIES, PESSARIES & OVULES	NOT RETAINED	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/1998
875	NDA/MAL/HDP/5093	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	LIPODAR 10	ATORVASTATIN	10MG	N/A	DAR AI DAWANA UR PLANT,AMMAN,JORDAN	N/A	NOT RETAINED	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011

876	NDA/MAL/HDP/5098	RIVA PHARMA FREE ZONE	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DIARIV	DI-IODO HYDROXYQUINOLINE/ PHTHALYL SULPHATHIAZOLE/ HOMATROPINE / STREPTOMYCIN	125MG/ 150MG/ 1MG/ 100MG	N/A	RIVA PHARMA FREE ZONENASR CITY CAIRO EGYPT	N/A	NOT RETAINED	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X60.0 ML BOTTLE	01/07/2011
877	NDA/MAL/HDP/5106	ESAPHARM SRL	BYAMAKA PHARMACEUTICAL COMPANY LTD	LEMONVATE CREAM	CLOBETASOL PROPIONATE	0.05%W/W	N/A	ESAPHARMA SRLVIA DE GASPERI, 13-20066 MELZO (MILAN) ITALY	N/A	NOT RETAINED	ITALY	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	01/07/2003
878	NDA/MAL/HDP/5120	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	GLYFORMIN 500 TABLETS	METFORMIN	500MG	N/A	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER	01/07/1999
879	NDA/MAL/HDP/5123	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	GLYFORMIN 850 TABLETS	METFORMIN	850MG	N/A	REMEDICA LIMITED AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010
880	NDA/MAL/HDP/5126	UNIVERSAL CORPORATION LTD	DELMAW ENTERPRISES LIMITED	KNAC-75	DICLOFENAC	75MG	N/A	UNIVERSAL CORPORATION LIMITED PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE	N/A	NOT RETAINED	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011

881	NDA/MAL/HDP/5132	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	KETROZOL 200 TABLETS	KETOCONAZOLE	200MG	N/A	REMEDICA LIMITED,LIMASSOL INDUSTRIAL ESTATE, AHARNON ST, P.O. BOX 51706,3508 LIMASSOL	MARKETING AUTHORIZATION FOR ORAL KETOCONAZOLE HAS BEEN WITHDRAWN; 18TH AUTHORITY RESOLUTION DATED 20/2/2023	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER	01/07/1997
882	NDA/MAL/HDP/5133	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GONAL-F PEN 900IU/1.5 ML(66MCG/1.5ML)	FOLLITROPIN ALFA	66MCG/1.5 ML	MERCK SERONO S.A. (MSA) - 1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND	MERCK SERONO SPA (BARI)-VIA DELLE MAGNOLIE, 15 (LOC FRAZ ZONA INDUSTRIALE) 70026, MODUGNO, BARI	GMP EXPIRED ON THE 24/09/2023 FOR BIOTECHNOLOGY PRODUCTS: SMALL VOLUME LIQUIDS, SVP LYOPHILISATES IN PRE-FILLED SYRINGES & CATRIDGES	RETAINED	ITALY	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
883	NDA/MAL/HDP/5137	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	KETOREN	KETOCONAZOLE	200MG	N/A	RENE INDUSTRIES LTDPLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	MARKETING AUTHORIZATION FOR ORAL KETOCONAZOLE HAS BEEN WITHDRAWN; 18TH AUTHORITY RESOLUTION DATED 20/2/2023	RETAINED	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/2010

884	NDA/MAL/HDP/5141	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	KETOMAC SHAMPOO	KETOCONAZOLE	2%W/V	N/A	TORQUE PHARMACEUTICALS LTD ISSAPUR P.O DAPPAR 140506	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL LIQUID SOAPS/WASHES	75.0 ML BOTTLE	01/07/2003
885	NDA/MAL/HDP/5144	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	KETOCONAZOLE 200MG	KETOCONAZOLE	200MG	N/A	HOVID BHDLOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MARKETING AUTHORIZATION FOR ORAL KETOCONAZOLE HAS BEEN WITHDRAWN; 18TH AUTHORITY RESOLUTION DATED 20/2/2023	NOT RETAINED	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008
886	NDA/MAL/HDP/5148	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	BETANASE TABLETS	GLIBENCLAMIDE	5MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAI	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X5.0X3.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER, 1.0X2.0X50.0 TABLET BLISTER	01/07/1997
887	NDA/MAL/HDP/5151	SOLVAY PHARMACEUTICALS BV	HARLEYS UGANDA LIMITED	BETASERC	BETAHISTINE	8MG	MYLAN LABORATORIES SASROUTE DE BELLEVILLE, LIEU DIT MAILLARD, 01400 CHATILLON-SUR-	N/A	GMP EXPIRED ON 08/12/2023 FOR Non-Beta Lactam: Hard Gelatin Capsules Tablets	RETAINED	FRANCE	ORAL SOLID ORDINARY TABLETS	4.0X25.0 TABLET BLISTER	01/07/2001

888	NDA/MAL/HDP/5165	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	GRISEOFULVIN 500 TABLETS	GRISEOFULVIN	500MG	N/A	REMEDICA LIMITEDLIMASSOL INDUSTRIAL ESTATE, AHAR	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER	01/07/2003
889	NDA/MAL/HDP/5166	UMEDICA LABORATORIES PVT LTD	VITACARE LIMITED	KETAMINE HYDROCHLORIDE	KETAMINE HYDROCHLORIDE	50MG/ML	N/A	UMEDICA LABORATORIES PVT LTDPLOT NO. 221, 2ND PHASE, GIDC, VAPI 396195, GUJARAT. INDIA.	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	01/07/2004
890	NDA/MAL/HDP/5174	BAYER AG	SURGIPHARM (U) LIMITED	CANESTEN CREAM	CLOTRIMAZOLE	1%W/V	BAYER AG-D-51368 LEVERKU	N/A	FACILITY NOT APPROVED FOR THIS LINE	RETAINED	GERMANY	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/1997
891	NDA/MAL/HDP/5175	JASSEN-CILAG (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	GYNO-DAKTARIN	MICONAZOLE NITRATE	20MG/G	N/A	SPECPHARM HOLDINGS 15TH ROAD HALFWAY HOUSE	N/A	NOT RETAINED	SOUTH AFRICA	VAGINAL CREAMS	1.0X40.0 G TUBE	01/07/1997
892	NDA/MAL/HDP/5178	VHB MEDI SCIENCES LTD	NORVIK ENTERPRISES LIMITED	CARBOTEEN	CARBOPLATIN	450 MG / 45 ML	N/A	VHB MEDI SCIENCES LTDPLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1X50 ML Vial	\N

893	NDA/MAL/ HDP/5183	PHARCO B PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	GYNOZOL VAGINAL CAPSULES	MICONAZOLE NITRATE	400MG	PHARCO PHARMACEUTICALS LTD- KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	N/A	GMP EXPIRED ON 28/9/2023 FOR BETA LACTAM (PENICILLIN): ORAL DRY POWDERS FOR SUSPENSION HARD GELATIN CAPSULES TABLETS SVP POWDERS (VIALS), NON-BETA LACTAM: ORAL DRY POWDERS (HUMAN & VETERINARY) HARD GELATIN CAPSULES TABLETS ORAL LIQUIDS ORAL POWDERS IN SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED) CREAMS, OINTMENTS, GELS, SUPPOSITORIES, PESSARIES & OVULES	RETAINED	EGYPT	VAGINAL SUPPOSITORIES	1.0X3.0 CAPSULE BLISTER	01/07/2000

894	NDA/MAL/ HDP/5184	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	GYNOZOL VAGINAL CREAM	MICONAZOLE NITRATE	2%W/W	PHARCO PHARMACEUTICALS LTD- KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	N/A	GMP EXPIRED ON 28/9/2023 FOR BETA LACTAM (PENICILLIN): ORAL DRY POWDERS FOR SUSPENSION HARD GELATIN CAPSULES TABLETS SVP POWDERS (VIALS), NON-BETA LACTAM: ORAL DRY POWDERS (HUMAN & VETERINARY) HARD GELATIN CAPSULES TABLETS ORAL LIQUIDS ORAL POWDERS IN SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED) CREAMS, OINTMENTS, GELS, SUPPOSITORIES, PESSARIES & OVULES	RETAINED	EGYPT	VAGINAL CREAMS	1.0X40.0 G TUBE	01/07/2000

895	NDA/MAL/HDP/5189	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	HEMOZEBEX	FERROUS SULPHATE+FOLIC ACID+PYRIDOXINE HCL+CYANOCOBALAMIN+ZINC SULPHATE	300MG+1000MCG+1.5MG+7.5MG+61.8MG	N/A	TRIVENI FORMULATIONS LIMITED -PLOT NO 52-54,62-64 ALEAP INDUSTRIAL ESTATE SURAMPALLI (V) VIJAYAWADA A.P	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014
896	NDA/MAL/HDP/5203	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM METRO	METRONIDAZOLE	200MG	N/A	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	UGANDA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER,1.0X250.0 TABLET CONTAINER, 1.0X500.0 TABLET CONTAINER, 1.0X1000.0 TABLET CONTAINER, 1.0X100.0 TABLET	01/07/1997

897	NDA/MAL/HDP/5215	J.B CHEMICALS & PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	METROGYL TABLETS	METRONIDAZOLE	200MG	GLOBELA PHARMA PVT.LTD. 357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	J.B. CHEMICALS AND PHARMACEUTICALS LTD .128/1, GIDC, ANKLESHWAR 393 002, GUJARAT	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, ORAL POWDER IN SACHETS AND BOTTLES. ONCOLOGY: TABLETS, HARD GELATIN CAPSULES	RETAINED	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, 1.0X5.0X2.0X10.0 TABLET BLISTER	01/07/2001
898	NDA/MAL/HDP/5221	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	DICLOFENAC SODIUM	DICLOFENAC SODIUM	75MG/3ML	NINGBO DAHONG YING PHARMA CEUTICAL CO.LTDNO. 396 MINGZHU ROAD, HI-TECH PARK, NINGBO CITY ZHEJIANG	REYOUNG PHARMACEUTICAL CO. LIMITEDNO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: TABLETS, CAPSULES, SVP LIQUIDS	RETAINED	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X3.0 ML AMPOULE,1.0X10.0X3.0 ML AMPOULE	01/07/2006

899	NDA/MAL/HDP/5235	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	DICLORAN DELAYED-RELEASE TABLETS	DICLOFENAC SODIUM	50MG	GLOBELA PHARMA PVT.LTD. 357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)-216-219 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, ORAL POWDER IN SACHETS AND BOTTLES. ONCOLOGY: TABLETS, HARD GELATIN CAPSULES	RETAINED	INDIA	ORAL SOLID RETARD ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER, 5.0X2.0X10.0 TABLET BLISTER	01/07/1997

900	NDA/MAL/ HDP/5250	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCOLIN SYRUP	SALBUTAMOL + AMMONIUM CHLORIDE	2MG/5ML +100MG/5 ML	PHARCO PHARMA CEUTICAL S LTD- KILO 31 ALEXAND RIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXAND RIA EGYPT	N/A	GMP EXPIRED ON 28/9/2023 FOR BETA LACTAM (PENICILLIN): ORAL DRY POWDERS FOR SUSPENSION HARD GELATIN CAPSULES TABLETS SVP POWDERS (VIALS), NON-BETA LACTAM: ORAL DRY POWDERS (HUMAN & VETERINARY) HARD GELATIN CAPSULES TABLETS ORAL LIQUIDS ORAL POWDERS IN SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED) CREAMS, OINTMENTS, GELS, SUPPOSITORIES, PESSARIES & OVULES	RETAINED	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/1998

901	NDA/MAL/HDP/5253	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCOZOL SUSPENSION	BENZOYL METRONIDAZOLE	200MG/5ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	N/A	GMP EXPIRED ON 28/9/2023 FOR BETA LACTAM (PENICILLIN): ORAL DRY POWDERS FOR SUSPENSION HARD GELATIN CAPSULES TABLETS SVP POWDERS (VIALS), NON-BETA LACTAM: ORAL DRY POWDERS (HUMAN & VETERINARY) HARD GELATIN CAPSULES TABLETS ORAL LIQUIDS ORAL POWDERS IN SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED) CREAMS, OINTMENTS, GELS, SUPPOSITORIES, PESSARIES & OVULES	NOT RETAINED	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X120.0 ML BOTTLE	01/07/1998
902	NDA/MAL/HDP/5254	PFIZER LABORATORIES LTD	LABOREX UGANDA LIMITED	FARMORUBICIN RD	EPIRUBICIN HYDROCHLORIDE	10MG	PHARMACIA AND UPJOHN S.P.A.-	N/A	FACILITY NOT GMP COMPLIANT	NOT RETAINED	EUROPE	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL,1.0X10.0 ML VIAL	01/07/1998

903	NDA/MAL/HDP/5255	GLAXOSMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ENO LEMONFRUIT SALT	MULTI-INGREDIENT	MULTI-INGREDIENT	GLAXOS MITHLINECAPE TOWN, S.A	GLAXO SMITH KLINE LTDLIKONI RD, INDUSTRIAL AREA,NAIROBI KENYA	APPLICATION FOR GMP RE-INSPECTION DOES NOT INCLUDE THE PRODUCT LINE	RETAINED	KENYA	ORAL LIQUID ORDINARY EFFERVESCENT POWDERS/GRANULES	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
904	NDA/MAL/HDP/5256	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	DIPROFOS INJECTION	BETAMETHASONE DISODIUM PHOSPHATE + BETAMETHASONE DIPROPIONATE	2MG + 5MG/ML	SCHERING-PLOUGH LABO N.V-- INDUSTRIE PARK 30, ZONE A 2220 HEIST-OP-DEN-BERG	MSD (PTY) LTD LOCATED AT 117 16TH ROAD HALFWAY HOUSE SOUTH AFRICA	NAME OF FACILITY (SCHERING PLOUGH) CHANGED TO ORGANON HEIST BV, APPLICATION REQUIRED TO APPLY FOR VARIATION FOR CHANGE OF NAME.	RETAINED	SOUTH AFRICA	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE	01/07/2001
905	NDA/MAL/HDP/5258	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	ERYMED ORAL SUSPENSION	ERYTHROMYCIN	125MG/5ML	N/A	MEDIPHARM INDUSTRIES (E.A) LTDPLOT 65, KAKAJJO ROAD (BWEYOGERERE)	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2007
906	NDA/MAL/HDP/5259	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CARDINOL TABLET	ATENOLOL	100MG	N/A	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	N/A	NOT RETAINED	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	2.0X14.0 TABLET STRIP	01/07/1997

907	NDA/MAL/ HDP/5263	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	DIPROSALIC OINTMENT	BETAMETHASONE + SALICYLIC ACID	0.5 %W/W + 0.3 %W/W	SCHERING-PLOUGH LABO N.V-- INDUSTRIE PARK 30, ZONE A 2220 HEIST-OP-DEN-BERG	N/A	NAME OF FACILITY (SCHERING PLOUGH) CHANGED TO ORGANON HEIST BV, APPLICATION REQUIRED TO APPLY FOR VARIATION FOR CHANGE OF NAME	RETAINED	BELGIUM	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 MG TUBE	01/07/2001

908	NDA/MAL/HDP/5279	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DOSIN	DOXAZOCIN	2MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2011

909	NDA/MAL/HDP/5282	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	DORFEN	ACECLOFENAC	100MG	N/A	TRIVENI FORMULATIONS LIMITED -PLOT NO 52-54,62-64 ALEAP INDUSTRIAL ESTATE SURAMPALLI (V) VIJAYAWADA A.P	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
910	NDA/MAL/HDP/5290	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	ELOCOM CREAM	MOMETASONE FUROATE	0.1%W/W	SCHERING-PLOUGH LABO N.V--INDUSTRIE PARK 30,B-2220 HEIST-OP-DEN-BERG,BELGIUM	N/A	NAME OF FACILITY (SCHERING PLOUGH) CHANGED TO ORGANON HEIST BV, APPLICATION REQUIRED TO APPLY FOR VARIATION FOR CHANGE OF NAME	RETAINED	BELGIUM	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2000
911	NDA/MAL/HDP/5294	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	ELOCOM OINTMENT	MOMETASONE FUROATE	0.1%W/W	SCHERING-PLOUGH LABO N.V--INDUSTRIE PARK 30,B-2220 HEIST-OP-DEN-BERG,BELGIUM	N/A	NAME OF FACILITY (SCHERING PLOUGH) CHANGED TO ORGANON HEIST BV, APPLICATION REQUIRED TO APPLY FOR VARIATION FOR CHANGE OF NAME	RETAINED	BELGIUM	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/2000

912	NDA/MAL/HDP/5296	VHB MEDI SCIENCES LTD	NORVIK ENTERPRISES LIMITED	ADROSAL	DOXORUBICIN	50MG	N/A	VHB MEDI SCIENCES LTDPLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1X1X50 MG Vial	\N
913	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	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	NOT RETAINED	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/1997

914	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	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	RETAINED	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/1997
915	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	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	RETAINED	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0 CAPSULE CONTAINER	01/07/2005

916	NDA/MAL/HDP/5329	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	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, COATED AND UNCOATED, ORAL LIQUIDS, ORAL REHYDRATION SALTS, HARD GELATIN CAPSULES, TOPICAL SEMI-SOLID PREPARATIONS (CREAMS & OINTMENTS)	NOT RETAINED	KENYA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 CAPSULE CONTAINER	01/07/1997
917	NDA/MAL/HDP/5340	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	HYDRYLLIN SYRUP	DIPHENHYDRAMINE HCL/DEXTROMETHORPHAN HBR	5MG/6.25 MG	THE SEARLE COMPANY-32-KM MULTAN ROAD, LAHORE	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, ORAL LIQUIDS FOR INTERNAL USE	RETAINED	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/1997

918	NDA/MAL/ HDP/5343	PHARCO PHARMACEUTICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CEFORAN 1GM	CEFOTAXIME SODIUM	1GM	PHARCO PHARMACEUTICALS LTD- KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	N/A	FACILITY NOT LICENSED TO MANUFACTURE CEPHALOSPORINS; GMP EXPIRED ON 28/9/2023 FOR BETA LACTAM (PENICILLIN): ORAL DRY POWDERS FOR SUSPENSION HARD GELATIN CAPSULES TABLETS SVP POWDERS (VIALS), NON-BETA LACTAM: ORAL DRY POWDERS (HUMAN & VETERINARY) HARD GELATIN CAPSULES TABLETS ORAL LIQUIDS ORAL POWDERS IN SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED) CREAMS, OINTMENTS, GELS, SUPPOSITORIES, PESSARIES & OVULES	NOT RETAINED	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 1X5ML AMPOULE OF WFI	01/07/2000

919	NDA/MAL/HDP/5345	VHB MEDI SCIENCES LTD	NORVIK ENTERPRISES LIMITED	CEFTRIMAX	SULBACTAM	1G + 0.5G	N/A	VHB MEDI SCIENCES LTDPLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1X20 ML Vial	\N
920	NDA/MAL/HDP/5350	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	CEPHADAR FORTE	CEPHALEXIN	250MG/5ML	N/A	DAR AI DAWANA UR PLANT,AMMAN,JORDAN	N/A	NOT RETAINED	JORDAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2010
921	NDA/MAL/HDP/5351	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	CEPHADAR	CEPHALEXIN MONOHYDRATE	125MG/5ML	N/A	DAR AI DAWANA UR PLANT,AMMAN,JORDAN	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	JORDAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2009
922	NDA/MAL/HDP/5365	NORVATIS PHARMA AG	SURGIPHARM (U) LIMITED	CATAFLAM ORAL DROPS	DICLOFENAC POTASSIUM	15MG/ML	NOVARTIS PHARMA SPA-RUE DE LA CHAPELLE, HUNIGUE	N/A	FACILITY CHANGED TO DELPHARM HUNINGUE SAS, APPLICANT REQUIRED TO APPLY FOR VARIATION FOR CHANGE OF NAME.	NOT RETAINED	FRANCE	ORAL LIQUID ORDINARY DROPS	1.0X15.0 ML BOTTLE	01/07/1997

923	NDA/MAL/HDP/5373	MICRO LABS LTD GOA	PHARMA VILLE LIMITED	LAMIVUDINE	LAMIVUDINE	150MG	N/A	MICRO LABS LTD GOAMICRO LABS LTD PLOT NO. S-155 TO S-159 VERNA INDUSTRIAL ESTATE III VERNA GOA 403722	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2013
924	NDA/MAL/HDP/5388	IPCA LABORATOIES LTD	MEDVIN PHARMA LIMITED	LARINATE-60	ARTESUNATE	60MG	IPCA LABORATORIES LTD,-SEJAVTA, RATLAM 457-002 REG.OFF. 48 KANDIVLI	N/A	FACILITY NOT APPROVED TO MANUFACTURE DRY POWDERS FOR INJECTION	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 1*5 ML SODIUM CHLORIDE INJECTION + 1*1 ML AMPOULE OF SODIUM BICARBONATE	01/07/2011
925	NDA/MAL/HDP/5401	PIRAMAL HEALTHCARE LTD	TATA UGANDA LIMITED	FLUOTHANE 250ML	HALOTHANE	250ML	N/A	PIRAMAL ENTERPRISES LTD - DIGWAL VILLAGE KOHIR MENDAL MEDAK DISTRICT,ANDHRA PRADESH	N/A	NOT RETAINED	INDIA	OTHER SYSTEMIC LIQUID INHALATIONS	1.0X250.0 ML BOTTLE	01/07/2005
926	NDA/MAL/HDP/5405	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	OLANDUS 10	OLANZAPINE	10MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

927	NDA/MAL/HDP/5409	LINCOLN P'CALS LTD	METRO PHARMACEUTICALS LIMITED	MINTO GEL	ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE	150 MG + 150 MG + 25 MG	LINCOLN PARENTERAL LTD .-11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ 382721 TA: KALOL DIST. GANDHIN	LINCOLN PARENTERAL LTD .11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ 382721 TA: KALOL DIST. GANDHINAGAR GUJARAT	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: SMALL VOLUME PARENTERAL SOLUTIONS SMALL VOLUME PARENTERAL POWDERS ORAL LIQUIDS	RETAINED	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X180.0 ML BOTTLE	01/07/2012
928	NDA/MAL/HDP/5420	MICRO LABS LTD	PHARMA VILLE LIMITED	EFAVIRENZ	EFAVIRENZ	200MG	N/A	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X90.0 CAPSULE CONTAINER	01/07/2014
929	NDA/MAL/HDP/5421	MICRO LABS LTD	PHARMA VILLE LIMITED	EFAVIRENZ	EFAVIRENZ	50MG	N/A	MICRO LABS LTD92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X30.0 CAPSULE CONTAINER	01/07/2014
930	NDA/MAL/HDP/5425	ROYAL GROUP	HARLEYS UGANDA LIMITED	PARACETAMOL	PARACETAMOL	500MG	HEBEI (JIHENG GRP) PHARMACEUTICALS CO.LTD-	N/A	GMP EXPIRED ON 30/9/2023 FOR NBL TABLETS	NOT RETAINED	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
931	NDA/MAL/HDP/5437	MEDIPHARM (EA) LTD	MEDIPHARM INDUSTRIES (E.A) LTD	ORALYTE ORANGE	GLUCOSE/NACL/TRISODIUM CITRATE/KCL	13.5G/ 2.6G/ 2.9G/ 1.5G	N/A	MEDIPHARM INDUSTRIES (E.A) LTDPLOT 65, KAKAJJO ROAD, BWEYOGERERE	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	UGANDA	ORAL SOLID ORDINARY POWDERS	1.0X20.8 G SACHET,1.0X10.4 G SACHET	01/07/2011

932	NDA/MAL/HDP/5441	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL NASATAB TABLETS	PARACETAMOL+CHLORPHENIRAMINE+PSEUDOEPHEDRINE	500MG+4MG+60MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	N/A	GMP EXPIRED ON THE 28/9/2023 FOR NON-BETA LACTAM: TABLETS COATED & UNCOATED HARD GELATIN CAPSULES ORAL LIQUIDS SVP LIQUIDS AND POWDER STERILE GELS , (BETA LACTAM) CEPHALOSPORIN: HARD GELATIN CAPSULES DRY POWDER FOR ORAL SUSPENSION SVP POWDER , CORTICOSTEROIDS: OINTMENTS AND CREAMS	RETAINED	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X100.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/2008

933	NDA/MAL/HDP/5444	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	AERIUS TABLETS	DESLORATIDINE	5MG	SCHERING PLOUGH LABO NV-INDUSTRIE PARK 30, ZONE A, 2220, HEIST OP-DEN-BERG	MSD (PTY) LTD-LOCATED AT 117 16TH ROAD HALFWAY HOUSE SOUTH AFRICA	NAME OF FACILITY (SCHERING PLOUGH) CHANGED TO ORGANON HEIST BV, APPLICATION REQUIRED TO APPLY FOR VARIATION FOR CHANGE OF NAME	RETAINED	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X15.0 TABLET BLISTER	01/07/2001
934	NDA/MAL/HDP/5447	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	DICLOFENAC	DICLOFENAC SODIUM	50MG	N/A	TRIVENI FORMULATION LTDPLOT NO.52,53,54,63,62,64, ALEAP INDUSTRIAL ESTATE SURAMPALI, AP-INDIA – 521212	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CARTON,1.0X10.0X10.0 TABLET BLISTER	01/07/2012

935	NDA/MAL/HDP/5453	PHARCO PHARMACEUTICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCONCIL 250MG/5ML	AMOXICILLIN	250MG/5ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	N/A	GMP EXPIRED ON 28/9/2023 FOR BETA LACTAM (PENICILLIN): ORAL DRY POWDERS FOR SUSPENSION HARD GELATIN CAPSULES TABLETS SVP POWDERS (VIALS), NON-BETA LACTAM: ORAL DRY POWDERS (HUMAN & VETERINARY) HARD GELATIN CAPSULES TABLETS ORAL LIQUIDS ORAL POWDERS IN SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED) CREAMS, OINTMENTS, GELS, SUPPOSITORIES, PESSARIES & OVULES	NOT RETAINED	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X10.0 ML BOTTLE	01/07/1998

936	NDA/MAL/HDP/5454	LEBEN LABORATORIES PVT.LTD	MALIX PHARMA (U) LIMITED	MOXILEB	AMOXICILLIN	125MG/5ML	N/A	LEBEN LABORATORIES PVT. LTDPLOT NO. L-4, PHASE-III, MIDC, AKOLA– 444 104 (MS).	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY POWDERS	1.0X100.0 ML BOTTLE	01/07/2010

937	NDA/MAL/ HDP/5456	PHARCO PHARMACEUTICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCONCIL 125MG/5 ML	AMOXICILLIN	125MG/5ML	PHARCO PHARMACEUTICALS LTD- KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	N/A	GMP EXPIRED ON 28/9/2023 FOR BETA LACTAM (PENICILLIN): ORAL DRY POWDERS FOR SUSPENSION HARD GELATIN CAPSULES TABLETS SVP POWDERS (VIALS), NON-BETA LACTAM: ORAL DRY POWDERS (HUMAN & VETERINARY) HARD GELATIN CAPSULES TABLETS ORAL LIQUIDS ORAL POWDERS IN SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED) CREAMS, OINTMENTS, GELS, SUPPOSITORIES, PESSARIES & OVULES	NOT RETAINED	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1998

938	NDA/MAL/HDP/5461	SANOFI AVENTIS	LABOREX UGANDA LIMITED	ARTESUNATE AMODIAQUINE	ARTESUNATE +AMODIAQUINE	25MG+67.5MG	MAPHAR S.A. GROUP OF SANOFI,-KM 10, ROUTE COTIERE 111 QUARTIER, INDUSTRIEL	N/A	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: TABLETS; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	MOROCCO	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X25.0X3.0 TABLET BLISTER,1.0X3.0 TABLET BLISTER	01/07/2008
939	NDA/MAL/HDP/5462	SANOFI AVENTIS	LABOREX UGANDA LIMITED	ARTESUNATE AMODIAQUINE WINTHROP	ARTESUNATE +AMODIAQUINE	50MG+135MG	MAPHAR S.A. GROUP OF SANOFI,-KM 10, ROUTE COTIERE 111 QUARTIER, INDUSTRIEL	N/A	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: TABLETS; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	MOROCCO	ORAL SOLID ORDINARY TABLETS	1.0X25.0X3.0 TABLET BLISTER,1.0X3.0 TABLET BLISTER	01/07/2010
940	NDA/MAL/HDP/5463	SANOFI AVENTIS	LABOREX UGANDA LIMITED	ARTESUNATE AMODIAQUINE WINTHROP	ARTESUNATE +AMODIAQUINE	100MG+270MG	MAPHAR S.A. GROUP OF SANOFI,-KM 10, ROUTE COTIERE 111 QUARTIER, INDUSTRIEL	N/A	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: TABLETS; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	MOROCCO	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X25.0X3.0 TABLET BLISTER,1.0X25.0X6.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X3.0 TABLET BLISTER	01/07/2008

941	NDA/MAL/HDP/5497	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	EXPEN	BENZYLPENICILLIN	1MU	SHANDONG XIER KANGTAI PHARMACEUTICALS CO. LTD PRIVATE-PRIVATE ECONOMY ZONE,XINYAN TOWN, YANZHOU DISTRICT	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	FACILITY FAILED GMP ON THE 31/8/2018 FOR NON-BETA LACTAM DOSAGE FORMS: • SMALL VOLUME PARENTERALS –SOLUTIONS IN AMPOULES	RETAINED	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
942	NDA/MAL/HDP/5639	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	OMASI MED LIMITED	FEROMAX	IRON SUCROSE	20MG/ML	N/A	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)AIRPORT ROAD, DIGDAGA, P.O.BOX: 997, RAS AL KHAIMAH, U.A.E.	N/A	NOT RETAINED	UNITED ARAB EMIRATES	PARENTERAL ORDINARY INFUSION AMPOULES	1.0X5.0X5.0 ML AMPOULE	01/07/2014

943	NDA/MAL/HDP/5642	SECOND PHARMACEUTICALS	SINO AFRICA MEDICINES & HEALTH LTD	FORTIFIED PROCAINE PENICILLIN	FORTIFIED PROCAINE PENICILLIN	4MEGA UNITS	SHIJIAZHUANG PHARMA GROUP, ZHOUGNUO, PHARMACEUTICAL-N0188 GONGNONG ROAD, SHIJIAZHUANG CITY HEBEI PROVINCE, PEOPLE'S REP. CHINA	N/A	GMP EXPIRED, APPLICANT REQUIRED TO APPLY FOR VARIATION TO UPDATE MANUFACTURER DETAILS TO CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) COMPANY LIMITED-NO. 88 YANGZI ROAD, ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, SHIJIAZHUANG, HEBEI, PEOPLE'S REPUBLIC OF CHINA, WORKSHOP 406 AND 407	NOT RETAINED	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 VIAL CARTON,1.0X50.0 VIAL CARTON	01/07/1998
944	NDA/MAL/HDP/6047	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	HERTRAZ 150	TRASTUZUMAB (R-DNA ORIGIN)	150MG	N/A	BIOCON LIMITEDSPECIAL ECONOMIC ZONE, PLOT NO.2-4, PHASE IV, BOMMASANDRA-JIGANI LINK ROAD BANGALORE-560 099	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES	1.0X150.0 MG VIAL ,1X10ML VIAL OF WFI	01/07/2017

945	NDA/MAL/HDP/6053	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	GLIMEPIRIDE	GLIMEPIRIDE	4MG	LEK S.S POLAND UI PODLIPIE 16 95-01O STRYKO	N/A	GMP EXPIRED ON THE 23/8/2023 FOR NBL TABLETS AND CAPSULES	NOT RETAINED	POLAND	ORAL SOLID ORDINARY TABLETS	1.0X9.0X10.0 TABLET BLISTER	01/07/2017
946	NDA/MAL/HDP/6054	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	GLIMEPIRIDE	GLIMEPIRIDE	1MG	LEK S.S POLAND UI PODLIPIE 16 95-01O STRYKO	N/A	GMP EXPIRED ON THE 23/8/2023 FOR NBL TABLETS AND CAPSULES	NOT RETAINED	POLAND	ORAL SOLID ORDINARY TABLETS	1.0X9.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2012
947	NDA/MAL/HDP/6073	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MILGA	BENFOTIAMINE + PYRIDOXINE + CYANOCOBALAMIN	40MG + 60MG + 20MCG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS FOR INTERNAL USE TABLETS (COATED AND UNCOATED) HARD GELATIN CAPSULES ORAL POWDER FOR SUSPENSION OINTMENTS, CREAMS AND GELS	NOT RETAINED	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017

948	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	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2017

949	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	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2017

950	NDA/MAL/HDP/6115	I-CARE PHARMA LTD	SUPER MEDIC LTD	TIZOL	TINIDAZOLE	500MG	WEST COAST PHARMA CEUTICAL WORKS LTD1143, MELDI ESTATE,N R PRASANG PARTY PLOT GO	MEDICO REMEDIES PVT LTD,.8 & 9 DEWAN AND SONS, UDYOG NAGAR, PALGHAR, DIST. THANE-401404, MAHARSHITRA	GMP EXPIRED	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1X4 TABLET Strip	01/07/1997
951	NDA/MAL/HDP/6116	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	ZOLEDRO-DENK 4MG/5ML	ZOLEDRONIC ACID	4MG/5ML	HAMELN PHARMA CEUTICAL S GMBH-LANGES FELD 13 31789 HAMELN	N/A	NAME OF FACILITY CHANGED TO SIEGFRIED HAMELN GMBH. APPLICANT REQUIRED TO APPLY FOR VARIATION FOR CHANGE OF NAME.	RETAINED	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLE S	1.0X5.0 ML VIAL	01/07/2017

952	NDA/MAL/HDP/6120	NATIONAL HEALTHCARE PVT LTD	MALIX PHARMA (U) LIMITED	KMINE	KETAMINE HYDROCHLORIDE	50MG/ML	NATIONAL HEALTHCARE PVT LTD-CHHATAPIPRA 3 BARA NEPAL	N/A	GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED & UNCOATED), HARD GELATIN CAPSULES, SMALL VOLUME PARENTERAL LIQUIDS (VIALS & AMPOULES), EYE/EAR DROPS, LYOPHILIZED POWDERS FOR INJECTION, , BETA LACTAM (PENICILLIN): TABLETS (COATED & UNCOATED), HARD GELATIN CAPSULES, SMALL VOLUME PARENTERAL POWDERS , BETA LACTAM (CEPHALOSPORIN): SMALL VOLUME PARENTERAL POWDERS	NOT RETAINED	NEPAL	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	01/07/2017
953	NDA/MAL/HDP/6133	UMEDICA LABORATORIES PVT LTD	VITACARE LIMITED	RILIF-100	ACECLOFENAC	100MG	N/A	UMEDICA LABORATORIES PVT, VAPIPLOT 221, GIDC II, VAPI-396195, INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016

954	NDA/MAL/HDP/6135	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TRIXONE-S	CEFTRIAXONE SODIUM+SULBACTAM	1000MG+500MG	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY	ZEISS PHARMA LIMITED-IGC,SIDCO, PHASE II, SAMBA, JAMMU - 184121,(J&K)	REYOUNG NOT APPROVED FOR THE MANUFACTURE OF THE CEPHALOSPORIN LINE.	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL	01/07/2016
955	NDA/MAL/HDP/6136	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	NUCOXIA 120	ETORICOXIB	120MG	CADILA HEALTHCARE LIMITED - PLOT 203-213, KUNDAIM INDUSTRIAL ESTATE	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
956	NDA/MAL/HDP/6138	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	NUCOXIA 60	ETORICOXIB	60MG	CADILA HEALTH CARE LIMITED - PLOT 203-213, KUNDAIM INDUSTRIAL ESTATE	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
957	NDA/MAL/HDP/6140	CLARIS OTSUKA LIMITED	REDDYS PHARMA LIMITED	KIDROLYTE	SODIUM ACETATE + DIBASIC POTASSIUM PHOSPHATE + MAGNESSIUM CHLORIDE + DEXTROSE MONONOHYDRATE + POTASSIUM CHLORIDE	(0.32G + 0.026G + 0.031G + 5.50G + 0.13G)/100 ML	CLARIS OTSUKA LIMITED .- VILLAGE VASANA CHACHARWADI TAL:SANAD DIST - AHMEDABAD 382 213	N/A	NAME OF FACILITY CHANGED TO OTSUKA PHARMACEUTICAL PVT INDIA LTD. CLIENT REQUIRED TO APPLY FOR A VARIATION	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2016

958	NDA/MAL/HDP/6144	NATIONAL HEALTHCARE PVT LTD	MALIX PHARMA (U) LIMITED	NIKO	PARACETAMOL	500MG	NATIONAL HEALTHCARE PVT LTD-CHHATAPIPRA 3 BARA	N/A	GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED & UNCOATED), HARD GELATIN CAPSULES, SMALL VOLUME PARENTERAL LIQUIDS (VIALS & AMPOULES), EYE/EAR DROPS, LYOPHILIZED POWDERS FOR INJECTION, , BETA LACTAM (PENICILLIN): TABLETS (COATED & UNCOATED), HARD GELATIN CAPSULES, SMALL VOLUME PARENTERAL POWDERS , BETA LACTAM (CEPHALOSPORIN): SMALL VOLUME PARENTERAL POWDERS	NOT RETAINED	NEPAL	ORAL SOLID ORDINARY TABLETS	1.0X10.0X100.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/2016

959	NDA/MAL/HDP/6149	AMANTA HEALTHCARE LTD	PHARMA VILLE LIMITED	SODIUM CHLORIDE INFUSION	SODIUM CHLORIDE	0.9%W/V	N/A	AMANTA HEALTHCARE LIMITED (FORMERLY KNOWN AS MARCK BIOSCIENCES LTD)PLOT NO. 876, N.H. NO. 8, VILLAGE - HARIYALA, DIST - KHEDA 387411, GUJARAT	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2016
960	NDA/MAL/HDP/6159	NORVATIS ACCESS	SURGIPHARM (U) LIMITED	AMLODIPINE	AMLODIPINE	10MG	LEK PHARMACEUTICALS .D.D - VEROVSKOVA 57, 1526 LJUBLJANA SLOVENIA	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: TABLETS HARD GELATIN CAPSULES LIQUIDS (NASAL SPRAYS)	NOT RETAINED	SLOVENIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/2016
961	NDA/MAL/HDP/6161	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	DICLAC	DICLOFENAC SODIUM	150MG	SALUTAS PHARMA GMBH-OTTO-VON-GUERICKE-ALLEE	N/A	GMP EXPIRED ON THE 12/11/2022 FOR HARD GELATIN CAPSULES AND TABLETS	NOT RETAINED	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016

962	NDA/MAL/HDP/6166	NATIONAL HEALTHCARE PVT LTD	MALIX PHARMA (U) LIMITED	GMICIN	GENTAMICIN SULPHATE	0.3%W/V	NATIONAL HEALTHCARE PVT LTD-CHHATAPIPRA 3 BARA	N/A	GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED & UNCOATED), HARD GELATIN CAPSULES, SMALL VOLUME PARENTERAL LIQUIDS (VIALS & AMPOULES), EYE/EAR DROPS, LYOPHILIZED POWDERS FOR INJECTION, , BETA LACTAM (PENICILLIN): TABLETS (COATED & UNCOATED), HARD GELATIN CAPSULES, SMALL VOLUME PARENTERAL POWDERS , BETA LACTAM (CEPHALOSPORIN): SMALL VOLUME PARENTERAL POWDERS	NOT RETAINED	NEPAL	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE	01/07/2016

963	NDA/MAL/HDP/6171	ROTEXMEDICA GMBH ARZNEIMITTELWERK	GITTOES PHARMACEUTICALS LIMITED	SUXAMETHONIUM CHLORIDE	SUXAMETHONIUM CHLORIDE	50MG/ML	PANPHARMA GMBH-BUNSENSTRASSE 4, 22946 TRITTAU	N/A	GMP EXPIRED ON 21/10/2023 FOR NON-BETA LACTAM: SMALL VOUME LIQUIDS (ASEPTICALLY PREPARED), LARGE VOLUME LIQUIDS (TERMINALLY STERILIZED)	RETAINED	GERMANY	PARENTERAL ORDINARY DRY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2016
964	NDA/MAL/HDP/6173	CIPLA LTD..	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	MONTAIR 5	MONTELUKAST SODIUM	5MG	N/A	CIPLA LTD ---L139 TO L-146 VERNA INDUSTRIAL ESTATE VERNA SALCETTE GOA 403 722	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016
965	NDA/MAL/HDP/6174	PANPHARMA GMBH	GITTOES PHARMACEUTICALS LIMITED	FLUPHENAZINE DECANOATE INJECTION USP 25MG/ML	FLUPHENAZINE DECANOATE	25MG/ML	PANPHARMA GMBH-BUNSENSTRASSE 4, 22946 TRITTAU	N/A	GMP EXPIRED ON 21/10/2023 FOR NON-BETA LACTAM: SMALL VOUME LIQUIDS (ASEPTICALLY PREPARED), LARGE VOLUME LIQUIDS (TERMINALLY STERILIZED)	RETAINED	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2016

966	NDA/MAL/HDP/6187	ALLY PHARMA OPTIONS PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	FLOXCIP	CIPROFLOXACIN HYDROCHLORIDE	500MG	MAXHEAL PHARMACEUTICALS INDIA LTDJ-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR-401506, DIST.THANE, MARAHA	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328 - 1330, VILLAGE MANPURA. TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH, 174101 - INDIA	FAILED GMP	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1X10X10 TABLET Blister	01/07/2016
967	NDA/MAL/HDP/6188	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	GIZLAN 150	IRBESARTAN	150MG	N/A	DAR AI DAWANA UR PLANT,AMMAN,JORDAN	N/A	NOT RETAINED	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
968	NDA/MAL/HDP/6189	UNEED GLOBAL GROUP LIMITED	ABACUS PHARMA (AFRICA) LIMITED	WORMEE-4	ALBENDAZOLE	400MG	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR-401506, DIST.THANE, MARAHASHTRA, INDIA	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	MAXHEAL FAILED GMP ON THE 14/5/2019 FOR NON BETA-LACTAM: TABLETS (COATED AND UNCOATED), EXTERNAL PREPARATIONS (CREAMS AND OINTMENTS), HARD GELATIN CAPSULES, DRY POWDER FOR ORAL SUSPENSION, ORAL LIQUIDS	RETAINED	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0 TABLET BLISTER	01/07/2016

969	NDA/MAL/HDP/6191	AMOUN PHARMACEUTICALS COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	KAPRON AMPOULE	TRANEXAMIC ACID	500MG/5ML	AMOUN PHARMACEUTICAL CO. S.A.E-1ST INDUSTRIAL ZONE A, PLOTS NO. 1B,2,3,4, 5 BLOCK 13015, EL-OBOUR CITY, KALYOUBIA CAIRO EGYPT	N/A	GMP EXPIRED ON THE 29/9/2023 FOR NON-BETA LACTAM: HARD GELATIN CAPSULES SOFT GELATIN CAPSULES TABLETS (COATED & UNCOATED) DRY POWDERS FOR SUSPENSION POWDERS PACKED IN SACHETS SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED LIQUIDS) SMALL VOLUME PARENTERAL – (ASEPTICALLY PREPARED POWDERS) EYE DROPS (ASEPTICALLY PREPARED) ORAL LIQUIDS NON-STERILE NASAL DROPS EXTERNAL SEMI-SOLIDS (CREAMS & GELS)	RETAINED	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X6.0X5.0 ML AMPOULE	01/07/2016

970	NDA/MAL/HDP/6196	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD	SURGIPHARM (U) LIMITED	MORPHINE SULPHATE FRESENIUS	MORPHINE SULPHATE	15MG/ML	N/A	FRESENIUS KABI MANUFACTURING SA (PTY) LTD6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH	N/A	NOT RETAINED	SOUTH AFRICA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2016
971	NDA/MAL/HDP/6197	ALLY PHARMA OPTIONS PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	NYSTATIN	NYSTATIN	100,000 IU	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR-401506, DIST.THANE, MARAHASHTRA, INDIA	MEDICAMEN BIOTECH LTD .-SP-1192 A&B PHASE IV INDUSTRIAL AREA BHIWADI 301019 DIST. ALWAR (RAJASTHAN)	FAILED GMP ON THE 14/5/2019 FOR NON BETA-LACTAM: TABLETS (COATED AND UNCOATED), EXTERNAL PREPARATIONS (CREAMS AND OINTMENTS), HARD GELATIN CAPSULES, DRY POWDER FOR ORAL SUSPENSION, ORAL LIQUIDS	NOT RETAINED	INDIA	VAGINAL TABLETS	1.0X14.0 PESSARY STRIP	01/07/2016
972	NDA/MAL/HDP/6203	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DEROX-5	AMLODIPINE BESILATE	5MG	HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH ,	N/A	FACILITY NOT APPROVED TO MANUFACTURE NBL TABLETS	RETAINED	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/2016

973	NDA/MAL/HDP/6204	AMANTA HEALTHCARE LTD	PHARMA VILLE LIMITED	GLUCOSE 5% I.V	GLUCOSE	5%W/V	N/A	AMANTA HEALTHCARE LIMITED (FORMERLY KNOWN AS MARCK BIOSCIENCES LTD)PLOT NO. 876, N.H. NO. 8, VILLAGE - HARIYALA, DIST - KHEDA 387411, GUJARAT	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2016
974	NDA/MAL/HDP/6215	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	NEORAL 25	CYCLOSPORIN	25MG	R P SCHERER GMBH & CO. EBERBACH BALEN-R P SCHERER	N/A	GMP EXPIRED ON THE 10/4/2008 FOR NBL SG CAPS	RETAINED	GERMANY	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X5.0X10.0 CAPSULE BLISTER	01/07/2016
975	NDA/MAL/HDP/6216	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	NEORAL 100	CYCLOSPORIN	100MG	R P SCHERER GMBH & CO. EBERBACH BALEN-R P SCHERER	N/A	GMP EXPIRED ON THE 10/4/2008 FOR NBL SG CAPS	RETAINED	GERMANY	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X5.0X10.0 CAPSULE BLISTER	01/07/2016
976	NDA/MAL/HDP/6223	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROPROST- RT	LATANOPROST	0.005%W/V	N/A	AUROLAB.SIVAGANGAI MAIN ROAD, VEERAPANJAN, MADURAI 625 020 TAMIL INDIA	N/A	NOT RETAINED	INDIA	OPHTHALMIC DROPS	1.0X2.5 ML BOTTLE	01/07/2016

977	NDA/MAL/HDP/6232	FREDUN PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	H-CURE	LANSOPRAZOLE + CLARITHROMYCIN + TINIDAZOLE	30MG + 250MG + 500MG	N/A	FREDUN PHARMACEUTICALS LTDVEOOR PALGHAR (E) 401 404	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X7.0X6.0 TABLET BLISTER (BLISTER CONTAINS 2CAPSULES OF LANSOPRAZOLE + 2 TABLETS OF CLARITHROMYCIN + 2 TABLETS OF TINIDAZOLE)	01/07/2016
978	NDA/MAL/HDP/6245	BIOLOGICAL E. LTD	ABACUS PHARMA (AFRICA) LIMITED	COSCOPIN LINCTUS	NOSCAPINE + CHLORPHENIRAMINE 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 DEHRAD	N/A	GMP EXPIRED ON 1/10/2023 FOR NBL ORAL LIQUIDS	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2016

979	NDA/MAL/HDP/6249	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL METRONIDAZOLE - 200 TABLETS	METRONIDAZOLE	200MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	N/A	GMP EXPIRED ON THE 28/9/2023 FOR NON-BETA LACTAM: TABLETS COATED & UNCOATED HARD GELATIN CAPSULES ORAL LIQUIDS SVP LIQUIDS AND POWDER STERILE GELS , (BETA LACTAM) CEPHALOSPORIN: HARD GELATIN CAPSULES DRY POWDER FOR ORAL SUSPENSION SVP POWDER , CORTICOSTEROIDS: OINTMENTS AND CREAMS	RETAINED	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
980	NDA/MAL/HDP/6267	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	TRAMADOL DENK 50	TRAMADOL HYDROCHLORIDE	50MG	LOSAN PHARMA GMBH OTTO-HAHN-STR 13	N/A	GMP EXPIRED ON 09/12/2023 FOR Non-Beta Lactam: Tablets	RETAINED	GERMANY	ORAL SOLID ORDINARY EFFERVESCENT TABLETS	1.0X10.0 TABLET BOTTLE	01/07/2016

981	NDA/MAL/ HDP/6284	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	PAEDIATRIC PARACETAMOL ORAL SOLUTION	PARACETAMOL	120MG/5ML	N/A	CIPLA LTD INDORE PLOT NO. 9 AND 10, INDORE SPECIAL ECONOMIC ZONE, PHASE –II, PITHAMPUR, DISTRICT DHAR, 454 775, MADHYA PRADESH - INDIA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1X100 ML Bottle	\N

982	NDA/MAL/HDP/6292	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VENAXAN 250 MG	LEVOFLOXACIN HEMIHYDRATE	250MG	SOUTH EGYPT DRUG INDUSTRIES CO-1ST INDUSTRIAL ZONE, 6 OCTOBER CITY, EGYPT.	N/A	GMP EXPIRED ON THE 28/09/2023 FOR NON-BETA LACTAM: ORAL VETERINARY POWDERS TABLETS POWDERS FOR ORAL SUSPENSION HARD GELATIN CAPSULES ORAL LIQUIDS OINTMENTS, CREAMS & GELS SUPPOSITORIES STERILE LIQUIDS IN AMPOULES POWDER SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED IN PLASTIC AMPOULE) SMALL VOLUME LYOPHILIZED POWDER (ASEPTICALLY PREPARED) SOFT GELATIN CAPSULES , BIOLOGICALS (SVP): RECOMBINANT INSULIN	RETAINED	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X5.0 TABLET BLISTER	27/11/2018

983	NDA/MAL/HDP/6298	UNOSOURCE PHARMA LTD.	MEDVIN PHARMA LIMITED	OFLOTECH-O SUSPENSION	OFLOXACIN + ORNIDAZOLE	50MG + 125MG	N/A	AKUMS DRUGS & PHARMACEUTICALS LTD19-20,21, SECTOR 6-4, SIDCUL, IIE, RANIPUR HARIDWAR-249403	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X60.0 ML BOTTLE	28/03/2019
984	NDA/MAL/HDP/6300	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	N/A	GMP EXPIRED ON 1/10/2023 FOR BETA LACTAM (PENICILLINS): TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SVP-POWDERS	RETAINED	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER, 1.0X2.0X10.0 CAPSULE BLISTER, 1.0X10.0X10.0 CAPSULE BLISTER	31/01/2018
985	NDA/MAL/HDP/6305	YELURI FORMULATIONS PVT LTD	SUPER MEDIC LTD	ELMOX-CV 375	AMOXICILLIN TRIHYDRATE +CLAVULANATE POTASSIUM	250MG+125MG	N/A	YELURI FORMULATIONS PVT. LTDSY. NO. 296 / 7 / 6 IDA BOLLARAM,MEDAK DIST.502325, TELANGANA,INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X5.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER	01/07/2018

986	NDA/MAL/HDP/6315	SQUARE PHARMACEUTICALS LTD.PABNA UNIT	GAMA PHARMACEUTICALS (U) LIMITED	ACE SYRUP, 100ML	PARACETAMOL	120MG/5ML	N/A	SQUARE PHARMACEUTICAL LIMITED (PABNA UNIT)SQUARE ROAD, SALGARIA PABNA-6600 BANGLADESH	N/A	NOT RETAINED	BANGLADESH	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	31/01/2018
987	NDA/MAL/HDP/6316	SQUARE PHARMACEUTICALS LTD.PABNA UNIT	GAMA PHARMACEUTICALS (U) LIMITED	OSMOLAX	LACTULOSE	3.40G/5ML	N/A	SQUARE PHARMACEUTICAL LIMITED (PABNA UNIT)SQUARE ROAD, SALGARIA PABNA-6600 BANGLADESH	N/A	NOT RETAINED	BANGLADESH	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE	25/07/2018
988	NDA/MAL/HDP/6317	YELURI FORMULATIONS PVT LTD	SUPER MEDIC LTD	ELMOX-CV 1000	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	875MG + 125MG	N/A	YELURI FORMULATIONS PVT. LTDSY. NO. 296 / 7 / 6 IDA BOLLARAM,MEDAK DIST.502325, TELANGANA,INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X5.0 TABLET BLISTER,1.0X3.0X5.0 TABLET BLISTER	01/07/2018
989	NDA/MAL/HDP/6325	LEBEN LABORATORIES PVT. LTD.	MALIX PHARMA (U) LIMITED	PZQ TABLET	PRAZIQUANTEL	600MG	N/A	LEBEN LABORATORIES PVT LTD -L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X4.0 TABLET BLISTER,4.0X10.0 TABLET BLISTER	29/11/2017

990	NDA/MAL/HDP/6326	RAJESHI PLASTICS	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ONCOGEM 1000	GEMCITABINE HYDROCHLORIDE	1000MG	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	N/A	FACILITY NOT APPROVED FOR THIS LINE; FACILITY LICENSED TO MANUFACTURE ORAL CYTOTOXICS	RETAINED	INDIA	PARENTERAL ORDINARY I V VIALS	1.0X1000.0 MG VIAL	27/11/2018
991	NDA/MAL/HDP/6335	BILTHOVEN BIOLOGICALS	NORVIK ENTERPRISES LIMITED	POLIOMYELITIS VACCINE	POLIOMYELITIS VIRUS TYPE 1, INACTIVATED + POLIOMYELITIS VIRUS TYPE 2, INACTIVATED + POLIOMYELITIS VIRUS TYPE 3, INACTIVATED	40 DU + 8 DU + 32 DU / 0.5ML	BILTHOVEN BIOLOGICALS BV-ANTONIE VAN LEEUWENHOEKLAAN, 9-13,3721 MA BILTHOVEN	N/A	GMP EXPIRED ON THE 13/02/2020 FOR SMALL VOLUME LIQUIDS - POLIO VACCINE	RETAINED	NETHERLANDS	PARENTERAL ORDINARY VIALS	1.0X0.5 ML VIAL	28/03/2019
992	NDA/MAL/HDP/6336	BILTHOVEN BIOLOGICALS	NORVIK ENTERPRISES LIMITED	POLIOMYELITIS VACCINE MULTIDOSE	POLIOMYELITIS VIRUS TYPE 1, INACTIVATED + POLIOMYELITIS VIRUS TYPE 2, INACTIVATED + POLIOMYELITIS VIRUS TYPE 3, INACTIVATED	40 DU + 8 DU + 32 DU / 0.5ML	BILTHOVEN BIOLOGICALS BV-ANTONIE VAN LEEUWENHOEKLAAN, 9-13,3721 MA BILTHOVEN	N/A	GMP EXPIRED ON THE 13/02/2020 FOR SMALL VOLUME LIQUIDS - POLIO VACCINE	RETAINED	NETHERLANDS	PARENTERAL ORDINARY VIALS	1.0X2.5 ML VIAL	28/03/2019

993	NDA/MAL/HDP/6339	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OXY-POL	OXYTETRACYCLINE HCL + POLYMYXIN B SULPHATE	5MG+10000IU/G	EGYPTIAN INT.PHARMACEUTICAL INDUSTRIES CO. E.I.P.C.O - 10TH OF RAMADAN CITY – INDUSTRIAL AREA B1- P.O BOX: 149 TENTH - EGYPT	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE	30/05/2018

994	NDA/MAL/HDP/6342	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIFENAC EYE DROPS	DICLOFENAC SODIUM SALT	1MG/ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B EGYPT	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	30/05/2018

995	NDA/MAL/ HDP/6345	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MAGNABI OTIC 600MG VAIL	AMOXYCILLIN SODIUM/ CLAVULANAT E POTASSIUM	500MG/10 0MG	SEDICO PHARMA CEUTICAL CO.-1ST INDUSTRI AL ZONE 6 TH OCTOBER CITY GIZA,EGY PT	N/A	GMP EXPIRED ON THE 28/09/2023 FOR NON-BETA LACTAM: ORAL VETERINARY POWDERS TABLETS POWDERS FOR ORAL SUSPENSION HARD GELATIN CAPSULES ORAL LIQUIDS OINTMENTS, CREAMS & GELS SUPPOSITORIES STERILE LIQUIDS IN AMPOULES POWDER SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED IN PLASTIC AMPOULE) SMALL VOLUME LYOPHILIZED POWDER (ASEPTICALLY PREPARED) SOFT GELATIN CAPSULES , BIOLOGICALS (SVP): RECOMBINANT INSULIN	RETAINED	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	25/07/2018

996	NDA/MAL/HDP/6357	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	NUCOXIA 90	ETORICOXIB	90MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/03/2019
997	NDA/MAL/HDP/6358	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYROVA 20	ROSUVASTATIN CALCIUM	20MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	27/03/2019
998	NDA/MAL/HDP/6360	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS LTD	ETOCOXX 90MG	ETORICOXIB	90MG	SUN PHARMACEUTICAL INDUSTRIES LIMITEDSUN HOUSE, PLOT NO. 201 B/1 WESTERN EXPRESS HIGHWAY, GOREGA	N/A	FACILITY ADDRESS NOT FOUND	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1X7 TABLET Blister	31/01/2018

999	NDA/MAL/HDP/6365	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	EASY PILL	LEVONORGESTREL	1.5MG	N/A	CORONA REMEDIES PVT LTDCORONA HOUSE, C MONDEAL BUSINESS PARK, NR. GURUDWARA GOVINDDHAM LANE, SG HIGHWAY, THALTEJ, AHMEDABAD 380059, GUJARAT	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0 TABLET BLISTER	27/03/2019
1000	NDA/MAL/HDP/6368	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS LTD	ETOCOXX 120MG	ETORICOXIB	120MG	SUN PHARMACEUTICAL INDUSTRIES LIMITEDSUN HOUSE, PLOT NO. 201 B/1 WESTERN EXPRESS HIGHWAY, GOREGA	N/A	FACILITY ADDRESS NOT FOUND	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1X7 TABLET Blister	31/01/2018

1001	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.	N/A	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: DRY POWDER FOR ORAL SUSPENSION TABLETS CAPSULES , BETA-LACTAM (CEPHALOSPORIN): DRY POWDER FOR ORAL SUSPENSION	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X60.0 ML BOTTLE	31/01/2018

1002	NDA/MAL/HDP/6380	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	N/A	GMP EXPIRED ON THE 28/09/2023 FOR NON-BETA LACTAM: ORAL VETERINARY POWDERS TABLETS POWDERS FOR ORAL SUSPENSION HARD GELATIN CAPSULES ORAL LIQUIDS OINTMENTS, CREAMS & GELS SUPPOSITORIES STERILE LIQUIDS IN AMPOULES POWDER SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED IN PLASTIC AMPOULE) SMALL VOLUME LYOPHILIZED POWDER (ASEPTICALLY PREPARED) SOFT GELATIN CAPSULES , BIOLOGICALS (SVP): RECOMBINANT INSULIN	RETAINED	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.2 G VIAL	25/07/2018

1003	NDA/MAL/HDP/6389	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	METRONIDAZOLE BP	METRONIDAZOLE	0.5%W/V	N/A	ABARIS HEALTHCARE PVT. LTD-PLOT NO: 1407-1411 VILLAGE: RAJPUR TALUKA: KADI, DIST.: MEHSANA 382 740, GUJARAT INDIA	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	28/03/2018
1004	NDA/MAL/HDP/6394	ADWIA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DANSET	ONDANSETRON HYDROCHLORIDE	8MG	N/A	ADWIA 1ST INDUSTRIAL ZONE, A1, 10TH OF RAMADAN CITY	N/A	NOT RETAINED	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X1.0X3.0X4.0 ML AMPOULE,1.0X1.0X4.0 ML AMPOULE	28/05/2019
1005	NDA/MAL/HDP/6396	NVS KENYA LTD	SURGIPHARM (U) LIMITED	LETROZOLE 2.5	LETROZOLE	2.5MG	N/A	NOVARTIS PHARMA STEIN AG.SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	N/A	NOT RETAINED	SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
1006	NDA/MAL/HDP/6406	LINCOLN PARENTERAL LIMITED	METRO PHARMACEUTICALS LIMITED	LIDOCAINE INJECTION BP 2%	LIDOCAINE HYDROCHLORIDE	2% W/V	LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR	N/A	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: SMALL VOLUME PARENTERAL SOLUTIONS SMALL VOLUME PARENTERAL POWDERS ORAL LIQUIDS	RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1.0X25.0X30.0 ML VIAL, 1.0X5.0X20.0ML VIAL	27/11/2018

1007	NDA/MAL/HDP/6408	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	N/A	GMP EXPIRED ON 28/09/2023 FOR NON-BETA LACTAM: STERILE EYE DROPS (ASEPTICALLY PREPARED) STERILE EYE OINTMENTS (ASEPTICALLY PREPARED) NON-STERILE NASAL DROPS NON-STERILE METERED DOSE NASAL SPRAYS OINTMENTS, CREAMS & LOTIONS	RETAINED	JORDAN	NASAL TOPICAL METERED DOSE AEROSOLS	1.0X10.0 ML BOTTLE	28/05/2019

1008	NDA/MAL/ HDP/6412	PHARCO PHARMACEUTICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BUCCAZOLE ORAL GEL	MICONAZOLE	2%W/W	PHARCO PHARMACEUTICALS LTD- KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	N/A	GMP EXPIRED ON 28/9/2023 FOR BETA LACTAM (PENICILLIN): ORAL DRY POWDERS FOR SUSPENSION HARD GELATIN CAPSULES TABLETS SVP POWDERS (VIALS), NON-BETA LACTAM: ORAL DRY POWDERS (HUMAN & VETERINARY) HARD GELATIN CAPSULES TABLETS ORAL LIQUIDS ORAL POWDERS IN SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED) CREAMS, OINTMENTS, GELS, SUPPOSITORIES, PESSARIES & OVULES	NOT RETAINED	EGYPT	ORAL TOPICAL GELS AND SOLS	1.0X20.0 G TUBE	01/07/2017

1009	NDA/MAL/HDP/6425	GETZ PHARMA PVT LIMITED	MU PHARMA CO -SMC LIMITED	CLARITEK	CLARITHROMYCIN	500MG	N/A	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	N/A	NOT RETAINED	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	25/11/2021
1010	NDA/MAL/HDP/6445	F. HOFFMANN-LA ROCHE LTD	LABOREX UGANDA LIMITED	XELODA	CAPECITABINE	500MG	PRODUCTOS ROCHE S.A DE CV -TOLUCA	N/A	GMP EXPIRED ON 9/9/2017 FOR • TABLETS	NOT RETAINED	MEXICO	ORAL SOLID ORDINARY TABLETS	1.0X12.0X10.0 TABLET BLISTER	01/07/2017
1011	NDA/MAL/HDP/6446	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	SNIP PAIN	PARACETAMOL + CAFFEINE	500MG + 50MG	MEDOCHEMIE LTD-CENTRAL FACTORY A-1-10 CONSTANTINOUPOLEUS STREET	N/A	FACILITY NOT APPROVED FOR THIS LINE	RETAINED	CYPRUS	ORAL SOLID RETARD FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/01/2019

1012	NDA/MAL/ HDP/6448	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIZOLONE-DEPOT 40 MG/ 1 ML VIAL	METHYLPREDNISOLONE ACETATE	40 MG/ ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B1,EGYPT	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	PARENTERAL ORDINARY VIALS	1.0X1.0X1.0 ML VIAL	25/07/2018

1013	NDA/MAL/HDP/6449	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES	GAMA PHARMACEUTICALS (U) LIMITED	DESLORAT SYRUP	DESLORATIDINE	0.5MG/ML	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS FOR INTERNAL USE TABLETS (COATED AND UNCOATED) HARD GELATIN CAPSULES ORAL POWDER FOR SUSPENSION OINTMENTS, CREAMS AND GELS	RETAINED	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2017
1014	NDA/MAL/HDP/6452	SANDOZ GMBH .	SURGIPHARM (U) LIMITED	AMLODIPINE 5MG TABLETS	AMLODIPINE	5MG	LEK PHARMACEUTICALS DD-VEROVSKOVA 57, SI-1526 LJUBLJANA	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: TABLETS HARD GELATIN CAPSULES LIQUIDS (NASAL SPRAYS)	NOT RETAINED	SLOVENIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/03/2019

1015	NDA/MAL/HDP/6453	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	ALLMYCIN	ERYTHROMYCIN STEARATE	125 MG/5 ML	N/A	LINCOLN PHARMACEUTICALS LTD .,.10,12,13, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ-382721 TA: KALOL, DIST. GHANDINAGAR, GUJARAT	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE WITH 10ML PLASTIC DOSING CAP	27/03/2019
1016	NDA/MAL/HDP/6454	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MAGRILAN 20MG	FLUOXETINE HYDROCHLORIDE	20MG	MEDOCHEMIE (FACTORY AZ).-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	29/01/2019
1017	NDA/MAL/HDP/6458	LIPTIS EGYPT FOR PHARMACEUTICALS AND MEDICAL PRODUCTS	GOODMAN INTERNATIONAL LTD	VAXATO	RIVAROXABAN	10 MG	N/A	LIPTIS EGYPY FOR PHARMACEUTICALS AND MEDICAL PRODUCTSPLOT NO. 2/B, 6TH INDUSTRIAL ZONE, 6TH OF OCTOBER CITY	N/A	NOT RETAINED	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	27/03/2019

1018	NDA/MAL/HDP/6463	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	SNIP	PARACETAMOL + PSEUDOEPHEDRINE + CHLORPHENAMINE	325MG + 15MG + 1MG	MEDOCHEMIE LTD-CENTRAL FACTORY A-1-10 CONSTANTINOUPOLEUS STREET	N/A	FACILITY NOT APPROVED FOR THIS LINE	RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	27/03/2019
1019	NDA/MAL/HDP/6466	S KAGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	NYSTATIN ORAL TABLETS USP 500,000 I.U.	NYSTATIN	500,000IU	N/A	S KANT HEALTHCARE LTD1802-1805 GIDC PHASE III VAPI 396 195 GUJARAT	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	31/01/2018
1020	NDA/MAL/HDP/6469	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	OMASI MED LIMITED	JUSPRIN 81 E/C TABLETS	ASPIRIN	81MG	N/A	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	N/A	NOT RETAINED	UNITED ARAB EMIRATES	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X20.0 TABLET BLISTER	01/07/2017
1021	NDA/MAL/HDP/6472	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	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X10.0 CAPSULE STRIP	29/01/2019

1022	NDA/MAL/HDP/6473	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	ALMIRAL	DICLOFENAC SODIUM	15MG/ML	MEDOCHEMIE LTD – FACTORY B-PLOT 48, IAPETOU STREET, AGIOS ATHANASSIOS INDUSTRIAL; AREA, 4101 AGIOS	N/A	FACILITY NOT APPROVED FOR THIS LINE	RETAINED	CYPRUS	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X3.0 ML AMPOULE	27/03/2019

1023	NDA/MAL/HDP/6476	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIZOLONE-DEPOT	METHYLPREDNISOLONE	80MG/2ML	EGYPTIAN INT.PHARMACEUTICAL INDUSTRIES CO. E.I.P.C.O - 10TH OF RAMADAN CITY – INDUSTRIAL AREA B1- P.O BOX: 149 TENTH - EGYPT	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	PARENTERAL RETARD VIALS	1.0X1.0X2.0 ML VIAL	25/07/2018

1024	NDA/MAL/HDP/6477	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MEDOFULVIN	GRISEOFULVIN	500 MG	MEDOCHEMIE (FACTORY AZ).-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	27/03/2019
1025	NDA/MAL/HDP/6481	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	OMASI MED LIMITED	MOXAL PLUS CHEWABLE TABLETS	DRIED ALUMINIUM HYDROXIDE GEL+MAGNESIUM HYDROXIDE+SIMETHICONE	200MG+200MG+25MG	N/A	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	N/A	NOT RETAINED	UNITED ARAB EMIRATES	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
1026	NDA/MAL/HDP/6485	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	OMASI MED LIMITED	CEFUZIME 750	CEFUROXIME SODIUM	750MG	N/A	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)AIRPORT ROAD, DIGDAGA, P.O.BOX: 997, RAS AL KHAIMAH, U.A.E.	N/A	NOT RETAINED	UNITED ARAB EMIRATES	PARENTERAL ORDINARY DRY VIALS	1.0X750.0 MG VIAL	31/01/2018

1027	NDA/MAL/HDP/6489	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	ASCORIL-SF	SALBUTAMOL +BROMHEXINE HYDROCHLORIDE+GUAIFENESIN	2MG+4MG +100MG/10ML	N/A	GLENMARK PHARMACEUTICALS LTD .VILLAGE KISHANPURA, BADDI-NALAGARH ROAD, TEHSIL BADDI, DISTRICT SOLAN HP 173205	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2017
1028	NDA/MAL/HDP/6492	UMEDICA LABORATORIES PVT LTD	VITACARE LIMITED	LIDOCAINE INJECTION BP 2%W/V	LIDOCAINE HYDROCHLORIDE	2%W/V	N/A	UMEDICA LABORATORIES PVT, VAPI - PLOT 221, GIDC II, VAPI-396195, VALSAD GUJARAT INDIA	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0X20.0 ML VIAL	28/03/2018
1029	NDA/MAL/HDP/6502	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	ALOVIR 400	ACYCLOVIR	400MG	N/A	HETERO LABS LIMITED (UNIT V)SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOOBNAGAR, DISTRICT ANDHRA PRADESH 509301	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET BOTTLE,1.0X10.0X8.0 TABLET BLISTER	29/05/2019

1030	NDA/MAL/HDP/6510	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	TACROZ	TACROLIMUS USP	0.03%W/W	N/A	GLENMARK PHARMACEUTICALS LTD .PLOT E-37, 39, D ROAD, MIDC, SATPUR, NASHIK 422007, MAHARASHTRA STATE	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X10.0 G TUBE	28/05/2019
1031	NDA/MAL/HDP/6511	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ABIDONE	POVIDONE IODINE	5%W/W	LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL	LINCOLN PARENTERAL LTD11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	FACILITY NOT APPROVED TO MANUFACTURE THIS PRODUCT LINE	NOT RETAINED	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE	28/05/2019
1032	NDA/MAL/HDP/6517	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	FERROTONE LIQUIZ	FERROUS FUMARATE + FOLIC ACID + CYANOCOBALAMIN	100MG + 0.5MG + 5MCG	N/A	FDC LIMITED, WALUJ .PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X 120.0 ML BOTTLE,1.0X 180.0 ML BOTTLE	29/05/2019

1033	NDA/MAL/HDP/6530	NATIONAL HEALTHCARE PVT LTD	MALIX PHARMA (U) LIMITED	NECIPRO	CIPROFLOXACIN HYDROCHLORIDE	0.3%W/V	NATIONAL HEALTHCARE PVT LTD.-VDC CHHATAPIPRA-3, BARA,	N/A	GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED & UNCOATED), HARD GELATIN CAPSULES, SMALL VOLUME PARENTERAL LIQUIDS (VIALS & AMPOULES), EYE/EAR DROPS, LYOPHILIZED POWDERS FOR INJECTION, , BETA LACTAM (PENICILLIN): TABLETS (COATED & UNCOATED), HARD GELATIN CAPSULES, SMALL VOLUME PARENTERAL POWDERS , BETA LACTAM (CEPHALOSPORIN): SMALL VOLUME PARENTERAL POWDERS	NOT RETAINED	NEPAL	OPHTHALMIC LIQUIDS	1.0X1.0X10.0 ML VIAL	28/03/2019

1034	NDA/MAL/HDP/6533	NATIONAL HEALTHCARE PVT LTD	MALIX PHARMA (U) LIMITED	NIKODIN	PARACETAMOL + CODEINE PHOSPHATE	500MG + 10MG	NATIONAL HEALTHCARE PVT LTD.-VDC CHHATAPIPRA-3, BARA,	N/A	GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED & UNCOATED), HARD GELATIN CAPSULES, SMALL VOLUME PARENTERAL LIQUIDS (VIALS & AMPOULES), EYE/EAR DROPS, LYOPHILIZED POWDERS FOR INJECTION, , BETA LACTAM (PENICILLIN): TABLETS (COATED & UNCOATED), HARD GELATIN CAPSULES, SMALL VOLUME PARENTERAL POWDERS , BETA LACTAM (CEPHALOSPORIN): SMALL VOLUME PARENTERAL POWDERS	NOT RETAINED	NEPAL	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER	28/03/2019

1035	NDA/MAL/HDP/6535	OCTOBER PHARMA S.A.E	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SARCOZIDE	CANDERSATAN + HYDROCHLOROZIDE	16MG + 12.5MG	OCTOBER PHARMA PLOT NO. 190, 1ST INDUSTRIAL ZONE-6 OCTOBER CITY	N/A	GMP EXPIRED ON 28/9/2023 FOR NON-BETA LACTAM: ORAL TABLETS ORAL CAPSULES ORAL LIQUIDS (SYRUP & SUSPENSION) TOPICAL SOLUTIONS	NOT RETAINED	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	28/03/2019
1036	NDA/MAL/HDP/6543	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CIFF-O	OFLOXACIN + CEFIXIME	200MG + 200MG	N/A	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	28/03/2019
1037	NDA/MAL/HDP/6544	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	OMASI MED LIMITED	ORAMAX 150MG	FLUCONAZOLE	150MG	N/A	GULF PHARMACEUTICALS INDUSTRIES"JULPHAR"P.O.BOX 997 AIRPORT ROAD,DIGDAGA STREET RAS AL KHAIMAH,U.A.E	N/A	NOT RETAINED	UNITED ARAB EMIRATES	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X1.0 CAPSULE BLISTER	28/03/2018

1038	NDA/MAL/HDP/6547	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	OMASI MED LIMITED	AMYDRAMINE PAEDIATRIC SYRUP	DIPHENHYDRAMINE HYDROCHLORIDE+SODIUM CITRATE+MENTHOL	7MG+28.5 MG+0.55 MG/5 ML	N/A	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	N/A	NOT RETAINED	UNITED ARAB EMIRATES	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2017
1039	NDA/MAL/HDP/6555	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	DERMIRIVOC	OFLOXACIN + ORNIDAZOLE + TERBINAFINE HYDROCHLORIDE + CLOBETASOL PROPIONATE	0.75%W/W + 2.0%W/W + 1.0%W/W + 0.05%W/W	N/A	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	28/08/2019
1040	NDA/MAL/HDP/6557	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	COMBIART-DT	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	STRIDES SHASUN LIMITED-NO. 36/7, SURAGAJAKKANAHALLI, INDLAVADI CROSS, ANEKAL TALUK, BENGALURU, KARNATA	N/A	FACILITY NAME CHANGED TO STRIDES PHARMA SCIENCE LIMITED; APPLICANT REQUIRED TO APPLY FOR VARIATION FOR CHANGE OF NAME	RETAINED	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X6.0 TABLET BLISTER,1.0X1.0X12.0 TABLET BLISTER,1.0X30.0X6.0 TABLET BLISTER,1.0X30.0X12.0 TABLET BLISTER	27/03/2019
1041	NDA/MAL/HDP/6559		JEET PHARMACEUTICALS LIMITED	BIOCOBAL 500MCG	MECOBALAMIN	500MCG / ML	N/A	SURGE LABORATORIES (PVT) LTD.,,10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA-PAKISTAN.	N/A	NOT RETAINED	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE	27/03/2019

1042	NDA/MAL/HDP/6561	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	OMASI MED LIMITED	RISEK	OMEPRAZOLE	20MG	N/A	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	N/A	NOT RETAINED	UNITED ARAB EMIRATES	ORAL SOLID ORDINARY CAPSULES	1.0X14.0 CAPSULE BOTTLE	31/01/2018
1043	NDA/MAL/HDP/6564	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ANATAX ® 24MG	BETAHISTINE DIHYDROCHLORIDE	24MG	N/A	UNITED PHARMACEUTICAL MANUFACTURING COMPANYJORDAN - NUZHAT SAHAB	N/A	NOT RETAINED	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	27/03/2019
1044	NDA/MAL/HDP/6565	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	IBUPROFEN	IBUPROFEN	200MG	N/A	TRIVENI FORMULATIONS LTDPLOT NO. 52,53,54,63,62,64 ALEAP INDUSTRIUAL ESTATE SARAMPALLI VIJAYWADA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	27/03/2019
1045	NDA/MAL/HDP/6574	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	ARCHIFAR	MEROPENEM	1G	MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101	N/A	FACILITY NOT APPROVED FOR THIS LINE	RETAINED	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X1.0 G VIAL	01/07/2017

1046	NDA/MAL/HDP/6580	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	OXEPTAL 600	XCARBAZEPINE	600 MG	CADILA HEALTHCARE LIMITED KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1X3X10 TABLET Blister	28/08/2019
1047	NDA/MAL/HDP/6581	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYDALIS 20	TADALAFIL	20 MG	CADILA HEALTH CARE LIMITED-KUNDAIM INDUSTRIAL ESTATE, PONDA, GOA-403401	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	27/08/2019
1048	NDA/MAL/HDP/6582	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BISOLOL 10	BISOPROLOL FUMARATE	10 MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	27/08/2019
1049	NDA/MAL/HDP/6595	RAVIAN LIFE SCIENCE PVT. LTD	ROYAL PHARMA 2011 LIMITED	MOLURAV	LEVOCETIRIZINE DIHYDROCHLORIDE + MONTELUKAST SODIUM	5MG + 10MG	N/A	RAVIAN LIFE SCIENCE PVT LTDPLOT NO.34,SECTOR-8A,IIE,HARIDWAR-249403, UTTARKHAND	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017

1050	NDA/MAL/HDP/6607	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	RANI	RANITIDINE HYDROCHLORIDE	150MG	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	N/A	GMP EXPIRED ON 28/9/2023 FOR BETA LACTAM (PENICILLIN): ORAL DRY POWDERS FOR SUSPENSION HARD GELATIN CAPSULES TABLETS SVP POWDERS (VIALS), NON-BETA LACTAM: ORAL DRY POWDERS (HUMAN & VETERINARY) HARD GELATIN CAPSULES TABLETS ORAL LIQUIDS ORAL POWDERS IN SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED) CREAMS, OINTMENTS, GELS, SUPPOSITORIES, PESSARIES & OVULES	NOT RETAINED	EGYPT	ORAL LIQUID ORDINARY EFFERVESCENT POWDERS/GRANULES	1.0X6.0X5.4G SACHET	28/05/2019

1051	NDA/MAL/HDP/6609	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIZOL	FLUCONAZOLE	200MG/200ML	AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL	N/A	FACILITY NOT APPROVED FOR MANUFACTURE OF THE PRODUCT LINE	RETAINED	JORDAN	PARENTERAL ORDINARY INFUSION BAGS	1.0X100.0 ML BAG	28/05/2019
1052	NDA/MAL/HDP/6614	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	AXETINE	CEFUROXIME SODIUM	1.5MG	MEDOCHEMIE LIMITED (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	PARENTERAL ORDINARY VIALS	1.0X10.0 VIAL CARTON	01/07/2008
1053	NDA/MAL/HDP/6619	ESAPHARM SRL	BYAMAKA PHARMACEUTICAL COMPANY LTD	ORANVATE	CLOBETASOL PROPIONATE	0.05G/100G	N/A	ESAPHARMA SRLVIA DE GASPERI, 13-20066 MELZO (MILAN) ITALY	N/A	NOT RETAINED	ITALY	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/2016
1054	NDA/MAL/HDP/6632	UMEDICA LABORATORIES PVT LTD	VITACARE LIMITED	CIPROFLOXACIN	CIPROFLOXACIN	500MG	N/A	UMEDICA LABORATORIES PVT, VAPIPLOT 221, GIDC II, VAPI-396195, INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2006

1055	NDA/MAL/HDP/6633	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	COLDRIL	PARACETAMOL + CHLORPHENIRAMINE MALEATE + PSEUDOEPHEDRINE HCL	500MG + 30MG + 2MG	SHELYS PHARMACEUTICALS LIMITED-PLOT NO. 696, BLOCK NO. 32, MIKOCHENI INDUSTRIAL AREA, NEW BAGAMOYO ROAD, MEWENGE	BETA HEALTHCARE INTERNATIONAL LTD -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	GMP EXPIRED ON THE 28/11/2019 FOR • TABLETS • HARD GELATIN CAPSULES. • ORAL LIQUIDS. • DRY POWDER FOR ORAL SUSPENSION • ORS • CREAMS AND OINTMENTS.	RETAINED	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X12.0X1.0X2.0X10.0 CAPSULE BLISTER	01/07/2017
1056	NDA/MAL/HDP/6648	UMEDICA LABORATORIES PVT LTD	VITACARE LIMITED	DEXAMETHASONE INJECTION	DEXAMETHASONE SODIUM PHOSPHATE	4MG/ML	N/A	UMEDICA LABORATORIES PVT. LTDPLOT 221-GIDC, 2ND PHASE, VAPI 396195 GUJARAT	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0X2.0 ML VIAL	01/07/2016
1057	NDA/MAL/HDP/6652	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LAMIVUDINE +TENOFOVIR DISOPROXIL FUMARATE	LAMIVUDINE +TENOFOVIR DISOPROXIL FUMARATE	300MG+300MG	N/A	CIPLA LTD MIDC PATALGANGA MS 410 220 INDIA MFG LIC: 845	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2016
1058	NDA/MAL/HDP/6674	UMEDICA LABORATORIES PVT LTD	VITACARE LIMITED	UMERAN-75	DICLOFENAC SODIUM	75MG/3ML	N/A	UMEDICA LABORATORIES PVT. LTDPLOT 221-GIDC, 2ND PHASE, VAPI 396195 GUJARAT	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X1.0X10.0X3.0 ML AMPOULE	01/07/2016

1059	NDA/MAL/HDP/6679	BLUE CROSS LABORATORIES LIMITED	STAR PHARMACEUTICALS LTD	WOMIBAN TABLETS	ALBENDAZOLE	400MG	BLUE CROSS LABORATORIES LTDA-12, M.I.D.C AMBAD NASHIK-422010	BLUE CROSS LABORATORIES LTDL-17, VERNA INDUSTRIAL ESTATE,VERNA GOA-403722	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, SMALL VOLUME LIQUIDS	RETAINED	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0 TABLET STRIP	01/07/1997
1060	NDA/MAL/HDP/6691	SANDOZ GMBH C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	BINOZYT 200 MG/ 5 ML	AZITHROMYCIN MONOHYDRATE	200MG/5ML	N/A	SANDOZ SRL LTDLIVEZENI STREET 7A540472 TARGU MURES ROMANIA	N/A	NOT RETAINED	ROMANIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X15.0 ML BOTTLE	01/07/2016
1061	NDA/MAL/HDP/6692	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	ASUNRA 100	DEFERASIROX	100MG	N/A	NOVARTIS PHARMA STEIN AG.SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	N/A	NOT RETAINED	SWITZERLAND	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X5.0X6.0 TABLET BLISTER	01/07/2016
1062	NDA/MAL/HDP/6699	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ATVIN-20	ATORVASTATIN	20MG	N/A	RAVIAN LIFE SCIENCE PVT LTDPLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	28/05/2019
1063	NDA/MAL/HDP/6700	CACHET PHAMACUITICALS PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	ARTIMED	DICLOFENAC SODIUM	50MG	N/A	CACHET PHARMACEUTICALS PVT LTD THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009

1064	NDA/MAL/HDP/6705	CACHET PHARMACEUTICALS PVT LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CACHEWORM	MEBENDAZOLE	100MG	N/A	CACHET PHARMACEUTICALS PVT LTD THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2010
1065	NDA/MAL/HDP/6706	CACHET PHARMACEUTICALS PVT LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CACH-E-WORM	MEBENDAZOLE	100MG/5ML	N/A	CACHET PHARMACEUTICALS PVT LTD THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2009
1066	NDA/MAL/HDP/6709	CACHET PHARMACEUTICALS PVT LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CACHPAR	PARACETAMOL	500MG	N/A	CACHET PHARMACEUTICALS PVT LTDVILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2012
1067	NDA/MAL/HDP/6711	CACHET PHARMACEUTICALS PVT LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CACHPAR	PARACETAMOL	125MG/5ML	N/A	CACHET PHARMACEUTICALS PVT LTD THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2009

1068	NDA/MAL/HDP/6712	CACHET PHARMACEUTICALS PVT LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CACID-O	OMEPRAZOLE	20MG	N/A	CACHET PHARMACEUTICALS PVT LTD THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	01/07/2011
1069	NDA/MAL/HDP/6714	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	HYDRYLLIN SYRUP	AMINOPHYLLINE+ AMMONIUM HCL+ DIPHENHYDRAMINE HCL	32MG +300MG+8MG	THE SEARLE COMPANY-32-KM MULTAN ROAD, LAHORE	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, ORAL LIQUIDS FOR INTERNAL USE	RETAINED	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/1997
1070	NDA/MAL/HDP/6731	SANDOZ GMBH C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	PIPTAZO 4.5G	PIPERACILLIN SODIUM+TAZOBACTAM SODIUM	4G+0.5G	N/A	SANDOZ GMBHBIOCHEMIESTRABE 10 A6250 KUNDL, TYROL, AUSTRIA	N/A	NOT RETAINED	AUSTRIA	PARENTERAL ORDINARY DRY VIALS	1.0X4.5 ML VIAL	01/07/2016

1071	NDA/MAL/HDP/6733	PACIFIC PHARMACEUTICALS LTD	HEALTHCARE LTD.	LOMEXIN	FENTICONAZOLE	2%W/W	PACIFIC PHARMACEUTICALS LTD-30TH KILOMETRE NULTAN ROAD LAHORE PAKISTAN	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS, HARD GELATIN CAPSULES , ORAL LIQUIDS, CREAMS AND OINTMENTS	NOT RETAINED	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X40.0 G TUBE	01/07/2005
1072	NDA/MAL/HDP/6739	PACIFIC PHARMACEUTICALS LTD	HEALTHCARE LTD.	PACIFIC'S JACK & JILL CHILDREN'S FORMULA	DEXTROMETHORPHAN + CHLORPHENIRAMINE	10MG + 2MG / 5ML	PACIFIC PHARMACEUTICALS LTD-30TH KILOMETRE NULTAN ROAD LAHORE PAKISTAN	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS, HARD GELATIN CAPSULES , ORAL LIQUIDS, CREAMS AND OINTMENTS	NOT RETAINED	PAKISTAN	ORAL LIQUID ORDINARY LIQUIDS	1.0X120.0 ML BOTTLE	01/07/2011
1073	NDA/MAL/HDP/6745	PACIFIC PHARMACEUTICALS LTD	HEALTHCARE LTD.	TYZORIN MOUTH WASH	TIBEZONIUM IODIDE	0.05G/100 ML	PACIFIC PHARMACEUTICALS LTD-30TH KILOMETRE NULTAN ROAD LAHORE PAKISTAN	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS, HARD GELATIN CAPSULES , ORAL LIQUIDS, CREAMS AND OINTMENTS	RETAINED	PAKISTAN	TOPICAL EXTERNAL LIQUIDS	1.0X120.0 ML BOTTLE	01/07/2005

1074	NDA/MAL/HDP/6747	PACIFIC PHARMACEUTICALS LTD	HEALTHCARE LTD.	TYZORIN	TIBEZONIUM IODIDE	5MG	PACIFIC PHARMACEUTICALS LTD-30TH KILOMETRE NULTAN ROAD LAHORE PAKISTAN	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS, HARD GELATIN CAPSULES , ORAL LIQUIDS, CREAMS AND OINTMENTS	RETAINED	PAKISTAN	ORAL SOLID ORDINARY LOZENGES	1.0X4.0X6.0 LOZENGE STRIP	01/07/2011
1075	NDA/MAL/HDP/6756	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	FEVEREX TOTO SUSPENSION	PARACETAMOL	120MG/5ML	N/A	BETA HEALTHCARE INTERNATIONAL LTD PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE	01/07/2007
1076	NDA/MAL/HDP/6765	CACHET PHARMACEUTICALS PVT LIMITED	ABACUS PHARMA (AFRICA) LIMITED	IBUCACH 200	IBUPROFEN	200MG	N/A	CACHET PHARMACEUTICALS PVT LTD THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2010

1077	NDA/MAL/HDP/6777	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL FUSIDIC ACID	FUSIDIC ACID	2%W/W	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	N/A	GMP EXPIRED ON THE 28/9/2023 FOR NON-BETA LACTAM: TABLETS COATED & UNCOATED HARD GELATIN CAPSULES ORAL LIQUIDS SVP LIQUIDS AND POWDER STERILE GELS	NOT RETAINED	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE,1.0X15.0 G TUBE	01/07/2016

1078	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	N/A	GMP EXPIRED ON THE 28/9/2023 FOR NON-BETA LACTAM: TABLETS COATED & UNCOATED HARD GELATIN CAPSULES ORAL LIQUIDS SVP LIQUIDS AND POWDER STERILE GELS , (BETA LACTAM) CEPHALOSPORIN: HARD GELATIN CAPSULES DRY POWDER FOR ORAL SUSPENSION SVP POWDER , CORTICOSTEROIDS: OINTMENTS AND CREAMS	RETAINED	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2016

1079	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	N/A	GMP EXPIRED ON THE 28/09/2023 FOR NON-BETA LACTAM: ORAL VETERINARY POWDERS TABLETS POWDERS FOR ORAL SUSPENSION HARD GELATIN CAPSULES ORAL LIQUIDS OINTMENTS, CREAMS & GELS SUPPOSITORIES STERILE LIQUIDS IN AMPOULES POWDER SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED IN PLASTIC AMPOULE) SMALL VOLUME LYOPHILIZED POWDER (ASEPTICALLY PREPARED) SOFT GELATIN CAPSULES , BIOLOGICALS (SVP): RECOMBINANT INSULIN	RETAINED	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2005

1080	NDA/MAL/HDP/6789	AFRICURE PHARMACEUTICALS (INDIA) LTD	DELMAW ENTERPRISES LIMITED	AFRINAC	DICLOFENAC SODIUM	75MG/3ML	STRIDES ARCOLAB LTD. - 36/7 SURAGAJAKKANA HALLI INDLAVADI CROSS ANEKAL TALUK KIVIPHARM CO. LTD-NO.5 HANGTIAN STREET DONGSHAN HIGH-TECH INDUSTRIAL DEVELOPMENT ZONE, SHALINGZI TOWN ZHANGJIAKOU	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II-31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	NAME OF FACILITY CHANGED TO STRIDES PHARMA SCIENCE LIMITED; APPLICANT REQUIRED TO APPLY FOR VARIATION FOR CHANGE OF NAME; GMP OF KIVIPHARM EXPIRED ON THE 25TH/09/2023 FOR NON BETA-LACTAM: SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED PACKED IN AMPOULES)	RETAINED	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X3.0 ML AMPOULE	01/07/2017
1081	NDA/MAL/HDP/6791	UMEDICA LABORATORIES PVT LTD	VITACARE LIMITED	CIMETIDINE	CIMETIDINE	200MG	N/A	UMEDICA LABORATORIES PVT. LTDPLOT 221-GIDC, 2ND PHASE, VAPI 396195 GUJARAT	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2005

1082	NDA/MAL/HDP/6795	PHARAONIA PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CRONOMESONE OINTMENT	BETAMETHASONE VALERATE	1%W/W	PHARAONIA PHARMACEUTICALS-NEW BORG EL ARAB CITY-ALEXANDRIA	N/A	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: STERILE EYE DROPS SMALL VOLUME LIQUIDS IN AMPOULES, TABLETS HARD GELATIN CAPSULES ORAL POWDERS IN SACHETS ORAL DRY POWDERS CREAMS, OINTMENTS & GELS SUPPOSITORIES ORAL SYRUP & SUSPENSION ORAL DROPS, NASAL DROPS & OTIC DROPS TOPICAL SOLUTIONS	NOT RETAINED	EGYPT	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/2016
1083	NDA/MAL/HDP/6837	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	ZEEL KIT	CLARITHROMYCIN + METRONIDAZOLE + PANTOPRAZOLE SODIUM SESQUIHYDRATE	250MG + 400MG +40MG	N/A	THE MADRAS PHARMACEUTICALS137-B,OLD MAHABALIPURAM ROAD,KARAPAKKAM,CHENNAI INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X7.0 TABLET STRIP	01/07/2016

1084	NDA/MAL/HDP/6878	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AMITIVIAN	AMITRIPTYLINE	25MG	N/A	RAVIAN LIFE SCIENCE PVT LTDPLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/05/2019
1085	NDA/MAL/HDP/6909	F.HOFFMANN-LA ROCHE LTD	LABOREX UGANDA LIMITED	HERCEPTIN	TRASFUZUMAB	600 MG	F.HOFFMANN LA ROACHE AG, KAISRAUGST - BETRIEBS STANDORT KAISERAUGST, 4303 KAIERAUGST	N/A	GMP OF THE FACILITY EXPIRED ON THE 30/7 2023 FOR BIOTECHNOLOGY PRODUCTS: SVP LIQUIDS IN VIALS SVP LYOPHILISATES PREFILLED SYRINGES , CEPHALOSPORIN: SVP POWDERS IN VIALS	RETAINED	SWITZERLAND	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	27/08/2019
1086	NDA/MAL/HDP/6912	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYROVA 5	ROSUVASTATIN CALCIUM	5 MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/08/2019

1087	NDA/MAL/HDP/6913	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYROVA 10	ROSUVASTATIN CALCIUM	10 MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/08/2019
1088	NDA/MAL/HDP/6917	COSMOS LIMITED	ASTRA PHARMA (U) LIMITED	DAPSONE	DAPSONE	100 MG	N/A	COSMOS LTD RANGWE ROAD OFF LUNGA LUNGA ROAD INDUSTRIAL AREA NAIROBI	N/A	NOT RETAINED	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	27/08/2019
1089	NDA/MAL/HDP/6918	RESONANT PHARMACEUTICALS	SHREEJI CARE LIMITED	NO COLD	PARACTAMOL + PHENYL HYDROCHLORIDE + CHLORPHENAMINE MALEATE + CAFFEINE ANHYDROUS	500MG + 10MG + 2MG + 30MG	CRIS PHARMA (INDIA) LIMITED-E-11, UPSIDC INDUSTRIAL AREA, SELAQUI, DEHRADUN, UTTARAKHAND	N/A	GMP EXPIRED ON THE 10/9/2022 FOR NON B-LACTAM: TABLETS (COATED AND UN COATED), ORAL LIQUID DOSAGE FORM	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X4.0 TABLET BLISTER,1.0X25.0X4.0 TABLET BLISTER	28/08/2019
1090	NDA/MAL/HDP/6920	I CARE PHARMA LIMITED	AIVEEN (U) LTD	OFZOLE	OFLOXACIN+ ORNIDAZOLE	200MG+500MG	N/A	CORONA REMEDIES PVT LTD..VILLAGE JATOLI, POST OFFICE - OACHGHAT, TEHSIL SOLAN, DIST. SOLAN HIMACHAL PRADESH	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	07/11/2018

1091	NDA/MAL/HDP/6924	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	NAC MR	DICLOFENAC POTASSIUM+PARACETAMOL+CHLORZOXAZONE	50MG+325MG+250MG	N/A	CORONA REMEDIES PVT LIMITEDVILLAGE JATOLI, POST OFFICE - OACHGHAT, TEHSIL SOLAN, DIST. SOLAN HIMACHAL PRADESH – 173223. INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER	31/01/2018
1092	NDA/MAL/HDP/6931	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AMORIV	AMBROXOL HYDROCHLORIDE	15MG/5ML	N/A	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	27/08/2019
1093	NDA/MAL/HDP/6934	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	ANASTROZOLE 1 MG	ANASTROZOLE	1MG	SALUTAS PHARMA GMBH-OTTO-VON-GUERICKE-ALLEE 1, 39179	N/A	GMP EXPIRED ON THE 12/11/2022 FOR HARD GELATIN CAPSULES AND TABLETS	NOT RETAINED	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
1094	NDA/MAL/HDP/6943	ADWIA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ADWIFLAM	DICLOFENAC POTASSIUM	25MG	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)-1ST INDUSTRIAL ZONE, 6	N/A	GMP EXPIRED ON THE 28/09/2023 FOR NON-BETA LACTAM: ORAL VETERINARY POWDERS	NOT RETAINED	EGYPT	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY STRIP	28/05/2019

1095	NDA/MAL/HDP/6944	SQUARE PHARMACEUTICALS LTD.PABNA UNIT	GAMA PHARMACEUTICALS (U) LIMITED	NEBANOL PLUS	NEOMYCIN SULPHATE+BACITRACIN ZINC+ POLYMYXIN B SULPHATE	3.5MG/GM +400I.U/GM+5000I.U/GM	N/A	SQUARE PHARMACEUTICALS LTD.SQUARE ROAD SALGARIA PABNA	N/A	NOT RETAINED	BANGLADESH	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	29/05/2019
1096	NDA/MAL/HDP/6945		JEET PHARMACEUTICALS LIMITED	TRICK-D	CHOLECALCIFEROL	5MG/ML	N/A	SURGE LABORATORIES (PVT) LTD.,,10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA-PAKISTAN.	N/A	NOT RETAINED	PAKISTAN	OTHER SYSTEMIC LIQUIDS	1.0X1.0 ML AMPOULE	28/05/2019

1097	NDA/MAL/ HDP/6950	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ARTESUNATE INJECTION	ARTESUNATE	30MG	N/A	SWISS PARENTERALS PVT LTD 809 KERALA INDUSTRIAL ESTATE GIDC NR. BAVLA DIST. AHMEDABAD-380220 GUJARAT M/S SCOTT-EDIL PHARMACIA LTD 56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA BLISS INDAS LIFESCIENCE P. LTD..PLOT 73-76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 VIAL CARTON + (1X1ML 5% NAHCO3 AMPOULE)+(1X5ML 0.9% NACL AMPOULE)	29/05/2019

1098	NDA/MAL/HDP/6953	SYNOKEM PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MISOFREE	MISOPROSTOL	200MCG	SYNOKEM PHARMACEUTICALS LIMITEDSYNOKEM PHARMACEUTICALS LIMITED, PLOT NO. 35-36, SECTOR-6A, IIE, (SIDCUL), RANIPUR (BHEL)	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM (HUMAN): TABLETS, HARD GELATIN CAPSULES, ORAL LIQUIDS, HORMONES: TABLETS	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	28/05/2019
1099	NDA/MAL/HDP/6957	WILSHIRE LABORATORIES (PVT) LTD	HEALTHCARE LTD.	ZEECIN	AZITHROMYCIN DIHYDRATE	250MG	WILSHIRE LABORATORIES (PVT) LTD-124/1 INDUSTRIAL AREA, KOT LAKHPAT LAHORE PAKISTAN	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: COATED AND UNCOATED TABLETS, HARD GELATIN CAPSULES, POWDERS FOR ORAL SUSPENSION, SMALL AND LARGE VOLUME PARENTERAL LIQUIDS, SMALL VOLUME POWDER FOR INJECTION	NOT RETAINED	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X3.0 TABLET BLISTER	28/05/2019

1100	NDA/MAL/HDP/6958	WILSHIRE LABORATORIES (PVT) LTD	HEALTHCARE LTD.	ZEECIN	AZITHROMYCIN DIHYDRATE	500MG	WILSHIRE LABORATORIES (PVT) LTD-124/1 INDUSTRIAL AREA, KOT LAKHPAT LAHORE PAKISTAN	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: COATED AND UNCOATED TABLETS, HARD GELATIN CAPSULES, POWDERS FOR ORAL SUSPENSION, SMALL AND LARGE VOLUME PARENTERAL LIQUIDS, SMALL VOLUME POWDER FOR INJECTION	NOT RETAINED	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER	28/05/2019
1101	NDA/MAL/HDP/6966	SANDOZ GMBH .	SURGIPHARM (U) LIMITED	TAMOXIFEN	TAMOXIFEN CITRATE	20MG	SALUTAS PHARMA GMBH-OTTO-VON-GUERICKE ALLEE-1, 39179	N/A	GMP EXPIRED ON THE 12/11/2022 FOR HARD GELATIN CAPSULES AND TABLETS	NOT RETAINED	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/05/2019

1102	NDA/MAL/HDP/6967	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	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS FOR INTERNAL USE TABLETS (COATED AND UNCOATED) HARD GELATIN CAPSULES ORAL POWDER FOR SUSPENSION OINTMENTS, CREAMS AND GELS	RETAINED	EGYPT	ORAL TOPICAL GELS AND SOLS	1.0X20.0 G TUBE	27/11/2019
1103	NDA/MAL/HDP/6968	F.HOFFMANN-LA ROCHE LTD	LABOREX UGANDA LIMITED	MABTHERA® SC 1400MG	RITUXIMAB	1400MG/13.4ML	F.HOFFMANN LA ROACHE AG, KAISRAUGST - BETRIEBSSTANDORT KAISERAUGST, 4303 KAIERAUGST	N/A	GMP OF THE FACILITY EXPIRED ON THE 30/7 2023 FOR BIOTECHNOLOGY PRODUCTS: SVP LIQUIDS IN VIALS SVP LYOPHILISATES PREFILLED SYRINGES , CEPHALOSPORIN: SVP POWDERS IN VIALS	RETAINED	SWITZERLAND	PARENTERAL ORDINARY S C VIALS	1.0X1.0X13.4 ML VIAL	27/08/2019

1104	NDA/MAL/HDP/6979	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	TERBIRIV	TERBINAFINE HYDROCHLORIDE	1.0%W/W	N/A	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	28/08/2019
1105	NDA/MAL/HDP/6983	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	FASICON	FLUCONAZOLE	200 MG	N/A	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	27/08/2019
1106	NDA/MAL/HDP/6987	MEDLEY PHARMACEUTICALS LTD	EUROPA HEALTHCARE (U) LTD	PORAZ CAPSULES	OMEPRAZOLE	20MG	N/A	MEDLEY PHARMACEUTICALS LTDPLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	01/07/2017
1107	NDA/MAL/HDP/6993	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AZIRIV-500	AZITHROMYCIN (AS DIHYDRATE)	500MG	N/A	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	28/05/2019

1108	NDA/MAL/HDP/6994	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	PERLEX DRY SYRUP	CEFALEXIN MONOHYRATE	125MG/5ML	EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMA CITY SELAQUI DEHRAD	N/A	FACILITY NOT APPROVED TO MANUFACTURE CEPHALOSPORIN ORAL POWDERS	RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE	28/05/2019
1109	NDA/MAL/HDP/6995	STALLION LABORATORIES PVT LTD	HARLEYS UGANDA LIMITED	T-MEF	TRANEXAMIC ACID + MEFENAMIC ACID	250MG + 500MG	N/A	ACME FORMULATION PVT. LTDROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	28/08/2019
1110	NDA/MAL/HDP/6997	HETERO LABS LTD	AIVEEN (U) LIMITED	EC-PRAM 10	ESCITALOPRAM OXALATE	10MG	N/A	HETERO LABS LTD. UNIT (V)S.N0.439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X1.0X10.0 TABLET BLISTER	30/05/2018
1111	NDA/MAL/HDP/6998	STALLION LABORATORIES PVT LTD	HARLEYS UGANDA LIMITED	L-DIPIN-55	LOSARTAN POTASSIUM + AMLODIPINE BESILATE	50MG + 5MG	N/A	ACME FORMULATION PVT. LTDROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	28/08/2019

1112	NDA/MAL/HDP/7000	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CIRAB	RABEPRAZOLE SODIUM	20 MG/VIAL	N/A	CIRON DRUGS & PHARMACEUTICALS PVT LTDN-118, N-119, N-113 MIDC TARAPUR BOISAR DIST. THANE 401506 MAHARASHTRA	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 MG VIAL	28/03/2019
1113	NDA/MAL/HDP/7002	CIPLA LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LOPINAVIR AND RITONAVIR	LOPINAVIR + RITONAVIR	40MG + 10MG	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	N/A	FACILITY NOT LICENSED TO MANUFACTURE THE PRODUCT LINE	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X120.0 CAPSULE BOTTLE	27/08/2019
1114	NDA/MAL/HDP/7003	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	NAC-SP	DICLOFENAC POTASSIUM + SERRATIOPEPTIDASE	50MG + 10MG	N/A	CORONA REMEDIES PVT LTD..VILLAGE JATOLI, POST OFFICE - OACHGHAT, TEHSIL SOLAN, DIST. SOLAN HIMACHAL PRADESH	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	07/11/2018

1115	NDA/MAL/HDP/7006	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	PREDNIMAX	PREDNISOLONE	5MG	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR-401506, DIST.THANE, MARAHASHTRA, INDIA	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	MAXHEAL FAILED GMP ON THE 14/5/2019 FOR NON BETA-LACTAM: TABLETS (COATED AND UNCOATED), EXTERNAL PREPARATIONS (CREAMS AND OINTMENTS), HARD GELATIN CAPSULES, DRY POWDER FOR ORAL SUSPENSION, ORAL LIQUIDS	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	27/08/2019
1116	NDA/MAL/HDP/7028	JAMJOOM PHARMACEUTICALS COMPANY	MU PHARMACO -SMC LIMITED	DEXAFLOX	OFLOXACIN + DEXAMETHASONE	3MG + 1MG PER ML	N/A	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	N/A	NOT RETAINED	SAUDI ARABIA	OPHTHALMIC LIQUIDS	1.0X5.0 ML BOTTLE	02/09/2019

1117	NDA/MAL/HDP/7042	MEDLEY PHARMACEUTICALS LTD	EUROPA HEALTHCARE (U) LTD	R.B.TONE SYRUP	FERROUS GLUCONATE + FOLIC ACID + CALCIUM LACTATE + VITAMIN B12	129.5MG + .25MG + 75MG +1.25MCG	N/A	MEDLEY PHARMACEUTICALS LTD..PLOT NO. 18 & 19, SURVEY NO. 378 / 7 & 8 & 379 / 2& 3, ZARI CAUSEWAY ROAD, KACHIGAM, DAMAN (U.T) 396210 - INDIA	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	28/08/2019
1118	NDA/MAL/HDP/7044	MEDLEY PHARMACEUTICALS LTD	EUROPA HEALTHCARE (U) LTD	R.B. TONE HAEMATINIC CAPSULES	FERROUS GLUCONATE + FOLIC ACID + CALCIUM LACTATE + ZINC SULFATE + VITAMIN B12	259MG + 0.5MG + 100MG + 33MG + 2.5MG	N/A	MEDLEY PHARMACEUTICALS LTD..PLOT NO. 18 & 19, SURVEY NO. 378 / 7 & 8 & 379 / 2& 3, ZARI CAUSEWAY ROAD, KACHIGAM, DAMAN (U.T) 396210 - INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X2.0 X15.0 CAPSULE BLISTER	27/08/2019
1119	NDA/MAL/HDP/7046	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	OMASI MED LIMITED	XEMADERM 0.1% CREAM	MOMETASONE FUROATE	0.1%W/W	N/A	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	N/A	NOT RETAINED	UNITED ARAB EMIRATES	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	01/07/2017

1120	NDA/MAL/HDP/7047	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	OMASI MED LIMITED	XEMADERM0.1% OINTMENT	MOMETASONE FUROATE	0.1%W/W	N/A	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	N/A	NOT RETAINED	UNITED ARAB EMIRATES	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE	01/07/2017
1121	NDA/MAL/HDP/7050	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	OMASI MED LIMITED	PANDERM SKIN OINTMENT	NYSTATIN+NEOMYCIN SULFATE+GRAMICIDIN+TRIAMCINOLONE	10,000,000I.U+2.5MG+0.25MG+1MG	N/A	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	N/A	NOT RETAINED	UNITED ARAB EMIRATES	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/2017
1122	NDA/MAL/HDP/7051	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	OMASI MED LIMITED	DEXIPAN CREAM	DEXPANTHENOL	0.05%W/W	N/A	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	N/A	NOT RETAINED	UNITED ARAB EMIRATES	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2017
1123	NDA/MAL/HDP/7055	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	VIREST 400	ACICLOVIR	400MG	HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH .	N/A	FACILITY NOT APPROVED TO MANUFACTURE NBL TABLETS	RETAINED	MALAYSIA	ORAL SOLID ORDINARY TABLETS	5.0X5.0 TABLET BLISTER	31/01/2018

1124	NDA/MAL/HDP/7058	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	NEURAN 300 MG CAPSULE	GABAPENTIN	300MG	HOVID BHD 121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH ,	HOVID BERHAD,LOT 56442, 7 1/2 MILES JALAN IPOH/CHEMOR 31200, CHEMOR PERAK	FACILITY NOT APPROVED TO MANUFACTURE THE PRODUCT LINE	RETAINED	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1X10X10 CAPSULE Blister	28/08/2019
1125	NDA/MAL/HDP/7066	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MABRON SR	TRAMADOL HYDROCHLORIDE	100MG	MEDOCHEMIE (FACTORY AZ).-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	ORAL SOLID RETARD CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER,1.0X3.0X10.0 BLISTER BLISTER	27/08/2019
1126	NDA/MAL/HDP/7086	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYLIN 75	PREGABALIN	75MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X3.0X10.0 CAPSULE BLISTER	27/03/2019

1127	NDA/MAL/ HDP/7087	HETERO DRUGS LTD	AIVEEN (U) LIMITED	Q-TAB-25	QUETIAPINE FUMARATE	25MG	N/A	HETERO LABS LIMITED (UNIT V)SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOOBNAGAR, DISTRICT ANDHRA PRADESH 509301	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10. 0 TABLET BLISTER	28/08/2019

1128	NDA/MAL/HDP/7096	GAMA PHARMACEUTICALS (U) LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DEXAPHEN SYRUP	DEXAMETHASONE + CHLORPHENIRAMINE MALEATE	10MG + 40MG/100 ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	N/A	GMP EXPIRED ON 28/9/2023 FOR BETA LACTAM (PENICILLIN): ORAL DRY POWDERS FOR SUSPENSION HARD GELATIN CAPSULES TABLETS SVP POWDERS (VIALS), NON-BETA LACTAM: ORAL DRY POWDERS (HUMAN & VETERINARY) HARD GELATIN CAPSULES TABLETS ORAL LIQUIDS ORAL POWDERS IN SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED) CREAMS, OINTMENTS, GELS, SUPPOSITORIES, PESSARIES & OVULES	RETAINED	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2017

1129	NDA/MAL/HDP/7100	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	COMBIART 80/480MG	ARTEMETHER + LUMEFANTRINE	80MG + 480MG	STRIDES SHASUN LIMITEDNO. 36/7, SURAGAJAKKANAHALLI, INDLAVADI CROSS, ANEKAL TALUK, BENGALURU, KARNATA	N/A	FACILITY NAME CHANGED TO STRIDES PHARMA SCIENCE LIMITED; APPLICANT REQUIRED TO APPLY FOR VARIATION FOR CHANGE OF NAME	RETAINED	INDIA	ORAL LIQUID ORDINARY EFFERVESCENT POWDERS/GRANULES	, 1X6 SACHET Carton	25/07/2018

1130	NDA/MAL/HDP/7104	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPISOPT	DOROZOLAMIDE + TIMOLOL	20MG/1ML + 5MG/1ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B EGYPT	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	30/05/2018

1131	NDA/MAL/HDP/7113	HETERO DRUGS LTD	AIVEEN (U) LIMITED	RILAST 500	RITUXIMAB	500MG/50 ML	HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOOBNAGAR	N/A	FACILITY NOT APPROVED FOR THE MANUFACTURE OF THE PRODUCT LINE; APPLICATION FOR RE-INSPECTION DOES NOT INCLUDE THIS PRODUCT LINE	RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL	27/08/2019
1132	NDA/MAL/HDP/7114	HETERO DRUGS LTD	AIVEEN (U) LIMITED	RILAST 100	RITUXIMAB	100MG/10 ML	HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOOBNAGAR	N/A	FACILITY NOT APPROVED FOR THE MANUFACTURE OF THE PRODUCT LINE; APPLICATION FOR RE-INSPECTION DOES NOT INCLUDE THIS PRODUCT LINE	RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	27/08/2019

1133	NDA/MAL/ HDP/7124	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VITAMIN E 400 MG.	VITAMIN E	400 MG	PHARCO PHARMACEUTICALS LTD- KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	N/A	GMP EXPIRED ON 28/9/2023 FOR BETA LACTAM (PENICILLIN): ORAL DRY POWDERS FOR SUSPENSION HARD GELATIN CAPSULES TABLETS SVP POWDERS (VIALS), NON-BETA LACTAM: ORAL DRY POWDERS (HUMAN & VETERINARY) HARD GELATIN CAPSULES TABLETS ORAL LIQUIDS ORAL POWDERS IN SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED) CREAMS, OINTMENTS, GELS, SUPPOSITORIES, PESSARIES & OVULES	RETAINED	EGYPT	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X12.0 CAPSULE BLISTER	01/07/2017

1134	NDA/MAL/HDP/7125	SYNOKEM PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	I-FREE 72	LEVONORGESTREL	1.5MG	SYNOKEM PHARMACEUTICALS LTD-PLOT NO.-35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL)	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM (HUMAN): TABLETS, HARD GELATIN CAPSULES, ORAL LIQUIDS, HORMONES: TABLETS	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X1.0 TABLET BLISTER	29/01/2019

1135	NDA/MAL/HDP/7136	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	AMIKACIN 100 MG / 2ML	AMIKACIN SULPHATE	100MG/2ML	EGYPTIAN INT.PHARMACEUTICAL INDUSTRIES CO. E.I.P.C.O - 10TH OF RAMADAN CITY – INDUSTRIAL AREA B1- P.O BOX: 149 TENTH - EGYPT	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	PARENTERAL ORDINARY VIALS	1.0X1.0X2.0 ML VIAL	25/07/2018

1136	NDA/MAL/HDP/7138	BEIJING HOLLEY-COTEC PHARMACEUTICALS CO.,LTD	SUPER PHARMACEUTICALS LIMITED	AMOCIN-CLA TABLETS	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	500MG + 125MG	REYOUNG PHARMACEUTICAL CO. LIMITED..-NO. 6, ERLANGSHAN RD, YIYUAN COUNTY	N/A	GMP EXPIRED; FACILITY ADDRESS CHANGED TO NO.1. APPLICANT REQUIRED TO APPLY FOR A VARIATION	NOT RETAINED	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER	29/08/2019
1137	NDA/MAL/HDP/7150	SAKAR HEALTHCARE LIMITED	ROYAL PHARMA 2011 LIMITED	SEFIXI - SB 1500	CEFTRIAXONE SODIUM +SULBACTAM SODIUM	1000 MG +500MG	N/A	SAKAR HEALTHCARE LIMITEDBLOCK NO. 10-13, SARKHEJ-BAVLA HIGHWAY, VILL: CHANGODAR, DIST: AHMEDABAD-382213, GUJARAT – INDIA.	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL + 1X10ML FFS PLASTIC BOTTLE FOR WFI	29/08/2019
1138	NDA/MAL/HDP/7154	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CIPROFLOXACIN HYDROCHLORIDE	CIPROFLOXACIN HYDROCHLORIDE	2MG/ML	N/A	ABARIS HEALTHCARE PVT LTD - SURVEY NO. 1407-11, VILLAGE RAJPUR, TALUKA KADI DIST. MEHSANA, GUJARAT-382740	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	29/11/2017
1139	NDA/MAL/HDP/7159	SQUARE PHARMACEUTICALS LTD.PABNA UNIT	GAMA PHARMACEUTICALS (U) LIMITED	XYLOCON 0.050%	OXYMETAZOLINE HYDROCHLORIDE	0.050W/V%	N/A	SQUARE PHARMACEUTICALS LIMITED.SQUARE ROAD, SALGARIA, PABNA	N/A	NOT RETAINED	BANGLADESH	NASAL TOPICAL DROPS	1.0X10.0 ML BOTTLE	27/08/2019

1140	NDA/MAL/HDP/7161	SQUARE PHARMACEUTICALS LTD.PABNA UNIT	GAMA PHARMACEUTICALS (U) LIMITED	XYLOCON 0.025%	OXYMETAZOLINE HYDROCHLORIDE	0.025W/V%	N/A	SQUARE PHARMACEUTICALS LIMITED.SQUARE ROAD, SALGARIA, PABNA	N/A	NOT RETAINED	BANGLADESH	NASAL TOPICAL DROPS	1.0X10.0 ML BOTTLE	27/08/2019
1141	NDA/MAL/HDP/7163	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	STODIL	LOPERAMIDE HYDROCHLORIDE	2MG	N/A	TRIVENI FORMULATIONS LTDPLOT NO. 52,53,54,63,62,64 ALEAP INDUSTRIUAL ESTATE SARAMPALLI VIJAYWADA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	27/08/2019
1142	NDA/MAL/HDP/7165	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	ERYMAC	ERYTHROMYCIN STEARATE	250MG	N/A	TRIVENI FORMULATIONS LTDPLOT NO. 52,53,54,63,62,64 ALEAP INDUSTRIUAL ESTATE SARAMPALLI VIJAYWADA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	27/08/2019
1143	NDA/MAL/HDP/7170	WOCKHARD LTD	ROYAL PHARMA 2011 LIMITED	PHYTON 4.5G	PIPERACILLIN + TAZOBACTAM	4.0G + 0.5G	ZEISS PHARMACEUTICALS PVT LTD - -PLOT 72, EPIP, PHASE 1, JHARMAJRI BADDI, 173205, DIST: SOLAN HIMACH	N/A	FACILITY NOT APPROVED FOR THE MANUFACTURE OF THE PENICILLIN LINE	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON +1X20ML WFI AMPOULE	27/08/2019

1144	NDA/MAL/HDP/7183	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	LEVOSUN-500	LEVOFLOXACIN HEMIHYDRATE	500MG	N/A	SUNRISE INTERNATIONAL LABS LTDPLOT NO. 100, LANE-5, SECTOR-II, PHASE-II, IDA, CHERLAPALLY INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	27/08/2019
1145	NDA/MAL/HDP/7184	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	EVOKE TABLETS	SILDENAFIL	50MG	N/A	LABORATORY & ALLIED LTD PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, NEXT TO LIBRA HOUSE, MOMBASA ROAD-NAIROBI - KENYA	N/A	NOT RETAINED	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	28/05/2019
1146	NDA/MAL/HDP/7188	HETERO LABS LTD	AIVEEN (U) LIMITED	TELMILO 80	TELMISARTAN	80 MG	N/A	HETERO LABS LTD (UNIT-V) SYSY. NO. 438, 439, 440 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOOBNAGAR	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/05/2019

1147	NDA/MAL/HDP/7189	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	MERONIR	MEROPENEM SODIUM	1000MG	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDA	N/A	FACILITY HAS NOT BEEN APPROVED FOR THE MANUFACURE OF CARBAPENEMS	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 1*20ML AMPOULE OF WFI	29/11/2017
1148	NDA/MAL/HDP/7191	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROSOL	HYPROMELLOSE	0.7%W/V	N/A	AUROLAB .NO. 1, SIVAGANGAI MAIN ROAD, VEERAPANJANI, MADURAI 1 - 625 020	N/A	NOT RETAINED	INDIA	OPHTHALMIC LIQUIDS	1.0X1.0X10.0 ML VIAL	29/01/2019
1149	NDA/MAL/HDP/7196	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	LORMAN	LORATADINE	10MG	N/A	SUNRISE INTERNATIONAL LABS LTDPLOT NO. 100, LANE-5, SECTOR-II, PHASE-II, IDA, CHERLAPALLY INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/08/2019

1150	NDA/MAL/HDP/7199	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES -	GAMA PHARMACEUTICALS (U) LIMITED	PREGAVALEX 75	PREGABALIN	75MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS FOR INTERNAL USE TABLETS (COATED AND UNCOATED) HARD GELATIN CAPSULES ORAL POWDER FOR SUSPENSION OINTMENTS, CREAMS AND GELS	NOT RETAINED	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	27/11/2018
1151	NDA/MAL/HDP/7202	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	VILDAGLIPTIN	VILDAGLIPTIN	50MG	N/A	NOVARTIS PHARMA STEIN AGSCHAFFHARVSERTRASSE CH-4332 STEIN SWITZERLAND. NOVARTIS FARMACEUTICA SARONDA DE SANTA MARIA,158, E-08210 BARBERA DEL VALLES BARCELONA SPAIN	N/A	NOT RETAINED	SPAIN SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER	01/07/2017

1152	NDA/MAL/HDP/7210	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	ARTECAP	ARTESUNATE	100MG	STRIDES SHASUN LIMITED-36/7, SURAGAJAKKANAHALLI, INDLAVADI CROSS, ANEKAL TALUK, BANGALORE – 562 106	N/A	FACILITY NAME CHANGED TO STRIDES PHARMA SCIENCE LIMITED. CLIENT REQUESTED TO APPLY FOR VARIATION FOR CHANGE OF NAME	RETAINED	INDIA	RECTAL SYSTEMIC CAPSULES	1.0X1.0X2.0 SUPPOSITORY BLISTER,1.0X1.0X6.0 SUPPOSITORY BLISTER	26/09/2018
1153	NDA/MAL/HDP/7212	PHARMACO DISTRIBUTION (PTY) LTD	ECHO PHARMACY (U) LIMITED	PHARMALGAN	PARACETAMOL	10MG/ML	N/A	AMANTA HEALTHCARE LIMITEDPLOT NO. 876 N.H. NO. 8 VILLAGE-HIRIYALA TALUKA, MATAR, DIST KHEDA-387 411, GUJARAT	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	31/01/2018

1154	NDA/MAL/HDP/7220	RAINBOW LIFE SCIENCES PVT.LTD.	EUROPA HEALTHCARE (U) LTD	NAPRIN	NAPROXEN	500MG	GLOBELA PHARMA PVT.LTD. 357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, ORAL POWDER IN SACHETS AND BOTTLES. ONCOLOGY: TABLETS, HARD GELATIN CAPSULES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/08/2019
1155	NDA/MAL/HDP/7221	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	OXYTOCIN	OXYTOCIN	10IU/ML	SALUTAS PHARMA GMBH-OTTO-VON-GUERICKE ALLEE-1, 39179 BARLEBEN	N/A	GMP EXPIRED ON THE 12/11/2022 FOR HARD GELATIN CAPSULES AND TABLETS; FACILITY NOT APPROVED TO MANUFACTURE PARENTERALS.	NOT RETAINED	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X10.0 AMPOULE CARTON	21/11/2019

1156	NDA/MAL/HDP/7222	I-CARE PHARMA LTD	AIVEEN (U) LIMITED	SAMSUNATE	ARTESUNATE	60MG	N/A	SAMRUDH PHARMACEUTICALS PVT LTDJ-174, J-168 & J-168/1, MIDC, TARAPUL, BOISAR, DIST THANE-401506	N/A	NOT RETAINED	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	21/11/2019
1157	NDA/MAL/HDP/7226	JAMJOOM PHARMACEUTICALS COMPANY	MU PHARMA CO -SMC LIMITED	ELICA-M	MOMETASONE FUROATE + MICONAZOLE NITRATE	0.1%W/W + 2%W/W	N/A	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	N/A	NOT RETAINED	SAUDI ARABIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	27/11/2019
1158	NDA/MAL/HDP/7228	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	AMOXICILLIN 250MG DISPERSIBLE TABLETS	AMOXICILLIN TRIHYDRATE	250 MG	N/A	SANDOZ GMBH BIOCHEMISTRASSE 106250 KUNDL, AUSTRIA	N/A	NOT RETAINED	AUSTRIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER	01/07/2017

1159	NDA/MAL/HDP/7231	NATIONAL HEALTHCARE PVT LTD	MALIX PHARMA (U) LIMITED	LIGNAT 2%	LIDOCAINE HYDROCHLORIDE	2% W/V	NATIONAL HEALTHCARE PVT LTD-CHHATAPIPRA 3 BARA	N/A	GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED & UNCOATED), HARD GELATIN CAPSULES, SMALL VOLUME PARENTERAL LIQUIDS (VIALS & AMPOULES), EYE/EAR DROPS, LYOPHILIZED POWDERS FOR INJECTION, , BETA LACTAM (PENICILLIN): TABLETS (COATED & UNCOATED), HARD GELATIN CAPSULES, SMALL VOLUME PARENTERAL POWDERS , BETA LACTAM (CEPHALOSPORIN): SMALL VOLUME PARENTERAL POWDERS	NOT RETAINED	NEPAL	PARENTERAL ORDINARY VIALS	1.0X30.0 ML VIAL	01/07/2017

1160	NDA/MAL/HDP/7232	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CIFF-100 DS	CEFIXIME	100MG/5ML	N/A	PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS & PHARMACEUTICALS PVT. LTD.) B-21/22, MIDC AREA, KALMESHWAR-441 501, NAGPUR, MAHARASHTRA	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE,1.0X 50.0 ML BOTTLE	29/08/2019
1161	NDA/MAL/HDP/7234	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	LEVOFLOXACIN INTRAVENOUS INFUSION	LEVOFLOXACIN HEMIHYDRATE + GLUCOSE ANHYDROUS	500MG + 5W/V%	N/A	ABARIS HEALTHCARE PVT. LTDSURVEY NO. 1407/11, VILLAGE RAJPUR, TAL KADI DIST. MEHSANA, GUJARAT-382740	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	27/08/2019

1162	NDA/MAL/HDP/7246	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES	GAMA PHARMACEUTICALS (U) LIMITED	DESLORAT	DESLORATIDINE	5MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS FOR INTERNAL USE TABLETS (COATED AND UNCOATED) HARD GELATIN CAPSULES ORAL POWDER FOR SUSPENSION OINTMENTS, CREAMS AND GELS	RETAINED	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	2.0X10.0 TABLET STRIP	01/07/2017

1163	NDA/MAL/HDP/7248	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES	GAMA PHARMACEUTICALS (U) LIMITED	ESOMELODAN 20	ESOMEPRAZOLE	20MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS FOR INTERNAL USE TABLETS (COATED AND UNCOATED) HARD GELATIN CAPSULES ORAL POWDER FOR SUSPENSION OINTMENTS, CREAMS AND GELS	RETAINED	EGYPT	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	25/07/2018

1164	NDA/MAL/HDP/7249	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES	GAMA PHARMACEUTICALS (U) LIMITED	ESOMELODAN 40	ESOMEPRAZOLE MAGNESIUM	40MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS FOR INTERNAL USE TABLETS (COATED AND UNCOATED) HARD GELATIN CAPSULES ORAL POWDER FOR SUSPENSION OINTMENTS, CREAMS AND GELS	RETAINED	EGYPT	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	25/07/2018
1165	NDA/MAL/HDP/7254	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	OXEPTAL 300	OXCARBAZEPINE	300MG	CADILA HEALTHCARE LIMITED KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	, 1X3X10 TABLET Blister	04/02/2019
1166	NDA/MAL/HDP/7255	ACULIFE HEALTHCARE	ASTRA PHARMA (U) LIMITED	NIRIXONE	CEFTRIAXONE SODIUM	1000MG	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDA	N/A	THE PRODUCT LINE WAS NOT INCLUDED IN THE APPLICATION FOR GMP RE-INSPECTION.	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 1*1 10ML WFI AMPOULE	29/11/2017

1167	NDA/MAL/HDP/7256	MICRO LABS LTD	LABOREX UGANDA LIMITED	ESOFAG KIT	AMOXICILLIN + CLARITHROMYCIN + ESOMEPRAZOLE	1000MG + 500MG + 20MG	MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126	N/A	FACILITY NOT APPROVED FOR THE MANUFACTURE OF PENICILLIN LINE. APPLICATION FOR RE-INSPECTION DOES NOT INCLUDE THE PRODUCT LINE	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X7.0X6.0 TABLET STRIP (2+2+2)	21/11/2019
1168	NDA/MAL/HDP/7258	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	DESCOVY 200MG/10MG	EMTRICITABINE + TENOFOVIR ALAFENAMIDE	200MG/10MG	ROTTENDORF PHARMA GMBH-OSTENFELDER STRAßE 51-61,59320 ENNIGERLOH GER	PATHEON INC.--TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9	GMP OF THE FACILITY EXPIRED ON THE 30/7/2023 FOR NBL TABLETS	RETAINED	CANADA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE	31/01/2018

1169	NDA/MAL/ HDP/7264	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MIOPAN PLUS SUSPENSION	MAGALDRATE +SIMETHICONE	540MG + 40MG/5ML	PHARCO PHARMACEUTICALS LTD- KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	N/A	GMP EXPIRED ON 28/9/2023 FOR BETA LACTAM (PENICILLIN): ORAL DRY POWDERS FOR SUSPENSION HARD GELATIN CAPSULES TABLETS SVP POWDERS (VIALS), NON-BETA LACTAM: ORAL DRY POWDERS (HUMAN & VETERINARY) HARD GELATIN CAPSULES TABLETS ORAL LIQUIDS ORAL POWDERS IN SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED) CREAMS, OINTMENTS, GELS, SUPPOSITORIES, PESSARIES & OVULES	RETAINED	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2017

1170	NDA/MAL/HDP/7270	ADCOCK INGRAM LIMITED	SURGIPHARM (U) LIMITED	MYPAID	IBUPROFEN +PARACETAMOL	200 MG +250 MG	N/A	ADCOCK INGRAM LIMITED 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE 560099, KARNATAKA STATE, INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	07/11/2018
1171	NDA/MAL/HDP/7274		CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ZENTAIR 0.5MG	ENTECAVIR	0.5MG	N/A	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITEDPLOT 1-7, LUZIRA	N/A	NOT RETAINED	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017
1172	NDA/MAL/HDP/7277	İLKO İLAÇ SANAYI VE TICARET A. Ş.	CORE ACCESS LIMITED	ALERINIT	LEVOCETIRIZINE HYDROCHLORIDE	5MG	N/A	İLKO İLAÇ SANAYI VE TICARET A. Ş3. ORGANIZE SANAYI BÖLGESI KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	N/A	NOT RETAINED	TURKEY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X20.0 TABLET BLISTER	27/08/2019

1173	NDA/MAL/HDP/7278	TIL HEALTHCARE PVT LTD	KAMCARE PHARMA LIMITED	NEUTROSE C	DL-METHIONINE + CHOLINE BITARTRATE + THIAMINE MONO NITRATE + RIBOFLAVIN + PYRIDOXINE HYDROCHLORIDE + NICOTINAMIDE + DEXPANTHENOL + BIOTIN + FOLIC ACID + CYANOCOBALAMIN + ALPHA TOCOPHERYL ACETATE	200MG + 200MG +3MG + 3MG + 1.5MG + 22.5MG + 4.5MG + 0.1MG + 0.5MG + 3MCG + 7.5.I.U	N/A	TIL HEALTHCARE PVT LIMITEDPLOT 100, WEST R-5, SOUTH, SRICITY SEZ, CHERIVE9 (VI), DISTRICT: CHITOOR 517588 ANDHRA PRADESH-	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/11/2019

1174	NDA/MAL/HDP/7283	TIL HEALTHCARE PVT LTD	KAMCARE PHARMA LIMITED	ASTYMIN-M FORTE	L-THREONINE + L-VALINE + DL-METHIONINE + L-ISOLEUCINE + L-LEUCINE + L-PHENYLALANINE + L-TRYPTOPHAN + L-LYSINE HYDROCHLORIDE + THIAMINE NITRATE + RIBOFLAVIN + PYRIDOXINE HYDROCHLORIDE + NICOTINAMIDE + CALCIUM PANTOTHENATE + FOLIC ACID + CYANOCOBALAMIN + AS	4.2MG + 6.7MG + 18.4MG + 5.9MG + 18.3MG + 5.0MG + 5.0MG + 25MG + 5MG + 3MG + 1.5MG + 25MG + 5MG+ 0.75MG + 2.5MCG+ 40MG + 2500 IU+ 200 IU + 7.5 IU + 0.1MG+ 20.5MG+ 4MG+ 1.4MG+ 7.425MG+ 3.3MG+ 10MCG	N/A	TIL HEALTHCARE PVT LIMITEDPLOT 100, WEST R-5, SOUTH, SRICITY SEZ, CHERIVE9 (VI), DISTRICT: CHITOOR 517588 ANDHRA PRADESH-	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	27/11/2019

1175	NDA/MAL/HDP/7286	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	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE	01/07/2017

1176	NDA/MAL/HDP/7287	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPISTIGMIN 0.05%	NEOSTIGMINE METHYLSULPHATE	0.05%W/V	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B1,EGYPT	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE	01/07/2017

1177	NDA/MAL/HDP/7289	TIL HEALTHCARE PVT LTD	KAMCARE PHARMA LIMITED	PEGLEC	POLYETHYLENE GLYCOL + SODIUM CHLORIDE + POTASSIUM CHLORIDE + SODIUM BICARBONATE + ANHYDROUS SODIUM SULFATE	118.0G +2.93G +1.484G + 3.370G + 11.360G / SACHET	N/A	TIL HEALTHCARE PVT LIMITEDPLOT 100, WEST R-5, SOUTH, SRICITY SEZ, CHERIVE9 (VI), DISTRICT: CHITOOR 517588 ANDHRA PRADESH-	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X1.0X137.15 G SACHET	27/11/2019
1178	NDA/MAL/HDP/7296	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MEDAXONUM 2G	CEFTRIAXONE SODIUM	2G	MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X2.0G VIAL	29/01/2019
1179	NDA/MAL/HDP/7303	AXA PARENTERALS LTD	VITACARE LIMITED	AXATOL-20	MANNITOL	20%W/V	N/A	AXA PARENTERALS LTDPLOT NO. 936, 937 & 939, VILLAGE KISHANPUR, JAMALPUR ROORKEE-247667, DIST. HARIDWAR, UTTARAKHAND	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	29/01/2019

1180	NDA/MAL/HDP/7308	STALLION LABORATORIES PVT LTD	HARLEYS UGANDA LIMITED	APSIDASE	ACECLOFENAC + PARACETAMOL + SERRATIOPEPTIDASE	100MG + 500MG + 10MG	N/A	ACME FORMULATION PVT. LTDROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	28/08/2019
1181	NDA/MAL/HDP/7316	CACHET PHARMACEUTICALS PVT LIMITED	ABACUS PHARMA (AFRICA) LIMITED	I-UP TABLETS	FERROUS ASCORBATE + FOLIC ACID	100MG + 1.5MG	N/A	CACHET PHARMACEUTICAL PVT LTD. VILLAGE-THANA, NEAR BADDI, TEHSIL_NALAGARH, DIST. SOLAN, HIMACHAL PRADESH - 173205	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/11/2019
1182	NDA/MAL/HDP/7318	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	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE STRIP	29/01/2019

1183	NDA/MAL/HDP/7332	DROGSAN İLAÇLARI SAN. VE TIC. A.Ş.	BUFFALO HEALTH CARE LTD	DIVATOR 20MG FILM TABLET	ATORVASTATIN	20MG	N/A	DROGSAN ILACLARI SAN VE TIC. A.S.ESENBOGA MERKEZ MAHALLESI CUBUK CADDESI NO: 31 CUBUK / ANKARA - TURKEY	N/A	NOT RETAINED	TURKEY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/01/2019
1184	NDA/MAL/HDP/7340	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	HIFEN -200	IBUPROFEN	200MG	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR-401506, DIST.THANE, MARAHASHTRA, INDIA	PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328 - 1330, VILLAGE MANPURA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH - 174101 KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	MAXHEAL FAILED GMP ON THE 14/5/2019 FOR NON BETA-LACTAM: TABLETS (COATED AND UNCOATED), EXTERNAL PREPARATIONS (CREAMS AND OINTMENTS), HARD GELATIN CAPSULES, DRY POWDER FOR ORAL SUSPENSION, ORAL LIQUIDS	RETAINED	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	21/11/2019

1185	NDA/MAL/HDP/7344	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	HEPANIR	HEPARIN SODIUM	1000IU/ML	N/A	ACULIFE HEALTH CARE, FORMALLY NIRMA(HEALTHCARE DIVISION)VILLAGE: SACHANA, TALUKA: VIRAMGAM DISTRICT: AHMEDABAD-382150 GUJARAT, INDIA	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL	29/11/2017
1186	NDA/MAL/HDP/7345	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	DELTACEF	CEFEPIME	1G	MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	21/11/2019

1187	NDA/MAL/HDP/7348	MSD (PTY) LTD	SURGIPHARM (U) LIMITED	ISENTRESS 25 MG	RALTEGRAVIR POTASSIUM	25MG	PATHEON PHARMACEUTICALS INC.- 2110 E. GALBRAITH ROAD CINCINNATI, OH 45237-1625, USA MERCK SHARP & DOHME BV.- WAARDERWEG 39 HAARLEM, - 2031 BN, NETHERLANDS	MSD (PTY) LTD. -117-16TH ROAD, HALFWAY HOUSE, 1685 SOUTH AFRICA	GMP FOR PATHEON EXPIRED ON THE 4/4/2020 FOR TABLETS; GMP FOR MERCK SHARP & DOHME EXPIRED ON THE 10/4/2021 FOR NON BETA LACTAM; • TABLETS (PRIMARY AND SECONDARY PACKAGING) • ORAL LIQUIDS (SECONDARY PACKAGING)	RETAINED	SOUTH AFRICA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X60.0 TABLET BOTTLE	28/03/2018
1188	NDA/MAL/HDP/7350	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	SULCEF	CEFOPERAZONE+ SULBACTUM	1G+1G	MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X1.0 ML VIAL	27/03/2019

1189	NDA/MAL/HDP/7351	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYFIX CV DS	CEFIXIME+CLAVULANIC ACID	50MG+31.25MG	N/A	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD-ROORKEE DISTT HARIDWAR	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
1190	NDA/MAL/HDP/7356	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DIABETMIN TABLET 500MG	METFORMIN HYDROCHLORIDE	500MG	HOVID BERHAD-121, JALAN TUNKU ABDUL RAHMAN, 30010 IPOH	N/A	FACILITY NOT APPROVED TO MANUFACTURE NBL TABLETS	RETAINED	MALAYSIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X5.0X20.0 TABLET BLISTER	01/07/2017
1191	NDA/MAL/HDP/7366	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYFIX	CEFIXIME	200MG	N/A	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD-ROORKEE DISTT HARIDWAR	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET STRIP	01/07/2017
1192	NDA/MAL/HDP/7367	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYFIX 100 DS	CEFIXIME	100MG/5ML	N/A	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD-ROORKEE DISTT HARIDWAR	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017

1193	NDA/MAL/HDP/7369	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	XOMOX CV DS	AMOXICILLIN TRIHYDRATE+ POTASSIUM CLAVULANATE	200MG+28.5MG/5ML	N/A	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTDUNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
1194	NDA/MAL/HDP/7370	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	XOMOX CV 625	AMOXICILLIN TRIHYDRATE+ POTASSIUM CLAVULANATE	500MG+125MG	N/A	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTDUNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET STRIP	01/07/2017
1195	NDA/MAL/HDP/7386	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYLEXIN 125 DS	CEFALEXIN MONOHYDRATE	125MG/5ML	N/A	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD-ROORKEE DISTT HARIDWAR	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017

1196	NDA/MAL/HDP/7388	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYFIX CV 200	CEFIXIME+CLAVULANIC ACID	200MG+125MG	N/A	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD-ROORKEE DISTT HARIDWAR	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET STRIP	01/07/2017
1197	NDA/MAL/HDP/7389	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES -	GAMA PHARMACEUTICALS (U) LIMITED	GAROPRIDE	ITOPRIDE HYDROCHLORIDE	50MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS FOR INTERNAL USE TABLETS (COATED AND UNCOATED) HARD GELATIN CAPSULES ORAL POWDER FOR SUSPENSION OINTMENTS, CREAMS AND GELS	RETAINED	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
1198	NDA/MAL/HDP/7394	AXA PARENTERALS LTD	VITACARE LIMITED	AXADEX (D50%)	GLUCOSE ANHYDROUS	50%W/V	N/A	AXA PARENTERALS LTDPLOT NO. 936, 937 & 939, VILLAGE KISHANPUR, JAMALPUR ROORKEE-247667, DIST. HARIDWAR, UTTARAKHAND	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	21/11/2019

1199	NDA/MAL/HDP/7406	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ARENA	ADRENALINE	0.1% W/V	LINCOLN PARENTERAL LTD - 11 TRIUL ESTATE KHATRAJ TAL KALOL DIST GANDHINAGAR GUJARAT	LINCOLN PARENTERAL LTD 11 TRIUL ESTATE KHATRAJ TAL KALOL DIST GANDHINAGAR GUJARAT	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: SMALL VOLUME PARENTERAL SOLUTIONS SMALL VOLUME PARENTERAL POWDERS ORAL LIQUIDS	RETAINED	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2017
1200	NDA/MAL/HDP/7408	ZIM LABORATORIES LTD	ROYAL PHARMA 2011 LIMITED	ZIFLAM 100	ACECLOFENAC	100MG	N/A	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
1201	NDA/MAL/HDP/7433	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED -	SURGIPHARM (U) LIMITED	KETOSTERIL	MULTIINGREDIENT	MULTIINGREDIENT	LABESFAL LABORATORIOS SLMIRO, S.A ,.- ZONA INDUSTRIAL DO LAGEDO 3465-157	N/A	FACILITY NOT APPROVED TO MANUFACTURE THE PRODUCT LINE	RETAINED	PORTUGAL	ORAL SOLID ORDINARY TABLETS	1.0X5.0X20.0 TABLET BLISTER	21/11/2019

1202	NDA/MAL/HDP/7449		CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LAMIVUDINE/ TENOFOVIR DF 300/300MG	LAMIVUDINE +TENOFOVIR DISOPROXIL FUMARATE	300MG+300MG	N/A	CIPLA QUALITY CHEMICALS INDUSTRIES LIMITED-PLOT 1-7 1ST RING ROAD, LUZIRA INDUSTRIAL PARK P O BOX 34871, KAMPALA, UGANDA	N/A	NOT RETAINED	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE	31/01/2018
1203	NDA/MAL/HDP/7453	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ANTIDIAZOX	NITAZOXANIDE	100MG/5ML	GLOBAL NAPI PHARMACEUTICALS -2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	N/A	FACILITY NOT APPROVED TO MANUFACTURE ORAL LIQUIDS; GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES	RETAINED	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X60.0 ML BOTTLE	01/07/2017
1204	NDA/MAL/HDP/7455	GETZ PHARMA PVT LTD	MU PHARMACO -SMC LIMITED	GETRYL 4MG	GLIMEPIRIDE	4 MG	N/A	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	N/A	NOT RETAINED	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	29/08/2022

1205	NDA/MAL/HDP/7458	HETERO DRUGS LTD	AIVEEN (U) LIMITED	DERISE™25	DARBEPOETIN ALFA	25MCG/0.42ML	HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOOBNAGAR	N/A	FACILITY NOT APPROVED FOR THE MANUFACTURE OF THE PRODUCT LINE; APPLICATION FOR RE-INSPECTION DOES NOT INCLUDE THIS PRODUCT LINE	RETAINED	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X0.42 ML PRE- FILLED SYRINGE (SINGLE DOSE)	21/11/2019
1206	NDA/MAL/HDP/7459	HETERO DRUGS LTD	AIVEEN (U) LIMITED	DERISE™40	DARBEPOETIN ALFA	40MCG/0.4ML	HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOOBNAGAR	N/A	FACILITY NOT APPROVED FOR THE MANUFACTURE OF THE PRODUCT LINE; APPLICATION FOR RE-INSPECTION DOES NOT INCLUDE THIS PRODUCT LINE	RETAINED	INDIA	PARENTERAL RETARD PRE-FILLED SYRINGES	1.0X0.2 ML PRE- FILLED SYRINGE	21/11/2019

1207	NDA/MAL/HDP/7470	AKRITI PHARMACEUTICALS PVT LTD	PHARMA VILLE LIMITED	AKSONE	CEFTRIAXONE SODIUM	1G	N/A	AKRITI PHARMACEUTICALS PVT LTDPLOT NO. D-10 & 11, MIDC, JEJURI, TAL. PURANDAR, DIST. PUNE (MAHARASHTRA) INDIA	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	21/11/2019
1208	NDA/MAL/HDP/7471	AMRING FARMA S.R.L	LABOREX UGANDA LIMITED	BEVACIZUMAB AMRING	BEVACIZUMAB	100 MG/4 ML	N/A	SINERGIUM BIOTECH SARUTA 9 KM 38.7, B1619IEA, GARIN, BUENOS AIRES - ARGENTINA MABXIENCE S.A.UCARLOS VILLAGE 5148 MUNRO, BUENOS AIRES B16054XL	N/A	NOT RETAINED	ARGENTINA	PARENTERAL ORDINARY VIALS	1.0X1.0X4.0 ML VIAL	21/11/2019
1209	NDA/MAL/HDP/7472	AMRING FARMA S.R.L	LABOREX UGANDA LIMITED	BEVACIZUMAB AMRING	BEVACIZUMAB	400 MG/16 ML	N/A	SINERGIUM BIOTECH SARUTA 9 KM 38.7, B1619IEA, GARIN, BUENOS AIRES - ARGENTINA MABXIENCE S.A.UCARLOS VILLAGE 5148 MUNRO, BUENOS AIRES B16054XL	N/A	NOT RETAINED	ARGENTINA	PARENTERAL ORDINARY VIALS	1.0X1.0X16.0 ML VIAL	21/11/2019

1210	NDA/MAL/HDP/7475	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	UMOCLOX 500	AMPICILLIN TRIHYDRATE+ CLOXACILLIN SODIUM	250MG+250MG	N/A	UNI MEDICOLABS. 2122 PHARMACITY SELAQUI DEHRADUN 248197	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2015
1211	NDA/MAL/HDP/7479	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ALLTERA 50	LOPINAVIR + RITONAVIR	40MG + 10MG / SACHET	MYLAN LABORATORIES LTD .-F/4 & F/12, MALEGAON MIDC, SINNAR, NASHIK-422 113	N/A	FACILITY NOT APPROVED FOR THE MANUFACTURE OF THIS PRODUCT LINE	RETAINED	INDIA	ORAL SOLID ORDINARY GRANULES	1.0X120.0 SACHET CARTON	21/11/2019
1212	NDA/MAL/HDP/7483	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APISOPT PLUS	DORZOLAMIDE HYDROCHLORIDE + TIMOLOL MALEATE	2%W/V + 0.5%W/V	AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	N/A	GMP EXPIRED ON 28/09/2023 FOR NON-BETA LACTAM: STERILE EYE DROPS (ASEPTICALLY PREPARED) STERILE EYE OINTMENTS (ASEPTICALLY PREPARED) NON-STERILE NASAL DROPS NON-STERILE METERED DOSE NASAL SPRAYS OINTMENTS, CREAMS & LOTIONS	RETAINED	JORDAN	OPHTHALMIC LIQUIDS	1.0X5.0 ML VIAL	21/11/2019

1213	NDA/MAL/HDP/7484	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ATORVAAM 10/20	AMLODIPINE BESYLATE + ATORVASTATIN CALCIUM	10MG + 20MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
1214	NDA/MAL/HDP/7485	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORVAAM 5/10	AMLODIPINE BESYLATE + ATORVASTATIN CALCIUM	5MG + 10MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
1215	NDA/MAL/HDP/7486	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORVAAM 5/20	AMLODIPINE BESYLATE + ATORVASTATIN CALCIUM	5MG + 20MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET CARTON	21/11/2019

1216	NDA/MAL/HDP/7492	LINCOLN PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	CYPRODINE	CYPROHEPTADINE HYDROCHLORIDE	2MG/5ML	N/A	LINCOLN PHARMACEUTICAL LIMITED..LINCOLN PHARMACEUTICALS LIMITED, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	27/08/2019
1217	NDA/MAL/HDP/7499	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CELDOL 200	CELECOXIB	200 MG	N/A	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	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	21/11/2019

1218	NDA/MAL/HDP/7500	RESONANT PHARMACEUTICALS	SHREEJI CARE LIMITED	DICLOZONE MR TABLETS	DICLOFENAC POTASSIUM + PARACETAMOL + CHLORZOXAZONE	50 MG + 325 MG + 250 MG	CRIS PHARMA (INDIA) LIMITED-E-11, UPSIDC INDUSTRIAL AREA, SELAQUI, DEHRADUN, UTTARAKHAND	N/A	GMP EXPIRED ON THE 10/9/2022 FOR NON B-LACTAM: TABLETS (COATED AND UN COATED), ORAL LIQUID DOSAGE FORM	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019
1219	NDA/MAL/HDP/7502	AMRING FARMA S.R.L	LABOREX UGANDA LIMITED	CLINDABIOX	CLINDAMYCIN PHOSPHATE	100 MG	FARMAPRIM LTD-5, CRINILOR STREET, PORUMBENI, CRIULENI DISTRICT, MD-4829	N/A	GMP EXPIRED ON THE 10/12/2021 FOR NON-BETA LACTAM HORMONAL, ANTIBIOTIC AND GENERAL: • SUPPOSITORIES • VAGINAL OVULES & PESSARIES • CREAMS • OINTMENTS • GELS;	NOT RETAINED	MOLDOVA	VAGINAL SUPPOSITORIES	1.0X1.0X3.0 PESSARY BLISTER	21/11/2019

1220	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	N/A	GMP EXPIRED ON 28/09/2023 FOR NON-BETA LACTAM: STERILE EYE DROPS (ASEPTICALLY PREPARED) STERILE EYE OINTMENTS (ASEPTICALLY PREPARED) NON-STERILE NASAL DROPS NON-STERILE METERED DOSE NASAL SPRAYS OINTMENTS, CREAMS & LOTIONS	RETAINED	JORDAN	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE	28/05/2019
1221	NDA/MAL/HDP/7517	RESONANT PHARMACEUTICALS PVT LTD	SHREEJI CARE LIMITED	LEVOCET-M	LEVOCETIRIZINE DIHYDROCHLORIDE + MONTELUKAST SODIUM	5MG + 10MG	CRIS PHARMA (INDIA) LIMITED-E-11, UPSIDC INDUSTRIAL AREA, SELAQUI, DEHRADUN, UTTARAKHAND	N/A	GMP EXPIRED ON THE 10/9/2022 FOR NON B-LACTAM: TABLETS (COATED AND UN COATED), ORAL LIQUID DOSAGE FORM	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	21/11/2019

1222	NDA/MAL/HDP/7518	RESONANT PHARMACEUTICALS	SHREEJI CARE LIMITED	LEVOCET-M SUSPENSION	LEVOCETIRIZINE DIHYDROCHLORIDE + MONTELUKAST SODIUM	2.5MG / 5ML + 4MG / 5ML	CRIS PHARMA (INDIA) LIMITED-E-11, UPSIDC INDUSTRIAL AREA, SELAQUI, DEHRADUN, UTTARAKHAND	CENTURION LABORATORIES PVT LTDPLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA	GMP EXPIRED ON THE 10/9/2022 FOR NON B-LACTAM: TABLETS (COATED AND UN COATED), ORAL LIQUID DOSAGE FORM	RETAINED	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	21/11/2019
1223	NDA/MAL/HDP/7524	AMMAN PHARMACEUTICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LOPROSTAN	LATANOPROST + TIMOLOL MALEATE	0.005% W/V + 0.5%W/V	AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	N/A	GMP EXPIRED ON 28/09/2023 FOR NON-BETA LACTAM: STERILE EYE DROPS (ASEPTICALLY PREPARED) STERILE EYE OINTMENTS (ASEPTICALLY PREPARED) NON-STERILE NASAL DROPS NON-STERILE METERED DOSE NASAL SPRAYS OINTMENTS, CREAMS & LOTIONS	RETAINED	JORDAN	OPHTHALMIC LIQUIDS	1.0X2.5 ML VIAL	21/11/2019

1224	NDA/MAL/ HDP/7526	I-CARE PHARMA LTD	AIVEEN (U) LIMITED	MANIGRA 100	SILDENAFIL CITRATE	100 MG	N/A	CORONA REMEDIES PVT. LTDVILLAGE JATOLI, POST OFFICE-OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	21/11/2019
1225	NDA/MAL/ HDP/7527	I-CARE PHARMA LTD	AIVEEN (U) LIMITED	MANIGRA 50	SILDENAFIL CITRATE	50 MG	N/A	CORONA REMEDIES PVT. LTDVILLAGE JATOLI, POST OFFICE-OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	21/11/2019
1226	NDA/MAL/ HDP/7528	I-CARE PHARMA LTD	AIVEEN (U) LIMITED	MANIGRA PLUS	SILDENAFIL CITRATE + DAPOXETINE HYDROCHLORIDE	100MG + 60MG	N/A	CORONA REMEDIES PVT. LTDVILLAGE JATOLI, POST OFFICE-OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	21/11/2019

1227	NDA/MAL/HDP/7533	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ASUNATE 60	ARTESUNATE	60 MG	LINCOLN PARENTERAL LIMITED-11, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT, INDIA.	LINCOLN PARENTERAL LIMITED 11, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT, INDIA.	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: SMALL VOLUME PARENTERAL SOLUTIONS SMALL VOLUME PARENTERAL POWDERS ORAL LIQUIDS	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1*5ML 0.9%W/W SODIUM CHLORIDE SOLUTION AMPOULE + 1*1ML 5.0%W/W SODIUM BICARBONATE SOLUTION AMPOULE	26/09/2018
1228	NDA/MAL/HDP/7560	SEV PHARMACEUTICALS LIMITED	SEV PHARMACEUTICALS LIMITED	VIOLGENT	CRYSTAL VIOLET	0.5%W/V	N/A	SEV PHARMACEUTICALS LIMITEDPLOT 100 NALUKOLONGO	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X25.0 ML BOTTLE	01/07/2014
1229	NDA/MAL/HDP/7593	AMRING PHARMA	LABOREX UGANDA LIMITED	PARACETAMOL AMRING	PARACETAMOL	10 MG/ML	CLARIS INJECTABLES LIMITED---CHACHARWADI VASANA 382 213 AHMEDABAD GUJARAT	N/A	GMP EXPIRED ON THE 17/11/2020 FOR • SMALL VOLUME PARENTERALS (VIALS AND AMPUOLES) • SMALL VOLUME PARENTERALS (EMULSIONS AND AQUEOUS SOLUTIONS IN GLASS BOTTLES)	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	21/11/2019

1230	NDA/MAL/HDP/7594	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	HYDROCHLOROTHIAZIDE 25MG TABLETS	HYDROCHLOROTHIAZIDE	25MG	SALUTAS PHARMA GMBH-OTTO-VON-GUERICKE-ALLEE 1, 39179	N/A	GMP EXPIRED ON THE 12/11/2022 FOR HARD GELATIN CAPSULES AND TABLETS	NOT RETAINED	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X4.0X25.0 TABLET BLISTER	01/07/2017
1231	NDA/MAL/HDP/7595	AMMAN PHARMACEUTICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LOPROST	LATANOPROST	0.005% W/V	AMMAN PHARMA CEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	N/A	GMP EXPIRED ON 28/09/2023 FOR NON-BETA LACTAM: STERILE EYE DROPS (ASEPTICALLY PREPARED) STERILE EYE OINTMENTS (ASEPTICALLY PREPARED) NON-STERILE NASAL DROPS NON-STERILE METERED DOSE NASAL SPRAYS OINTMENTS, CREAMS & LOTIONS	RETAINED	JORDAN	OPHTHALMIC VIALS	1.0X2.5 ML VIAL	21/11/2019

1232	NDA/MAL/HDP/7599	AMRING FARMA S.R.L	LABOREX UGANDA LIMITED	RITUXIMAB AMRING	RITUXIMAB AMRING	100 MG/10 ML	N/A	SINERGIUM BIOTECH SARUTA 9 KM 38.7, B1619IEA, GARIN, BUENOS AIRES - ARGENTINA MABXIENCE S.A.UCARLOS VILLAGE 5148 MUNRO, BUENOS AIRES B16054XL	N/A	NOT RETAINED	ARGENTINA	PARENTERAL ORDINARY VIALS	1.0X2.0X10.0 ML VIAL	21/11/2019
1233	NDA/MAL/HDP/7600	RESONANT PHARMACEUTICALS PVT LTD	SHREEJI CARE LIMITED	NO COLD SYRUP	PARACTAMOL + PHENYL HYDROCHLORIDE + CHLORPHENAMINE MALEATE + SODIUM CITRATE	125MG + 5MG + 1MG + 60MG / 5ML	CRIS PHARMA (INDIA) LIMITED-E-11, UPSIDC INDUSTRIAL AREA, SELAQUI, DEHRADUN, UTTARAKHAND	N/A	GMP EXPIRED ON THE 10/9/2022 FOR NON B-LACTAM: TABLETS (COATED AND UN COATED), ORAL LIQUID DOSAGE FORM	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE	27/11/2019
1234	NDA/MAL/HDP/7601	AMRING FARMA S.R.L	LABOREX UGANDA LIMITED	RITUXIMAB AMRING	RITUXIMAB	500 MG/50 ML	N/A	SINERGIUM BIOTECH SARUTA 9 KM 38.7, B1619IEA, GARIN, BUENOS AIRES - ARGENTINA MABXIENCE S.A.UCARLOS VILLAGE 5148 MUNRO, BUENOS AIRES B16054XL	N/A	NOT RETAINED	ARGENTINA	PARENTERAL ORDINARY VIALS	1.0X1.0X50.0 ML VIAL	21/11/2019

1235	NDA/MAL/HDP/7614	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS UGANDA LTD	TOPCLIN	CLINDAMYCIN PHOSPHATE	1 %W/W	N/A	KREMOINT PHARMA PVT LTD PLANT IIB-8, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST) DIST. THANE 421506	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL EMULSION GELS	1.0X25.0 G TUBE	21/11/2019
1236	NDA/MAL/HDP/7615	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVCLAV-625	AMOXICILLIN + CLAVULANIC ACID	500MG + 125MG	MEDICEF PHARMA-NO. 28, PHASE 1, EPIP, JHARRMAJRI, BADDI, DIST SOLAN (HP)	AMN LIFE SCIENCE PVT LTD-67/P-1, MALAV, AREA-BHILAD, VALSAD-396105, GUJARAT	GMP EXPIRED FOR 30/9/2023 FOR BETA LACTAM (PENICILLIN): TABLETS, DRY POWDER FOR ORAL SUSPENSION	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X2.0X7.0 TABLET BLISTER	21/11/2019
1237	NDA/MAL/HDP/7617	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	EFAVIRENZ, LAMIVUDINE & TENOFOVIR DISOPROXIL FUMARATE TABLETS 600 MG/300 MG /300	EFAVIRENZ + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE	600 MG + 300 MG + 300 MG	N/A	CIPLA QUALITY CHEMICALS INDUSTRIES LIMITED-PLOT 1-7 1ST RING ROAD, LUZIRA INDUSTRIAL PARK P O BOX 34871, KAMPALA, UGANDA	N/A	NOT RETAINED	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE	28/03/2018

1238	NDA/MAL/HDP/7618	INCEPTA PHARMACUTICALS LIMITED	PHARMA VILLE LIMITED	XIMEPROX 200	CEFPODOXIME PROXETIL	200MG	INCEPTA PHARMA CEUTICALS LTD .- DEWAN IDRIS ROAD, BARA RANGAMATIA, ZIRABO, SAVAR-DHAKA	N/A	GMP EXPIRED ON 25/09/2023 FOR STERILE PRODUCTS (NON BETA-LACTAM): LYOPHILIZED (SVP) POWDER (UNIT 6) SMALL VOLUME PARENTERAL (SVP) POWDER (UNIT 1 AND 3) LARGE VOLUME PARENTERAL (LVP) SOLUTION (UNIT 1 AND 3) SMALL VOLUME PARENTERAL (SVP) SOLUTION (UNIT 1 AND 3) EYE/EAR DROPS, NON-STERILE PRODUCTS (NON BETA-LACTAM): ORAL LIQUID (UNIT 5) TABLETS (UNIT 1 AND 3) HARD GELATIN CAPSULES (UNIT 3) GRANULES (UNIT 1) EXTERNAL LIQUIDS (UNIT 5)	NOT RETAINED	BANGLADESH	ORAL SOLID ORDINARY TABLETS	1.0X3.0X4.0 TABLET BLISTER	26/11/2019
1239	NDA/MAL/HDP/7631	ADWIA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	AMADOL 100MG SR TABLET	TRAMADOL HYDROCHLORIDE	100MG	N/A	ADWIA CO. S.A.E10TH OF RAMADAN CITY, INDUSTRIAL AREA A2, EGYPT	N/A	NOT RETAINED	EGYPT	ORAL SOLID RETARD TABLETS	1.0X1.0X10.0 TABLET BLISTER	25/07/2018

1240	NDA/MAL/HDP/7632	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	BISOPROLOL 2.5 MG FILM-COATED TABLETS	BISOPROLOL FUMARATE	2.5MG	LEK S.A.-16 PODLIPIE STR. 95-010 STRYKOW	N/A	GMP EXPIRED ON THE 23/8/2023 FOR NBL TABLETS AND CAPSULES	NOT RETAINED	POLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER	01/07/2017
1241	NDA/MAL/HDP/7634	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	BISOPROLOL	BISOPROLOL	5 MG	LEK S.A.-16 PODLIPIE STR. 95-010 STRYKOW	N/A	GMP EXPIRED ON THE 23/8/2023 FOR NBL TABLETS AND CAPSULES	NOT RETAINED	POLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X25.0 TABLET BLISTER	01/07/2017
1242	NDA/MAL/HDP/7635	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	BISOPROLOL 10MG FILM-COATED TABLETS	BISOPROLOL FUMARATE	10MG	SALUTAS PHARMA GMBH-OTTO-VON-GUERICKE-ALLEE LEK S.A-95 - 010 STRYKÓW, PODLIPIE 16, POLAND	N/A	GMP FOR SALUTAS EXPIRED ON THE 12/11/2022 FOR HARD GELATIN CAPSULES AND TABLETS; GMP FOR LEK S.A EXPIRED ON THE 23/8/2023 FOR NBL TABLETS AND CAPSULES	NOT RETAINED	POLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X25.0 TABLET BLISTER	01/07/2017
1243	NDA/MAL/HDP/7663		CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ZENTAIR	ENTECAVIR MONOHYDRATE	1.0MG	N/A	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITEDPLOT 1-7, LUZIRA	N/A	NOT RETAINED	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017

1244	NDA/MAL/HDP/7673	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	VALSARTAN	VALSARTAN	80MG	N/A	NOVARTIS PHARMA STEIN AG.SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND NOVARTIS FARMACEUTICA SARONDA DE SANTA MARIA,158, E-08210 BARBERA DEL VALLES BARCELONA SPAIN	N/A	NOT RETAINED	SPAIN SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2017
1245	NDA/MAL/HDP/7675	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	VALSARTAN	VALSARTAN	160MG	N/A	NOVARTIS PHARMA STEIN AG.SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND NOVARTIS FARMACEUTICA SARONDA DE SANTA MARIA,158, E-08210 BARBERA DEL VALLES BARCELONA SPAIN	N/A	NOT RETAINED	SPAIN SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2017
1246	NDA/MAL/HDP/7681	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	ZEECEL 200	CELECOXIB	200MG	N/A	THE MADRAS PHARMACEUTICALS.. NO. 137B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI 600096	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2017

1247	NDA/MAL/HDP/7682	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AB-TETRA-250	TETRACYCLINE	250MG	JIANGSU PENGYAO PHARMACEUTICAL CO LTD .- NO. 10 CHAQUAN ROAD YICHENG TOWN YIXING CITY JIANGSU PROVINCE	N/A	FAILED GMP ON THE 28/8/2018 FOR NON BETA LACTAM: • SVP-SOLUTIONS IN AMPOULES • TABLETS • HARD GELATIN CAPSULES; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2017
1248	NDA/MAL/HDP/7683	GLOBAL NAPI FOR PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DELAREX	DESLORATADINE	5MG	GLOBAL NAPI PHARMACEUTICALS -2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	N/A	GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES	RETAINED	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2017

1249	NDA/MAL/HDP/7686	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OPTIGENT EYE/EAR DROPS	GENTAMICIN SULPHATE	0.3W/V	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2017

1250	NDA/MAL/HDP/7687	ABACUS PHARMA (AFRICA) LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DI - QUIN	DIHYDROARTEMISININ+PIPERAQUINE PHOSPHATE	40MG + 320MG	JIANGSU PENGYAO PHARMACEUTICALS CO. LTDNO. 10 CHAQUAN ROAD,YIXING CITY, CHINA	N/A	FAILED GMP ON THE 28/8/2018 FOR NON BETA LACTAM: • SVP-SOLUTIONS IN AMPOULES • TABLETS • HARD GELATIN CAPSULES; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	CHINA	ORAL SOLID ORDINARY TABLETS	1X9 TABLET Blister,	\N
1251	NDA/MAL/HDP/7689	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	CUFO LOZENGES(LEMON)	2, 4 DICHLOROBENZYL ALCOHOL + AMYLMETACRESOL	1.2MG + 0.6MG	N/A	UNIQUE PHARMACEUTICALS LABORATORIESSURVEY NO. 101/2 AND 102/1, DAMAN INDUSTRIAL ESTATE, AIRPORT ROAD, KADAIYA, DAMAN – 396 210 INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X2.0X12.0 LOZENGE BLISTER	01/07/2017
1252	NDA/MAL/HDP/7708	LEBEN LABORATORIES PVT.LTD	MALIX PHARMA (U) LIMITED	LAMPYKLOX CAPSULES	AMPICILLIN TRIHYDRATE+ CLOXACILLIN SODIUM	250MG+250MG	N/A	LEBEN LABORATORIES PVT. LTDPLOT NO. L-4, PHASE-III, MIDC, AKOLA– 444 104 (MS).	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2017

1253	NDA/MAL/HDP/7711	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DIABETMIN 850 MG	METFORMIN HYDROCHLORIDE	850MG	HOVID BHD (IPOH SITE)-121 ,JALAN TUNKU ABDUL RAHMAN , 30010	N/A	FACILITY NOT APPROVED TO MANUFACTURE NBL TABLETS	RETAINED	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017

1254	NDA/MAL/ HDP/7714	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROXONE 1GM	CEFTRIAXONE SODIUM	1 G	N/A	ZEISS PHARMACEUTICALS PVT LTD - PLOT 72, EPIP, PHASE 1, JHARMAJRI BADDI, 173205, DIST: SOLAN HIMACHAL PRADESH, INDIA M/S SCOTT-EDIL ADVANCE RESEARCH LABORATORIES AND EDUCATION LIMITEDHILL-TOP, INDUSTRIAL AREA, BHATOLI KALAN, BADDI, DISTT. SOLAN (HP) - 173205, INDIA INNOVA CAPTAB PVT. LTD1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.)	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	07/11/2018

1255	NDA/MAL/HDP/7724	FERRING GMBH	MACNAUGHTON LIMITED	MENOPUR	HIGHLY PURIFIED MENOTROPHIN [CORRESPONDING TO FOLLICLE STIMULATING HORMONE ACTIVITY (FSH) 75 IU + LUTEINISING HORMONE ACTIVITY (LH) 75 IU]	75 IU + 75 IU/ 4ML VIAL	FERRING (PTY) LTD-WITTLAND II 24146 KIEL	N/A	GMP EXPIRED ON THE 29/06/2019 FOR SVP HORMONES; CURRENTLY, COMPLIANT ADDRESS IS WITTLAND 11, 24109 KIEL, GPS COORDINATES: N 54.3263 E 10.0823 - GERMANY; APPLICANT REQUIRED TO UPDATE MANUFACTURER DETAILS	RETAINED	GERMANY	PARENTERAL ORDINARY DRY VIALS	10.0X4.0 ML VIAL 10*1ML CLEAR COLOURLESS GLASS AMPOULES CONTAINING 9.0MG/ML OF NACL	01/07/2017
1256	NDA/MAL/HDP/7727	AMANTA HEALTHCARE LTD	PHARMA VILLE LIMITED	RINGER LACTATE	COMPOUND SODIUM LACTATE	MULTI-INGREDIENT	N/A	AMANTA HEALTHCARE LIMITED (FORMERLY KNOWN AS MARCK BIOSCIENCES LTD)PLOT NO. 876, N.H. NO. 8, VILLAGE - HARIYALA, DIST - KHEDA 387411, GUJARAT	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X500.0 ML BOTTLE	01/07/2017

1257	NDA/MAL/HDP/7906	AXA PARENTERALS LTD	VITACARE LIMITED	IVMOL	PARACETAMOL	10MG/ML	N/A	AXA PARENTERAL LIMITEDPLOT NO.936,937&939, VILL. KISHANPUR, JAMALPUR,ROORKEE 247667, DISTT. HARIDWAR (UTTARAKHAND) INDIA.	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2016
1258	NDA/MAL/HDP/7909	SANOFI-AVENTIS KENYA	SURGIPHARM (U) LIMITED	LANTUS	INSULIN GLARGINE	100 UNITS/ML	N/A	BAYER HEALTHCAREINDUSTRIEPARK HOECHST, BRUNINGSTRASSEN, BUILDING D-65926 FRANKFURT AM MAIN, GERMANY	N/A	NOT RETAINED	GERMANY	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL	01/07/2017
1259	NDA/MAL/HDP/7910	SANOFI-AVENTIS KENYA	SURGIPHARM (U) LIMITED	LANTUS	INSULIN GLARGINE	100 UNITS/ML	N/A	BAYER HEALTHCAREINDUSTRIEPARK HOECHST, BRUNINGSTRASSEN, BUILDING D-65926 FRANKFURT AM MAIN, GERMANY	N/A	NOT RETAINED	GERMANY	PARENTERAL ORDINARY CARTRIDGES	1.0X5.0X3.0 ML CARTRIDGE	01/07/2017
1260	NDA/MAL/HDP/7911	SANOFI-AVENTIS KENYA	SURGIPHARM (U) LIMITED	LANTUS SOLOSTAR	INSULIN GLARGINE	100 UNITS/ML	N/A	BAYER HEALTHCAREINDUSTRIEPARK HOECHST, BRUNINGSTRASSEN, BUILDING D-65926 FRANKFURT AM MAIN, GERMANY	N/A	NOT RETAINED	GERMANY	PARENTERAL ORDINARY PRE-FILLED PENS	1.0X5.0X3.0 ML PREFILLED PEN	01/07/2017

1261	NDA/MAL/HDP/8023	DENK PHARMA GMB H &CO. KG	BENLE CONSULT LIMITED	AMOXICLAV-DENK 500/62.5	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500 MG + 62.5 MG	PENCEF PHARMA GMBHBRITENBACH STR ASSE 13 D-13509 BERLIN	N/A	GMP EXPIRED ON 29/12/2023 FOR Beta Lactam (Human): Tablets Oral Powders for Oral Suspension Hard Gelatin Capsules	RETAINED	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X8.0 TABLET BLISTER	01/07/2011
1262	NDA/MAL/HDP/8061	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	LYRICA 25MG	PREGABALIN	25 MG	N/A	PFIZER GMBH ARZEIMITELWORK MOOSWADALLE 179090, FREIBERG GERMANY	N/A	NOT RETAINED	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER	01/07/2007
1263	NDA/MAL/HDP/8073	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	TRILEPTAL	OXCARBAZEPINE	300MG	NOVARTIS PHARMA SPA,-TORRE ANNUNZI	N/A	GMP EXPIRED ON THE 30/7/2023 FOR NBL TABLETS	RETAINED	ITALY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X50.0 TABLET CONTAINER	01/07/1997
1264	NDA/MAL/HDP/8112	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	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	ORAL SOLID ORDINARY POWDERS	1.0X100.0 ML BOTTLE	01/07/2016

1265	NDA/MAL/HDP/8113	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	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	ORAL SOLID ORDINARY POWDERS	1.0X100.0 ML BOTTLE	01/07/2016
1266	NDA/MAL/HDP/8114	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	RUPAN	IBUPROFEN	400MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANAS	N/A	GMP OF FACILITY EXPIRED ON 29/10/2023	RETAINED	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
1267	NDA/MAL/HDP/8116	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	EMTRICITABINE + TENOFOVIR DISOPROXIL FUMARATE	EMTRICITABINE + TENOFOVIR DISOPROXIL FUMARATE	200MG + 300MG	N/A	MACLEODS PHARMACEUTICALS LTD .PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2013
1268	NDA/MAL/HDP/8124	RENE PHARMACY(R) LTD..	RENE PHARMACY LTD	CODEINE PHOSPHATE	CODEINE PHOSPHATE	30 MG	N/A	CYANO PHARMA(P)115-C IND ESTATE POLOGROUND, INDORE 452015	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET BOTTLE	01/07/1997

1269	NDA/MAL/HDP/8125	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO. LTD	GAMA PHARMACEUTICALS (U) LIMITED	MATADOR	LEVOFLOXACIN	500MG	N/A	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO. LTD, NA'UR PRINCE HASHEM BIN AL-HUSSEIN STREET, AMMAN, JORDAN	N/A	NOT RETAINED	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X7.0 TABLET BLISTER	01/07/2009
1270	NDA/MAL/HDP/8140	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	FUROSEMIDE	FUROSEMIDE	40MG	SANDOZ PVT LTD.--MIDC IND, AREA KALWE BLOCK VILLAGE DIGHE NAVI MUMBAI	N/A	GMP EXPIRED ON THE 30/8/2022 FOR NON-BETA LACTAM: TABLETS, HARD GELATIN CAPSULES	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X25.0 TABLET BLISTER	01/07/2017
1271	NDA/MAL/HDP/8141	ADCOCK INGRAM HEALTH CARE (PTY) LTD	SURGIPHARM (U) LIMITED	LOTEM SUSPENSION	PARACETAMOL + IBUPROFEN	125MG + 100MG / 5ML	ADCOCK INGRAM HEALTHCARE (PTY) LTD, CLAYVILLE-CORNER AXLE DRIVE AND BARSTEEN ROAD CLAYVILL	N/A	GMP EXPIRED ON THE 4/10/2019 FOR ORAL LIQUIDS	NOT RETAINED	SOUTH AFRICA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	21/11/2019

1272	NDA/MAL/HDP/8165	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	CUFO BLACK CURRANT	2,4 DICHLOROBENZYL ALCOHOL + AMYLMETACRESOL	1.2MG + 0.6MG	N/A	UNIQUE PHARMACEUTICAL LABORATORIES (A DIVISION OF J.B CHEMICALS & PHARMACEUTICALS LTD)SURVEY NO. 101/2 & 102/1 DAMAN INDUSTRIAL ESTATE KADAIYA DAMAN 396 210	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X2.0X12.0 LOZENGE BLISTER	01/07/2017
1273	NDA/MAL/HDP/8166	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	CUFO ORANGE	2,4 DICHLOROBENZYL ALCOHOL + AMYLMETACRESO	1.2MG + 0.6MG	N/A	UNIQUE PHARMACEUTICAL LABORATORIES (A DIVISION OF J.B CHEMICALS & PHARMACEUTICALS LTD)SURVEY NO. 101/2 & 102/1 DAMAN INDUSTRIAL ESTATE KADAIYA DAMAN 396 210	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X2.0X12.0 LOZENGE BLISTER	01/07/2017

1274	NDA/MAL/HDP/8184	AFRICURE PHARMACEUTICALS (INDIA) LTD	AFRICURE PHARMACEUTICALS U LIMITED	TETRASIM	TETRACYCLINE HYDROCHLORIDE	250MG	N/A	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER, 1.0X500.0 CAPSULE CONTAINER	01/07/2008
1275	NDA/MAL/HDP/8193	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	ECOX 400	ETHAMBUTOL	400MG	N/A	MACLEODS PHARMACEUTICALS LTD.PLOT NO. 25-27 SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN (UT) - 396210, INDIA. MACLEODS PHARMACEUTICALS LTD- PLOT 25-27, SURVEY NO. 306, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN (UT)- 396210, INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	01/07/2017

1276	NDA/MAL/HDP/8194	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	SOLONEX-100	ISONIAZID	100MG	MACLEODS PHARMACEUTICALS LTD .- PLOT 1 & 2 MAHIM ROAD NEAR KULDEEP NAGAR	OXALIS LAB-VILLAGE THEDA, P.O. LODHIMAJRA, TEHSIL BADDI, DIST. SOLAN (HP) PIN CODE 174101	GMP EXPIRED 29/6/2012 FOR TABLETS HARD GELATIN CAPSULES ORAL LIQUIDS PELLETS/GRANULES	RETAINED	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
1277	NDA/MAL/HDP/8195	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	RH-COM	RIFAMPICIN & ISONIAZID	150MG +75MG	MACLEODS PHARMACEUTICALS LTD .- PLOT 1 & 2 MAHIM ROAD NEAR KULDEEP NAGAR, PALGHAR (W) 401 404	MACLEODS PHARMACEUTICALS LTD-BLOCK N3, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101	GMP EXPIRED 29/6/2012 FOR TABLETS HARD GELATIN CAPSULES ORAL LIQUIDS PELLETS/GRANULES	RETAINED	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

1278	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	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	PARENTERAL ORDINARY VIALS	1.0X2.0 ML VIAL	01/07/2017

1279	NDA/MAL/HDP/8204	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD	SURGIPHARM (U) LIMITED	DOPAMINE HCL FRESENIUS	DOPAMINE HYDROCHLORIDE	200MG/5ML	N/A	FRESNIUS KABI MANUFACTURING SA (PTY) LTD6 GIBAUD ROAD KORSTEN PORT ELIZABETH 6020	N/A	NOT RETAINED	SOUTH AFRICA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X5.0 ML AMPOULE	01/07/2017

1280	NDA/MAL/HDP/8221	NATIONAL HEALTHCARE PVT LTD	MALIX PHARMA (U) LIMITED	NEMADOL	TRAMADOL HYDROCHLORIDE	50MG/ML	NATIONAL HEALTHCARE PVT LTD-CHHATAPIPRA 3 BARA	N/A	GMP EXPIRED ON 29/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED & UNCOATED), HARD GELATIN CAPSULES, SMALL VOLUME PARENTERAL LIQUIDS (VIALS & AMPOULES), EYE/EAR DROPS, LYOPHILIZED POWDERS FOR INJECTION, , BETA LACTAM (PENICILLIN): TABLETS (COATED & UNCOATED), HARD GELATIN CAPSULES, SMALL VOLUME PARENTERAL POWDERS , BETA LACTAM (CEPHALOSPORIN): SMALL VOLUME PARENTERAL POWDERS	NOT RETAINED	NEPAL	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE	01/07/2017

1281	NDA/MAL/HDP/8224	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OPTIGENT OINTMENT	GENTAMICIN SULFATE	0.3%W/W	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B EGYPT	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE	01/07/2017

1282	NDA/MAL/HDP/8225	LINCOLN PARENTERAL LIMITED	METRO PHARMACEUTICALS LIMITED	ARTELIN 60	ARTESUNATE	60MG	LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE KHATRAJ DISI. GANDHINAGAR-38272, GUJARAT	LINCOLN PARENTERAL LTD11, TRIMUL ESTATE KHATRAJ DISI. GANDHINAGAR-38272, GUJARAT	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: SMALL VOLUME PARENTERAL SOLUTIONS SMALL VOLUME PARENTERAL POWDERS ORAL LIQUIDS	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 1*1 ML AMPOULE OF 5.0%W/V SODIUM BICARBONATE INJECTION B.P + 1*5 ML AMPOULE OF 0.9%W/V NACL	01/07/2017
1283	NDA/MAL/HDP/8227	HETERO LABS LTD	AIVEEN (U) LIMITED	ALZER 5	DONEPEZIL HYDROCHLORIDE	5MG	N/A	HETERO LABS LTD. UNIT (V) .S.N0.439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X1.0X10.0 TABLET BLISTER	01/07/2017

1284	NDA/MAL/HDP/8228	AFRICURE PHARMACEUTICALS (INDIA) LTD	AFRICURE PHARMACEUTICALS U LIMITED	VITAMIN B-COMPLEX (BEEKO)	VITAMINS B1 + B2 + B6 + NIACINAMIDE	1MG +1MG +1MG +15MG	N/A	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017
1285	NDA/MAL/HDP/8244	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	HERTRAZ 440	TRASTUZUMAB (R-DNA ORIGIN)	440MG	N/A	BIOCON LIMITEDSPECIAL ECONOMIC ZONE, PLOT NO.2-4, PHASE IV, BOMMASANDRA-JIGANI LINK ROAD BANGALORE-560 099	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X440.0 MG VIAL ,1X2X10ML VIALS OF WFI	01/07/2017
1286	NDA/MAL/HDP/8247	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	E-DOL	TRAMADOL HYDROCHLORIDE	50MG/ML	N/A	SAKAR HEALTH CARE PVT, LTDBLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382-213,GUJARAT-INDIA	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X2.0 ML AMPOULE	01/07/2017

1287	NDA/MAL/HDP/8248	CACHET PHARMACEUTICALS PVT LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ACINET DRY SYRUP 457MG/5ML	AMOXICILLIN TRIHYDRATE+ CLAVULANATE POTASSIUM	457MG/5ML	N/A	INDCHEMIE HEALTH SPECIALITIES PVT. LTDVILLAGE-THANA, BADDI, DIST. SOLAN, HIMACHAL PRADESH-173 205.	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
1288	NDA/MAL/HDP/8254	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	N/A	GMP EXPIRED ON 20/11/2023 FOR BETA LACTAM (CEPHALOSPORIN): TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, DRY POWDER FOR ORAL SUSPENSION	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET STRIP	01/07/2017
1289	NDA/MAL/HDP/8300	AFRICURE PHARMACEUTICALS (INDIA) PRIVATELIMITED	AFRICURE PHARMACEUTICALS U LIMITED	CIPRONE-500	CIPROFLOXACIN HYDROCHLORIDE	500MG	N/A	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007

1290	NDA/MAL/HDP/8307	NAME AFRICURE PHARMACEUTICALS (INDIA) PRIVATELIMITED	AFRICURE PHARMACEUTICALS U LIMITED	METFORMIN 500	METFORMIN	500MG	N/A	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA.	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008
1291	NDA/MAL/HDP/8309	INDUS PHARMA PVT LTD	HEALTHCARE LTD.	SNOLIP 20MG	ATORVASTATIN	20MG	INDUS PHARMA (PVT) LTD ,-PLOTS NO. 64, 65, 66 & 67, SECTOR - 27, KORANGI INDUSTRIAL AREA, KARACHI - 74900	N/A	GMP EXPIRED ON 22/10/2023 FOR NON-BETA LACTAM: SMALL VOLUME PARENTERAL LIQUIDS, TABLETS, POWDER IN SACHETS FOR ORAL SUSPENSION, ORAL LIQUIDS, BETA LACTAM: HARD GELATIN CAPSULES, ORAL LIQUIDS;	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	01/07/2010

1292	NDA/MAL/HDP/8310	INDUS PHARMA PVT LTD	HEALTHCARE LTD.	MAXPAN-100	CEFIXIME	100MG/5ML	INDUS PHARMA (PVT) LTD ,-PLOTS NO. 64, 65, 66 & 67, SECTOR - 27, KORANGI INDUSTRIAL AREA, KARACHI - 74900	N/A	GMP EXPIRED ON 22/10/2023 FOR NON-BETA LACTAM: SMALL VOLUME PARENTERAL LIQUIDS, TABLETS, POWDER IN SACHETS FOR ORAL SUSPENSION, ORAL LIQUIDS, BETA LACTAM: HARD GELATIN CAPSULES, ORAL LIQUIDS;	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X30.0 ML BOTTLE	01/07/2010
1293	NDA/MAL/HDP/8317	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	MERONIR 500	MEROPENEM	500MG	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDA	N/A	FACILITY HAS NOT BEEN APPROVED FOR THE MANUFACURE OF CARBAPENEMS	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL + 1*10ML AMPOULE OF WFI	29/11/2017
1294	NDA/MAL/HDP/8318	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	B-CANE HEAVY	BUPIVACAINE HYDROCHLORIDE BP	5 MG/ML	N/A	ACULIFE HEALTHCARE PVT. LTDVILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X4.0 ML AMPOULE	29/11/2017

1295	NDA/MAL/HDP/8335	RIVA PHARMA FREE ZONE	WIDE SPECTRUM ENTERPRISES (U) LIMITED	RIVAMOX	AMOXICILLIN TRIHYDRATE	500MG	N/A	RIVA PHARMA FREE ZONENASR CITY CAIRO EGYPT	N/A	NOT RETAINED	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	31/01/2018
1296	NDA/MAL/HDP/8337	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ARTESUNATE 120 MG	ARTESUNATE	120 MG	N/A	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	N/A	NOT RETAINED	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
1297	NDA/MAL/HDP/8342	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ANCOLIN 75	PREGABALIN	75MG	N/A	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	30/05/2018

1298	NDA/MAL/HDP/8349	TIL HEALTHCARE PVT LTD	KAMCARE PHARMA LIMITED	ASTYMIN-C DROPS	L-LEUCINE USP + L-ISOLEUCINE USP + L-LYSINE HYDROCHLORIDE USP + L-PHENYLALANINE USP + L-THREONINE USP + L-VALINE USP+ L-TRYPTOPHAN USP + DL-METHIONINE USP + ASCORBIC ACID BP	0.84M+1.43MG+1.84MG+1.18MG+3.66MG+1.00MG+1.00MG+5.00MG+100MG	N/A	TIL HEALTH CAREPLOT 100,WEST,R-5,SOUTH;SRICITY SEZ,CHERIVI,IRUHULAM,PSOT,SATYAVEDU MANDAL,CHITOOR DISTRICT-ANDRA PRADESH-517588, INDIA	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X15.0 ML BOTTLE	29/11/2017

1299	NDA/MAL/HDP/8351	TIL HEALTHCARE PVT LTD	KAMCARE PHARMA LIMITED	ASTYMIN SYRUP	L-LEUCINE+L-ISOLEUCINE+L-LYSINE HYDROCHLORIDE+L-PHENYLALNINE+L-THREONINE+L-METHIONINE +L-TRYPTOPHAN +L-VALINE+THIAMINE HYDROCHLORIDE+RIBOFLAVING HYDROCHLORIDE+NICOTINAMIDE+CALCIUM PANTOTHENATE+CYANOCOBALAMIN+FOLIC ACID+COLECALCIFEROL+ALPHATOCOPHERYLACETATE	10.3MG + 5.9MG + 25MG + 5MG + 4.2MG + 9.2MG + 5MG + 6.7MG + 5MG + 1.5MG +25MG + 5MG + 2.5MCG + 0.75MG + 200IU AND 7.5IU	N/A	TIL HEALTH CAREPLOT 100,WEST,R-5,SOUTH;SRICITY SEZ,CHERIVI,IRUHULAM,PSOT,SATYAVEDU MANDAL,CHITOOR DISTRICT-ANDRA PRADESH-517588, INDIA	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	29/11/2017
1300	NDA/MAL/HDP/8358	TIL HEALTHCARE PVT LTD	KAMCARE PHARMA LIMITED	ASTYMIN FORTE	MULTI-INGREDIENT	MULTI-INGREDIENT	N/A	TIL HEALTH CAREPLOT 100,WEST,R-5,SOUTH;SRICITY SEZ,CHERIVI,IRUHULAM,PSOT,SATYAVEDU MANDAL,CHITOOR DISTRICT-ANDRA PRADESH-517588, INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X3.0X10.0 CAPSULE BLISTER	29/11/2017

1301	NDA/MAL/HDP/8359	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ASUNATE 120	ARTESUNATE	120MG	LINCOLN PARENTERAL LIMITED-11, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT, INDIA.	LINCOLN PARENTERAL LIMITED 11, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT, INDIA.	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: SMALL VOLUME PARENTERAL SOLUTIONS SMALL VOLUME PARENTERAL POWDERS ORAL LIQUIDS	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X120.0 MG VIAL + 1*10 ML SODIUM CHLORIDE IN GLASS AMPOULE + 1*2 ML SODIUM BICARBONATE IN GLASS AMPOULE	29/11/2017
1302	NDA/MAL/HDP/8412	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AMINOPHYLLINE	AMINOPHYLLINE	25 MG / ML	SHANDONG XIER KANGTAI PHARMACEUTICAL CO. LTD-PRIVATE ECONOMY ZONE,YANZHOU DISTRICT, SHANDONG, CHINA PR	N/A	FACILITY FAILED GMP ON THE 31/8/2018 FOR NON-BETA LACTAM DOSAGE FORMS: • SMALL VOLUME PARENTERALS –SOLUTIONS IN AMPOULES.;	RETAINED	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0 ML AMPOULE,1.0X50.0X10.0 ML AMPOULE	01/07/2016
1303	NDA/MAL/HDP/8419	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	VB COMPLEX	VIT B1+ VIT B2 +VIT B3 + NICOTINAMIDE+PANTOTHENOL	10MG +1MG +1MG +16MG +0.5MG	KIVI PHARM CO. LTD .-NO.5 HANGTIAN STREET,	SCOTT-EDIL PHARMACIA LTD (UNIT I)-56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	GMP EXPIRED ON THE 25TH/09/2023 FOR NON BETA-LACTAM: SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED PACKED IN AMPOULES)	RETAINED	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE,1.0X100.0X2.0 ML AMPOULE	01/07/2018

1304	NDA/MAL/HDP/8424	LINCOLN PARENTERAL LIMITED	METRO PHARMACEUTICALS LIMITED	HAEMRICH	FERRIC AMMONIUM CITRATE+ FOLIC ACID+PYRIDOXINE HCL + THIAMINE HCL + NICOTINAMIDE	50MG + 0.55MG +2.4MG + 1.2MG +11MG /5ML	LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE KHATRAJ DISI. GANDHINAGAR-38272, GUJARAT	N/A	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: SMALL VOLUME PARENTERAL SOLUTIONS SMALL VOLUME PARENTERAL POWDERS ORAL LIQUIDS	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X90.0 ML BOTTLE	01/07/2017
1305	NDA/MAL/HDP/8473	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	NYSTATIN VAGINAL INSERTS	NYSTATIN	100000 I.U	N/A	S KANT HEALTHCARE LTD1802-1805 GIDC PHASE III VAPI 396 195 GUJARAT	N/A	NOT RETAINED	INDIA	VAGINAL TABLETS	1.0X10.0X10.0 TABLET STRIP	31/01/2018
1306	NDA/MAL/HDP/8475	LINCOLN PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	OROCAN	MICONAZOLE	2%W/W	N/A	LINCOLN PHARMACEUTICALS LTD-TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA	N/A	NOT RETAINED	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X15.0 G TUBE	31/01/2018

1307	NDA/MAL/HDP/8481	LINCOLN PARENTERAL LIMITED	METRO PHARMACEUTICALS LIMITED	PARACETAMOL BP INJECTION	PARACETAMOL	150MG/ML	LINCOLN PARENTERAL LTD - 11 TRIUL ESTATE KHATRAJ TAL KALOL DIST GANDHINAGAR GUJARAT	LINCOLN PARENTERAL LTD 11 TRIUL ESTATE KHATRAJ TAL KALOL DIST GANDHINAGAR GUJARAT	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: SMALL VOLUME PARENTERAL SOLUTIONS SMALL VOLUME PARENTERAL POWDERS ORAL LIQUIDS	RETAINED	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	31/01/2018
1308	NDA/MAL/HDP/8483	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	GLIMEPIRIDE 2MG	GLIMEPIRIDE	2MG	LEK S.A--U1, PODLIPIE 16, 95-0140 STRYKOW	N/A	GMP EXPIRED ON THE 23/8/2023 FOR NBL TABLETS AND CAPSULES	NOT RETAINED	POLAND	ORAL SOLID ORDINARY TABLETS	1.0X9.0X10.0 TABLET BLISTER	31/01/2018
1309	NDA/MAL/HDP/8484	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	AVERNOL	CARVEDILOL	25MG	MEDOCHEMIE LTD-CENTRAL FACTORY A-1-10 CONSTANTINOUPOLEUS STREET	N/A	FACILITY NOT APPROVED FOR THIS LINE	RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	31/01/2018
1310	NDA/MAL/HDP/8488	ZIM LABORATORIES LTD	REDDYS PHARMA LIMITED	CEFRAZ 200	CEFIXIME TRIHYDRATE	200MG	N/A	ZIM LABORATORIES LIMITEDB-21122, MIDC AREA, KALMESHWAR -441 501, DIST. NAGPUR,INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	31/01/2018

1311	NDA/MAL/HDP/8493	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	DESCOVY 200MG/25 MG	EMTRICITABINE/TENOFOVIR ALAFENAMIDE	200MG + 25 MG	ROTTENDORF PHARMA GMBH-OSTENFELDER STRAßE 51-61,59320 ENNIGERLOH GER	PATHEON INC.--TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9	GMP OF THE FACILITY EXPIRED ON THE 30/7/2023 FOR NBL TABLETS	RETAINED	CANADA GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	31/01/2018
1312	NDA/MAL/HDP/8495	CACHET PHARMACEUTICALS PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CACEF 50	CEFPODOXIME PROXETIL USP	50MG / 5ML	N/A	ALKEM LABORATORIES LTD.VILLAGE THANA, BADDI, DISTT. SOLAN,HIMACHAL PRADESH 173205 INDIA.	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X30.0 ML BOTTLE	31/01/2018
1313	NDA/MAL/HDP/8497	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYOXIM 500	CEFUROXIME AXETIL	500 MG	N/A	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD - UNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE-247668. DIST.-HARIDWAR, UTTARAKHAND	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	31/01/2018

1314	NDA/MAL/HDP/8498	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR)	OMASI MED LIMITED	TRIAXONE 0.5G	CEFTRIAXONE	0.5G	N/A	GULF PHARMACEUTICALS INDUSTRIES"JULPHAR"P.O.BOX 997 AIRPORT ROAD,DIGDAGA STREET RAS AL KHAIMAH,U.A.E	N/A	NOT RETAINED	UNITED ARAB EMIRATES	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 5 ML AMPOULE OF WATER FOR INJECTION	31/01/2018
1315	NDA/MAL/HDP/8504	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LEDVIR	LEDIPASVIR + SOFOSBUVIR	90MG + 400MG	N/A	MYLAN LABORATORIES LIMITEDF- 4 & F-12, MIDC, MALEGAON, SINNAR, NASHIK - 422 113 MAHARASHTRA, INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X28.0 TABLET BOTTLE	29/11/2017
1316	NDA/MAL/HDP/8522	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS UGANDA LTD	DAYPENAM	MEROPENEM	500MG	SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDA	ZEISS PHARMACEUTICALS PRIVATE LIMITED-PLOT NO. 72 EPIP-PHASE-1 JHARMAJRI BADDI DISTRICT SOLAN (H.P.) - INDIA	FACILITY NOT APPROVED FOR THE MANUFACTURE OF THIS PRODUCT LINE	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X500.0 MG VIAL	07/01/2017
1317	NDA/MAL/HDP/8606	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	DIPHEX COUGH EXPECTORANT	DIPHENHYDRAMINE HYDROCHLORIDE + SODIUM CITRATE + AMMONIUM CHLORIDE	0.014 MG / 5 ML + 0.057 MG / 5 ML + 0.135 MG / 5 ML	N/A	MAVID PHARMACEUTICAL INDUSTRIES LIMITEDPLOT 490 BIRONGO, KITIIKO	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2005

1318	NDA/MAL/HDP/8611	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	SURGICAL SPIRIT	METHYLSALICYLATE + DIETHYLPHTHALATE + CASTOR OIL	0.5W/V% + 2.0W/V%+ 2.5W/V%	N/A	MAVID PHARMACEUTICAL INDUSTRIES LIMITEDPLOT 490 BIRONGO, KITIIKO	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X100.0 ML BOTTLE	01/07/2005
1319	NDA/MAL/HDP/8615	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	CALAMINE LOTION	CALAMINE + ZINC OXIDE	0.75 MG / 5 ML + 0.25 MG / 5 ML	N/A	MAVID PHARMACEUTICAL INDUSTRIES LIMITEDPLOT 490 BIRONGO, KITIIKO	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	UGANDA	TOPICAL EXTERNAL SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2005
1320	NDA/MAL/HDP/8617	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	MAVID'S KEVLON	CHLORHEXIDINE GLUCONATE 20% + CETRIMIDE	0.015 G / 5 ML +0.15 G / 5 ML	N/A	MAVID PHARMACEUTICAL INDUSTRIES LIMITEDPLOT 490 BIRONGO, KITIIKO	NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	NOT RETAINED	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X125.0 ML BOTTLE	01/07/2007

1321	NDA/MAL/HDP/8639	MSD (PTY) LTD	SURGIPHARM (U) LIMITED	ISENTRESS 100MG	RALTEGRAVIR POTASSIUM	100MG	PATHEON PHARMACEUTICALS INC.- 2110 E. GALBRAITH ROAD CINCINNATI, OH 45237-1625, USA MERCK SHARP & DOHME BV.- WAARDERWEG 39 HAARLEM, - 2031 BN, NETHERLANDS	MSD (PTY) LTD. -117-16TH ROAD, HALFWAY HOUSE, 1685 SOUTH AFRICA	GMP FOR PATHEON EXPIRED ON THE 4/4/2020 FOR TABLETS; GMP FOR MERCK SHARP & DOHME EXPIRED ON THE 10/4/2021 FOR NON BETA LACTAM; • TABLETS (PRIMARY AND SECONDARY PACKAGING) • ORAL LIQUIDS (SECONDARY PACKAGING)	RETAINED	SOUTH AFRICA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X60.0 TABLET BOTTLE	28/03/2018
1322	NDA/MAL/HDP/8642	EGYPHAR	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LORAFAST	DESLORATADINE	2.5MG/5ML	N/A	EGYPHAR FACTORYOBOUR CITY- INDUSTRIAL ZONE (A), BLOCK NO 13026. PIECE NO 9,0-EGYPT	N/A	NOT RETAINED	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	21/11/2019

1323	NDA/MAL/HDP/8644	CACHET PHARMACEUTICALS PVT LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LOOBID SUSPENSION	OFLOXACIN + ORNIDAZOLE	50MG + 125MG / 5ML	N/A	CACHET PHARMACEUTICALS PVT LTDVILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X30.0 ML BOTTLE	28/03/2018
1324	NDA/MAL/HDP/8645	EGYPHAR	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MODAZAR	LOSARTAN + HYDROCHLOROTHIAZIDE	100MG + 25MG	N/A	EGYPHAR FACTORYOBOUR CITY- INDUSTRIAL ZONE (A), BLOCK NO 13026. PIECE NO 9,0-EGYPT	N/A	NOT RETAINED	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X4.0 TABLET STRIP	21/11/2019
1325	NDA/MAL/HDP/8647	EGYPHAR	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ZISROCIN	AZITHROMYCIN DIHYDRATE	100MG/5ML	N/A	EGYPHAR FACTORYOBOUR CITY- INDUSTRIAL ZONE (A), BLOCK NO 13026. PIECE NO 9,0-EGYPT	N/A	NOT RETAINED	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	21/11/2019
1326	NDA/MAL/HDP/8653	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	LEFLOXIN 500	LEVOFLOXACIN HEMIHYDRATE	500MG	N/A	ZIM LABORATORIES LTDB-21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA,	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	28/03/2018

1327	NDA/MAL/HDP/8658	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	METFORMIN 1000MG	METFORMIN HYDROCHLORIDE	1000MG	LEK S.A.-16 PODLIPIE STR. 95-010 STRYKOW	N/A	GMP EXPIRED ON THE 23/8/2023 FOR NBL TABLETS AND CAPSULES	NOT RETAINED	POLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X15.0 TABLET BLISTER	28/03/2018
1328	NDA/MAL/HDP/8659	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	METFORMIN 500MG	METFORMIN HYDROCHLORIDE	500MG	LEK S.A.-16 PODLIPIE STR. 95-010 STRYKOW	N/A	GMP EXPIRED ON THE 23/8/2023 FOR NBL TABLETS AND CAPSULES	NOT RETAINED	POLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X6.0X10.0 TABLET BLISTER	28/03/2018
1329	NDA/MAL/HDP/8690	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ARTESUNATE SUPPOSITORIES 100MG	ARTESUNATE	100MG	CIPLA LIMITED.,-PLOT NO.D-7 MIDC INDUSTRIAL AREA, KURKUMBH,DIST: PUNE	N/A	APPLICATION FOR GMP RE-INSPECTION DOES NOT INCLUDE SUPPOSITORIES	RETAINED	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X2.0 BLISTER CARTON	26/09/2018
1330	NDA/MAL/HDP/8691	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	QUETRA 1000	LEVETIRACETAM	1000MG	N/A	REMEDICA LTD.AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE,3056 LIMASSOL CYPRUS	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	30/05/2018
1331	NDA/MAL/HDP/8692	PHARMA BAVARIA INTERNACIONAL(PBI) PORTUGUAL	GOODMAN INTERNATIONAL LTD	PARAFUSIV	PARACETAMOL	10 MG/ML	N/A	S.M FARMACEUTICI SRLZONA INDUSTRIALE, 85050 TITO-POTENZA (PZ) ITALY	N/A	NOT RETAINED	ITALY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X50.0 ML VIAL,1.0X100.0 ML VIAL	30/05/2018

1332	NDA/MAL/HDP/8693	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	QUETRA 100MG/ML	LEVETIRACETAM	100 MG/ML	N/A	REMEDICA LTD.AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE,3056 LIMASSOL CYPRUS	N/A	NOT RETAINED	CYPRUS	ORAL LIQUID ORDINARY LIQUIDS	1.0X300.0 ML BOTTLE	30/05/2018
1333	NDA/MAL/HDP/8694	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ERBITUX	CETUXIMAB	5MG/ML	BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG - - BIRKENDORFER STRASSE 65	MERCK KGAA-250 FRANKFURTERSTRASSE, D-6100 DARMSTADT	GMP EXPIRED ON THE 23/4/2021 FOR BIOLOGICS • SMALL VOLUME PARENTERALS	RETAINED	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X20.0 ML VIAL	07/11/2018

1334	NDA/MAL/HDP/8696	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BABY COL	SIMETICONE	40MG/0.6 ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	N/A	GMP EXPIRED ON 28/9/2023 FOR BETA LACTAM (PENICILLIN): ORAL DRY POWDERS FOR SUSPENSION HARD GELATIN CAPSULES TABLETS SVP POWDERS (VIALS), NON-BETA LACTAM: ORAL DRY POWDERS (HUMAN & VETERINARY) HARD GELATIN CAPSULES TABLETS ORAL LIQUIDS ORAL POWDERS IN SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED) CREAMS, OINTMENTS, GELS, SUPPOSITORIES, PESSARIES & OVULES	NOT RETAINED	EGYPT	ORAL LIQUID ORDINARY EMULSIONS	1.0X1.0X15.0 ML BOTTLE	30/05/2018
1335	NDA/MAL/HDP/8699	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	ACETAZOLAMIDE	ACETAZOLAMIDE	250 MG	N/A	REMEDICA LTD.AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE,3056 LIMASSOL CYPRUS	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	30/05/2018

1336	NDA/MAL/HDP/8743	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	ISONIAZID	ISONIAZID	300 MG	N/A	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X24.0X28.0 TABLET BLISTER	01/07/2010
1337	NDA/MAL/HDP/8781	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVXIM-400	CEFIXIME	400MG	ASSOCIATED BIOTECH-KRISHAN PURA, P. O GURUMAJRA, BADDI, DIST. SOLAN	N/A	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: DRY POWDER FOR ORAL SUSPENSION TABLETS CAPSULES , BETA-LACTAM (CEPHALOSPORIN): DRY POWDER FOR ORAL SUSPENSION	NOT RETAINED	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
1338	NDA/MAL/HDP/8783	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVCLAV-375	AMOXICILLIN + CLAVULANIC ACID	250MG + 125MG	MEDICEF PHARMA-NO. 28, PHASE 1, EPIP, JHARRMAJRI, BADDI, DIST SOLAN (HP)	AMN LIFE SCIENCE PVT LTD-67/P-1, MALAV, AREA-BHILAD, VALSAD-396105, GUJARAT	GMP EXPIRED FOR 30/9/2023 FOR BETA LACTAM (PENICILLIN): TABLETS, DRY POWDER FOR ORAL SUSPENSION	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER	21/11/2019

1339	NDA/MAL/HDP/8784	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVCEF-500	CEFUROXIME AXETIL	500MG	ASSOCIATED BIOTECH-KRISHAN PURA, P. O GURUMAJRA, BADDI, DIST. SOLAN	N/A	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: DRY POWDER FOR ORAL SUSPENSION TABLETS CAPSULES , BETA-LACTAM (CEPHALOSPORIN): DRY POWDER FOR ORAL SUSPENSION	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	21/11/2019
1340	NDA/MAL/HDP/8785	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVCEF SUSPENSION	CEFUROXIME AXETIL	125MG/5ML	ASSOCIATED BIOTECH-KRISHAN PURA, P. O GURUMAJRA, BADDI, DIST. SOLAN	N/A	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: DRY POWDER FOR ORAL SUSPENSION TABLETS CAPSULES , BETA-LACTAM (CEPHALOSPORIN): DRY POWDER FOR ORAL SUSPENSION	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X60.0 ML BOTTLE	21/11/2019

1341	NDA/MAL/HDP/8787	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVXIM-200	CEFIXIME	200MG	ASSOCIATED BIOTECH-KRISHAN PURA, P. O GURUMAJRA, BADDI, DIST. SOLAN	N/A	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: DRY POWDER FOR ORAL SUSPENSION TABLETS CAPSULES , BETA-LACTAM (CEPHALOSPORIN): DRY POWDER FOR ORAL SUSPENSION	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	21/11/2019
1342	NDA/MAL/HDP/8788	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVPOD-200	CEFPODOXIME PROXETIL	200MG	ASSOCIATED BIOTECH-KRISHAN PURA, P. O GURUMAJRA, BADDI, DIST. SOLAN	N/A	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: DRY POWDER FOR ORAL SUSPENSION TABLETS CAPSULES , BETA-LACTAM (CEPHALOSPORIN): DRY POWDER FOR ORAL SUSPENSION	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	21/11/2019

1343	NDA/MAL/HDP/8822	ABACUS PARENTERAL DRUGS LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	ALIDO	LIDOCAINE HYDROCHLORIDE	2%W/V	LINCOLN PARENTERAL LIMITED-11, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT, INDIA.	LINCOLN PARENTERAL LIMITED 11, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT, INDIA.	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: SMALL VOLUME PARENTERAL SOLUTIONS SMALL VOLUME PARENTERAL POWDERS ORAL LIQUIDS	RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X30.0 ML VIAL	30/05/2018
1344	NDA/MAL/HDP/8825	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	LAXALINK	LACTULOSE	3.35G/5ML	LINCOLN PARENTERAL LIMITED-11, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT, INDIA.	LINCOLN PARENTERAL LIMITED 11, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT, INDIA.	GMP EXPIRED ON THE 30/9/2023 FOR NON-BETA LACTAM: SMALL VOLUME PARENTERAL SOLUTIONS SMALL VOLUME PARENTERAL POWDERS ORAL LIQUIDS	RETAINED	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X150.0 ML BOTTLE	30/05/2018

1345	NDA/MAL/ HDP/8838	HETERO LABS LTD	AIVEEN (U) LIMITED	PREGA 150	PREGABALIN	150MG	N/A	HHETERO LABS LIMITED (UNIT III)KALYANPUR, CHAKKAN ROAD, BADDI, DIST. SOLAN, HIMACHAL PRADESH INDIA HETERO LABS PRIVATE LIMITED UNIT IIISURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) JEEDIMETLA, HYDERABAD-500 055, TELANGANA STATE	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1X100 ML Bottle, 1X3X10 CAPSULE Blister	26/11/2019

1346	NDA/MAL/HDP/8844	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VENAXAN 500 MG	LEVOFLOXACIN HEMIHYDRATE	500 MG	SOUTH EGYPT DRUG INDUSTRIES CO- 1ST INDUSTRIAL ZONE, 6 OCTOBER CITY, EGYPT.	N/A	GMP EXPIRED ON THE 28/09/2023 FOR NON-BETA LACTAM: ORAL VETERINARY POWDERS TABLETS POWDERS FOR ORAL SUSPENSION HARD GELATIN CAPSULES ORAL LIQUIDS OINTMENTS, CREAMS & GELS SUPPOSITORIES STERILE LIQUIDS IN AMPOULES POWDER SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED IN PLASTIC AMPOULE) SMALL VOLUME LYOPHILIZED POWDER (ASEPTICALLY PREPARED) SOFT GELATIN CAPSULES , BIOLOGICALS (SVP): RECOMBINANT INSULIN	RETAINED	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X5.0 TABLET BLISTER	07/11/2018

1347	NDA/MAL/HDP/8921	SUN PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	VESIZEN 5	SOLIFENACIN SUCCINATE	5 MG	N/A	SUN PHARMACEUTICALS LTD-,SEZ UNIT –I, PLOT NO. A-41, INDUSTRIAL AREA, PHASE VIIIA S.A.S NAGAR MOHALI-160 071 PUNJAB, INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	25/07/2018
1348	NDA/MAL/HDP/8931	CARITAS HEALTHCARE PVT. LTD	REDDYS PHARMA LIMITED	SODIUM CHLORIDE INTRAVENOUS INFUSION BP	SODIUM CHLORIDE	0.9%W/V	N/A	SICHUAN KELUN PHARMACEUTICAL CO., LTDSOUTH OF NO.2 ROAD, XINDU SATELLITE CITY INDUSTRIAL DEVELOPMENT ZONE, CHENGDU, SICHUAN PROVINCE 610500, P. R. CHINA	N/A	NOT RETAINED	CHINA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	25/07/2018
1349	NDA/MAL/HDP/8935	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD	HEALTHCARE LTD.	FECLO GEL	DICLOFENAC DIETHYLAMMONIUM SALT	1%W/W	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD-PLOT 20,21,22-DEFENCE INDUSTRIAL ZONE-MOMAN PURA, 16KM SHEIKHU PURA ROAD	N/A	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS, HARD GELATIN CAPSULES, OINTMENTS/CREAMS/GELS	NOT RETAINED	PAKISTAN	TOPICAL EXTERNAL EMULSION GELS	1.0X1.0X20.0 G TUBE,1.0X1.0X15.0 G TUBE	25/07/2018

1350	NDA/MAL/HDP/8936	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD	HEALTHCARE LTD.	ESOFOLE	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40MG	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD-PLOT 20,21,22-DEFENCE INDUSTRIAL ZONE-MOMAN PURA, 16KM SHEIKHU PURA ROAD	N/A	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS, HARD GELATIN CAPSULES, OINTMENTS/CREAMS/GELS	RETAINED	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER	25/07/2018
1351	NDA/MAL/HDP/8939	FREDUN PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	RHINOCOLD	PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + CHLORPHENIRAMINE MALEATE + CAFFEINE (ANHYDROUS)	500MG + 10MG + 2MG + 30MMG	N/A	FREDUN PHARMACEUTICALS LTD -14, 15, 16, ZORABIAN INDUSTRIAL COMPLEX, VILLAGE, VEOOR, PALGHAR (EAST) DIST: THANE – 401 404 - INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X1.0X4.0 TABLET BLISTER	25/07/2018

1352	NDA/MAL/HDP/8944	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	N/A	GMP EXPIRED ON 1/10/2023 FOR BETA LACTAM (PENICILLINS): TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SVP-POWDERS	RETAINED	CHINA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	25/07/2018
1353	NDA/MAL/HDP/8946	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	N/A	GMP EXPIRED ON 1/10/2023 FOR BETA LACTAM (PENICILLINS): TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SVP-POWDERS	RETAINED	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X0.6 G VIAL	25/07/2018

1354	NDA/MAL/HDP/8947	B & O PHARMZAC	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	N/A	GMP EXPIRED ON 1/10/2023 FOR BETA LACTAM (PENICILLINS): TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SVP-POWDERS	RETAINED	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X1.2 G VIAL	25/07/2018
1355	NDA/MAL/HDP/8948	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	OMASI MED LIMITED	JULMENTIN ES	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	600 MG / 5 ML + 42.9 MG / 5 ML	N/A	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR) - DIGDAGA, AIRPORT STREET RAS AL KHAIMAH UNITED ARAB EMIRATES	N/A	NOT RETAINED	UNITED ARAB EMIRATES	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X1.0X100.0 ML BOTTLE	25/07/2018

1356	NDA/MAL/HDP/8949	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CETAL SUPOSITORIES	PARACETAMOL	120MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B1,EGYPT	N/A	GMP EXPIRED ON 28/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, SOFT GELATIN CAPSULES, CREAMS, OINTMENTS AND SUPPOSITORIES, ORAL LIQUIDS, EYE OINTMENTS, EYE STERILE DROPS, ORAL POWDER FOR SUSPENSION, SMALL VOLUME PARENTERALS-POWDERS-LYOPHILIZED, SMALL VOLUME PARENTERALS-SOLUTIONS-HORMONES. BETA LACTAM (CEPHALOSPORINS): SMALL VOLUME PARENTERALS-POWDERS, BETA LACTAM (PENICILLIN):	RETAINED	EGYPT	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY BLISTER	25/07/2018

1357	NDA/MAL/HDP/9130	AUROLAB	SWASTIK PHARMACEUTICAL LTD	MFLOX-DM	MOXIFLOXACIN + DEXAMETHASONE SODIUM PHOSPHATE	0.5%W/V + 0.1%W/V	N/A	AUROLAB LIMITEDNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU INDIA	N/A	NOT RETAINED	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	21/11/2019
1358	NDA/MAL/HDP/9137	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	DOM R	RABEPRAZOLE SODIUM + DOMPERIDONE SR	20MG + 30MG	N/A	CORONA REMEDIES PVT. LTDVILLAGE JATOLI, POST OFFICE-OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	21/11/2019
1359	NDA/MAL/HDP/9140	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	CLOMIPHENE CITRATE	CLOMIPHENE CITRATE	50MG	N/A	CORONA REMEDIES PVT. LTDVILLAGE JATOLI, POST OFFICE-OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	21/11/2019
1360	NDA/MAL/HDP/9141	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	RABZOLE	RABEPRAZOLE SODIUM + LEVOSULPIRIDE	20MG + 75MG	N/A	CORONA REMEDIES PVT. LTDVILLAGE JATOLI, POST OFFICE-OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	21/11/2019

1361	NDA/MAL/HDP/9169	CADILA PHARMACEUTICALS LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	PROCTICAD	LACTITOL MONOHYDRATE	10 GM/15ML	N/A	CADILA PHARMACEUTICALS LIMITED1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X60.0 ML BOTTLE,1.0X 100.0 ML BOTTLE,1.0X 200.0 ML BOTTLE	27/11/2019
1362	NDA/MAL/HDP/9191	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANDOX-DS 50	CEFPODOXIME PROXETIL	50 MG/5ML	N/A	SANCE LABORATORIES PVT LTDVI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X100.0 ML BOTTLE	08/09/2020
1363	NDA/MAL/HDP/9192	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANDOX-200	CEFPODOXIME PROXETIL	200 MG	N/A	SANCE LABORATORIES PVT LTDVI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	08/09/2020

1364	NDA/MAL/HDP/9194	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MAGNABIOTIC	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	875 MG + 125 MG	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)-1ST INDUSTRIAL ZONE, 6 OCTOVER CITY, P.O. BOX 43	N/A	GMP EXPIRED ON THE 28/09/2023 FOR NON-BETA LACTAM: ORAL VETERINARY POWDERS TABLETS POWDERS FOR ORAL SUSPENSION HARD GELATIN CAPSULES ORAL LIQUIDS OINTMENTS, CREAMS & GELS SUPPOSITORIES STERILE LIQUIDS IN AMPOULES POWDER SACHETS SMALL VOLUME LIQUIDS (ASEPTICALLY PREPARED IN PLASTIC AMPOULE) SMALL VOLUME LYOPHILIZED POWDER (ASEPTICALLY PREPARED) SOFT GELATIN CAPSULES , BIOLOGICALS (SVP): RECOMBINANT INSULIN	RETAINED	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BOTTLE	08/09/2020

1365	NDA/MAL/HDP/9205	SYNOKEM PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GASTROSYN	ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE	250 MG + 250 MG + 50 MG / 5ML	SYNOKEM PHARMACEUTICALS LTD-PLOT NO.-35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL)	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM (HUMAN): TABLETS, HARD GELATIN CAPSULES, ORAL LIQUIDS, HORMONES: TABLETS	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	08/09/2020
1366	NDA/MAL/HDP/9207	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	FLIPTOR 10	ROSUVASTATIN CALCIUM	10MG	N/A	MADRAS PHARMACEUTICALS 137-B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI – 600 096, INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/09/2020
1367	NDA/MAL/HDP/9209	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	NOFONG	TERBINAFINE HYDROCHLORIDE	1%W/W	N/A	MADRAS PHARMACEUTICALS 137-B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI – 600 096, INDIA	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	08/09/2020

1368	NDA/MAL/ HDP/9216	TIL HEALTHCARE PVT LTD	KAMCARE PHARMA LIMITED	URELOG	CALCIUM-4-METHYL-2 OXO-VALERATE + CALCIUM-3-METHYL-2 OXO-BUTYRATE + CALCIUM-2-OXO-3-PHENYL PROPIONATE + CALCIUM-3-METHYL-2 OXO-VALERATE + CALCIUM-DL-2 HYDROXY (4 METHYLTHIO) BUTYRATE + L-LYSINE ACETATE + L-THREONINE + L-HISTIDINE + L-TYROSINE + L-TRYPTOP	101 MG +86 MG + 68 MG + 67 MG + 59 MG + 105 MG + 53 MG + 38 MG + 30 MG + 23 MG +36 MG 0.05 G	N/A	TIL HEALTHCARE PVT LIMITEDPLOT 100, WEST R-5, SOUTH, SRICITY SEZ, CHERIVE9 (VI), DISTRICT: CHITOOR 517588 ANDHRA PRADESH-	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10 .0 TABLET BLISTER	08/09/2020

1369	NDA/MAL/HDP/9224	WILSHIRE LABORATORIES (PVT) LTD	HEALTHCARE LTD.	XAAR	PREGABALIN	75 MG	WILSHIRE LABORATORIES (PVT) LTD-124/1 INDUSTRIAL AREA, KOT LAKHPAT LAHORE PAKISTAN	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: COATED AND UNCOATED TABLETS, HARD GELATIN CAPSULES, POWDERS FOR ORAL SUSPENSION, SMALL AND LARGE VOLUME PARENTERAL LIQUIDS, SMALL VOLUME POWDER FOR INJECTION	NOT RETAINED	PAKISTAN	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X4.0X5.0 CAPSULE BLISTER	08/09/2020
1370	NDA/MAL/HDP/9225	ZIM LABORATORIES LTD	ROYAL PHARMA 2011 LIMITED	ZIMADOL 50	TRAMADOL HYDROCHLORIDE	50 MG	N/A	ZIM LABORATORIES LIMITEDB-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	08/09/2020
1371	NDA/MAL/HDP/9226	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZURIG 80	FEBUXOSTAT	80MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/09/2020

1372	NDA/MAL/HDP/9228	LIFEWAY PHARMACEUTICAL INDUSTRIES LIMITED	LIFEWAY PHARMACEUTICAL INDUSTRIES LIMITED	SUREDOL	PARACETAMOL	500MG	LIFEWAY PHARMACEUTICAL INDUSTRIES LIMITED-BLOCK 198, PLOT 478,	N/A	GMP EXPIRED ON THE 3/11/2022 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), CAPSULE (HARD GELATIN)	RETAINED	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/09/2020
1373	NDA/MAL/HDP/9234	CACHET PHARMACEUTICALS PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	I-UP	FERROUS ASCORBATE + FOLIC ACID	30 MG + 550 MCG/5 ML	N/A	CACHET PHARMACEUTICALS PVT LTD .VILLAGE THANA, BADDI, TEHSIL-NALAGARH DIST. SOLAN, HIMACHAL PRADESH-173205	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	08/09/2020
1374	NDA/MAL/HDP/9236	LUPIN LTD	AIVEEN (U) LIMITED	RIFAMPICIN, ISONIAZID AND ETHAMBUTOL HYDROCHLORIDE	RIFAMPIN + ISONIAZID + ETHAMBUTOL HYDROCHLORIDE	150 MG + 75 MG + 275 MG	N/A	LUPIN LIMITED A-28/1 MIDC CHIKALTHANA AURANGABAD	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X24.0X28.0 TABLET BLISTER	08/09/2020

1375	NDA/MAL/HDP/9249	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LOXAMOX	LEVOFLOXACIN HEMIHYDRATE	5 MG/ML	N/A	MS PHARMA - JORDANPLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL- HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE.	N/A	NOT RETAINED	JORDAN	PARENTERAL ORDINARY INFUSION BAGS	1.0X1.0X100.0 ML BAG	08/09/2020
1376	NDA/MAL/HDP/9253	MSD (PTY) LTD	SURGIPHARM (U) LIMITED	ERVEBO	EBOLA ZAIRE VACCINE (RVSVΔG-ZEBOV-GP, LIVE ATTENUATED)	72MILLION PFU/ML	BIORELIANCE CORPORATION-9900 BLACKWELL ROAD, ROCKVILLE, MARYLAND 20850-3349 BIORELIANCE CORPORATION-9610 MEDICAL CENTER DRIVE, ROCKVILLE, MARYLAND 20850	N/A	GMP EXPIRED ON THE FEBRUARY 2023 FOR VACCINES	RETAINED	GERMANY UNITED STATES	PARENTERAL ORDINARY VIALS	1.0X10.0 VIAL CARTON	08/09/2020

1377	NDA/MAL/HDP/9255	AMRING FARMA S.R.L	LABOREX UGANDA LIMITED	METROMICON FORTE	METRONIDAZOLE + MICONAZOLE NITRATE	750MG + 200MG	FARMAPRIM LTD-5, CRINILOR STREET, PORUMBENI, CRIULENI DISTRICT, MD-4829	N/A	GMP EXPIRED ON THE 10/12/2021 FOR NON-BETA LACTAM HORMONAL, ANTIBIOTIC AND GENERAL: • SUPPOSITORIES • VAGINAL OVULES & PESSARIES • CREAMS • OINTMENTS • GELS;	NOT RETAINED	MOLDOVA	PESSARIES	1.0X2.0X7.0 PESSARY STRIP	08/09/2020
1378	NDA/MAL/HDP/9256	AMRING FARMA S.R.L	LABOREX UGANDA LIMITED	ESTRINORM	ESTRIOL	0.5MG	FARMAPRIM LTD-5, CRINILOR STREET, PORUMBENI, CRIULENI DISTRICT, MD-4829	N/A	GMP EXPIRED ON THE 10/12/2021 FOR NON-BETA LACTAM HORMONAL, ANTIBIOTIC AND GENERAL: • SUPPOSITORIES • VAGINAL OVULES & PESSARIES • CREAMS • OINTMENTS • GELS;	NOT RETAINED	MOLDOVA	PESSARIES	1.0X3.0X5.0 PESSARY STRIP	08/09/2020

1379	NDA/MAL/HDP/9257	AMRING FARMA S.R.L	LABOREX UGANDA LIMITED	BISACODYL AMRING	BISACODYL	10MG	FARMAPRIM LTD-5, CRINILOR STREET, PORUMBENI, CRIULENI DISTRICT, MD-4829	N/A	GMP EXPIRED ON THE 10/12/2021 FOR NON-BETA LACTAM HORMONAL, ANTIBIOTIC AND GENERAL: • SUPPOSITORIES • VAGINAL OVULES & PESSARIES • CREAMS • OINTMENTS • GELS;	NOT RETAINED	MOLDOVA	SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY STRIP	08/09/2020
1380	NDA/MAL/HDP/9277	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	CLOZOL CREAM	CLOTRIMAZOLE	1%W/W	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPUR	N/A	FACILITY NOT APPROVED TO MANUFACTURE SEMI-SOLIDS	RETAINED	INDIA	TOPICAL EXTERNAL CREAMS	1X1X15 G Tube,	28/09/2020
1381	NDA/MAL/HDP/9284	AMRING FARMA S.R.L	LABOREX UGANDA LIMITED	METROMICON-NEO	METRONIDAZOLE + MICONAZOLE NITRATE	500 MG + 100 MG	FARMAPRIM LTD-5, CRINILOR STREET, PORUMBENI, CRIULENI DISTRICT, MD-4829	N/A	GMP EXPIRED ON THE 10/12/2021 FOR NON-BETA LACTAM HORMONAL, ANTIBIOTIC AND GENERAL: • SUPPOSITORIES • VAGINAL OVULES & PESSARIES • CREAMS • OINTMENTS • GELS;	NOT RETAINED	MOLDOVA	VAGINAL TABLETS	1.0X2.0X7.0 PESSARY STRIP	08/09/2020

1382	NDA/MAL/HDP/9289	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	CLAMOXIN 1200 INJECTION	AMOXICILLIN SODIUM + POTASSIUM CLAVULANATE	1000 MG + 200 MG/VIAL	N/A	INJECT CARE PARENTERALS PVT LTDPLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES	1.0x1.0 Vial Carton + 1*20ML LDPE WFI	28/03/2023
1383	NDA/MAL/HDP/9297	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD	TATA UGANDA LIMITED	MEROPENEM FOR INJECTION USP 500 MG	MEROPENEM TRIHYDRATE	500 MG/VIAL	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD-PLOT 14, 2ND PHASE, PEENYA	N/A	FACILITY NOT APPROVED TO MANUFACTURE CARBAPENEMS	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X500.0 MG VIAL	08/09/2020
1384	NDA/MAL/HDP/9307	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS UGANDA LTD	PYL-X OINTMENT	LIDOCAINE + ZINC OXIDE + ALLANTOIN + HYDROCORTISONE ACETATE	3.0%W/W + 5.0% W/W + 0.5%W/W + 0.25W/W	N/A	KREMOINT PHARMA PVT LTD PLANT IIB-8, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST) DIST. THANE 421506	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X30.0 G TUBE + PRODUCT APPLICATOR	08/09/2020
1385	NDA/MAL/HDP/9308	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS UGANDA LTD	LIDOMAX	LIDOCAINE + PRILOCAINE	25 MG + 25 MG	N/A	KREMOINT PHARMA PVT LTD PLANT IIB-8, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST) DIST. THANE 421506	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X15.0 G TUBE + SPATULA AND SEPARATOR	08/09/2020

1386	NDA/MAL/HDP/9314	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	GVITHER FORTE INJECTION	ARTEMETHER	80 MG/ML	BLISS INDAS LIFESCIENCE P. LTD..-PLOT 73-76, SILVER	N/A	FAILED GMP ON THE 30/11/2018 FOR AMPOULES	RETAINED	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE,1.0X6.0X1.0 ML AMPOULE	08/09/2020
1387	NDA/MAL/HDP/9317	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD	HEALTHCARE LTD.	FEPAR	ALBENDAZOLE	200 MG/5 ML	AL FAZAL PHARMA INDUSTRIES (PVT) LTD-PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN	N/A	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS, HARD GELATIN CAPSULES, OINTMENTS/CREAMS/GELS	NOT RETAINED	PAKISTAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X10.0 ML BOTTLE	25/09/2020
1388	NDA/MAL/HDP/9318	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	N/A	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS, HARD GELATIN CAPSULES, OINTMENTS/CREAMS/GELS	RETAINED	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	25/09/2020

1389	NDA/MAL/HDP/9319	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD	HEALTHCARE LTD.	COFFRID SYRUP	ACEFYLLINE PIPERAZINE +DIPHENHYDRAMINE HYDROCHLORIDE	45 MG + 8 MG	AL FAZAL PHARMA INDUSTRIES (PVT) LTD-PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN	N/A	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS, HARD GELATIN CAPSULES, OINTMENTS/CREAMS/GELS	NOT RETAINED	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE,1.0X1.0X120.0 ML BOTTLE	08/09/2020
1390	NDA/MAL/HDP/9324	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	PROP PLUS	IBUPROFEN + PARACETAMOL	400 MG + 325 MG	N/A	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,10.0X1.0X10.0 TABLET BLISTER	08/09/2020
1391	NDA/MAL/HDP/9347	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	COLODIUM	LOPERAMIDE HYDROCHLORIDE	2MG	HOVID BERHAD (IPOH SITE)121, JALAN TUNKU ABDUL RAHMAN 30010 IPOH	N/A	FACILITY NOT APPROVED TO MANUFACTURE THE PRODUCT LINE	RETAINED	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1X10X10 CAPSULE Blister,	22/12/2020
1392	NDA/MAL/HDP/9348	PHARCO B INTERNATIONAL,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	PARACETAMOL - PHARCO B INTERNATIONAL	PARACETAMOL	1G/100ML	N/A	PHARCO-B INTERNATIONAL PHARMACEUTICALSB ORG EL-ARAB 3D INDUSTRIAL ZONE, BLOCK 18 AREA, 10, 11, ALEXANDRIA EGYPT	N/A	NOT RETAINED	EGYPT	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML VIAL	09/12/2020

1393	NDA/MAL/HDP/9354	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ONCOGEM-200	GEMCITABINE HYDROCHLORIDE	200MG	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	N/A	FACILITY NOT APPROVED TO MANUFACTURE THE PRODUCT LINE	RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X10.0 ML VIAL	09/12/2020
1394	NDA/MAL/HDP/9357	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BISOLOL H 5/6.25	BISOPROLOL FUMARATE + HYDROCHLOROTHIAZIDE	5 MG + 6.25 MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	09/12/2020

1395	NDA/MAL/HDP/9366	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TOBRASON	TOBRAMYCIN + DEXAMETHASONE	3 MG + 1 MG/1G	AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	N/A	GMP EXPIRED ON 28/09/2023 FOR NON-BETA LACTAM: STERILE EYE DROPS (ASEPTICALLY PREPARED) STERILE EYE OINTMENTS (ASEPTICALLY PREPARED) NON-STERILE NASAL DROPS NON-STERILE METERED DOSE NASAL SPRAYS OINTMENTS, CREAMS & LOTIONS	RETAINED	JORDAN	OPHTHALMIC OINTMENTS	1.0X1.0X5.0 MG TUBE	09/12/2020
1396	NDA/MAL/HDP/9370	RAINBOW LIFE SCIENCES PVT.LTD.	EUROPA HEALTHCARE (U) LTD	MONTLIV	MONTELUKAST + LEVOCETIRIZINE DIHYDROCHLORIDE	10 MG+ 5 MG	GLOBELA PHARMA PVT.LTD. 357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, ORAL POWDER IN SACHETS AND BOTTLES. ONCOLOGY: TABLETS, HARD GELATIN CAPSULES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	09/12/2020

1397	NDA/MAL/HDP/9371	MEDINOVATION ENTERPRISES LTD	MEDINOVATION ENTERPRISES LTD	MEDSUNATE- 60	ARTESUNATE	60MG	N/A	EAST AFRICAN (INDIA) OVERSEASPLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA BLISS INDASI LIFESCIENCE PRIVATE LIMITEDPLOT NO. 73 TO 76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN-396 210	N/A	NOT RETAINED	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
1398	NDA/MAL/HDP/9378	SANDOZ GMBH, KUNDL	KIMSY MEDS LTD	BICALUTAMIDE SANDOZ 50 MG	BICALUTAMIDE	50MG	SALUTAS PHARMA GMBH-OTTO-VON-GUERICKE ALLEE-1, 39179	N/A	GMP EXPIRED ON THE 12/11/2022 FOR HARD GELATIN CAPSULES AND TABLETS	NOT RETAINED	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER	09/12/2020
1399	NDA/MAL/HDP/9380	SANDOZ GMBH, KUNDL	KIMSY MEDS LTD	BICALUTAMIDE SANDOZ 150 MG	BICALUTAMIDE	150MG	SALUTAS PHARMA GMBH-OTTO-VON-GUERICKE ALLEE-1, 39179	N/A	GMP EXPIRED ON THE 12/11/2022 FOR HARD GELATIN CAPSULES AND TABLETS	NOT RETAINED	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER	09/12/2020

1400	NDA/MAL/HDP/9381	POPULATION SERVICES INTERNATIONAL, UGANDA (PSIU)	POPULATION SERVICES INTERNATIONAL - UGANDA	PRONTA 1	LEVONORGESTREL	1.5 MG	N/A	MYLAN LABORATORIES LIMITEDPLOT NO. 20 & 21, PHARMEZ, SARKHEJ - BAVLA, NATIONAL HIGHWAY NO. 8 - A, NEAR VILLAGE - MATODA, TAL - SANAND, DIST., AHMEDABAD - 382213	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X1.0 TABLET BLISTER	09/12/2020
1401	NDA/MAL/HDP/9392	MANEESH EXPORTS (EOU)	PLANET PHARMACEUTICALS UGANDA LTD	BOOSTIMDS	AMOXICILLIN TRIHYDRATE + DILUTED POTASSIUM CLAVULANATE BP	200 MG + 28.5MG/5 ML	N/A	MANEESH EXPORTS (EOU)PLOT D-16/7, TTC INDUSTRIAL AREA, MIDC TURBHE, NAVI MUMBAI – 400 703, DIST. THANE, MAHARASHTRA, INDIA	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X70.0 ML CONTAINER	09/12/2020
1402	NDA/MAL/HDP/9396	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	KORANDIL	ENALAPRIL MALEATE	20 MG	N/A	REMEDICA LTDAHARNON STREET, LIMASSOL INDUSTRIAL ESTATE, 3056 LIMASSOL	N/A	NOT RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	09/12/2020

1403	NDA/MAL/HDP/9397	ROYAL GROUP TRADING FZC E LOB OFFICE	HARLEYS UGANDA LIMITED	ROGOXONE	CEFTRIAXONE SODIUM	1GM/VIAL	N/A	CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHUANG) CO. LTDNO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, (WORKSHOP 402)CHINA	N/A	NOT RETAINED	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL,1.0X10.0X1.0 G VIAL	09/12/2020
1404	NDA/MAL/HDP/9399	PHARCO B INTERNATIONAL,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CEFZIM	CEFTAZIDIME PENTAHYDRATE	1G	N/A	PHARCO-B INTERNATIONAL PHARMACEUTICALSB ORG EL-ARAB 3D INDUSTRIAL ZONE, BLOCK 18 AREA, 10, 11, ALEXANDRIA EGYPT	N/A	NOT RETAINED	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + (2*5ML WFI)	09/12/2020
1405	NDA/MAL/HDP/9400	PHARCO B INTERNATIONAL,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CEFAZONE 1 G	CEFOPERAZONE	1G	N/A	PHARCO-B INTERNATIONAL PHARMACEUTICALSB ORG EL-ARAB 3D INDUSTRIAL ZONE, BLOCK 18 AREA, 10, 11, ALEXANDRIA EGYPT	N/A	NOT RETAINED	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + (1*5 ML WFI)	09/12/2020

1406	NDA/MAL/HDP/9417	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	UNIBET CREAM	BETAMETHASONE DIPROPIONATE	0.05 % W/W	N/A	PINNACLE LIFE SCIENCE PVT LTDKHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	09/12/2020
1407	NDA/MAL/HDP/9427	SANOFI AVENTIS KENYA LTD	LABOREX UGANDA LIMITED	SHANIPV	CONCENTRATED TRIVALENT OF INACTIVATED POLIOMYELITIS VIRUS; TYPE 1 (MAHONEY) + TYPE 2 (MEF-1) + TYPE 3 (SAUKETT)	40 DU + 8 DU + 32 DU/DOSE	SHANTHA BIOTECHNICS LTD-SURVEY NO. 274, ATHVELLI VILLAGE MEDCHAL MANDAL RANGWA REDDY DISTRICT	N/A	FACILITY NAME CHANGED TO SANOFI HEALTHCARE INDIA PRIVATE LIMITED; APPLICANT REQUIRED TO APPLY FOR A VARIATION	RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1.0X30.0X1.0X5.0 DOSE VIAL	09/12/2020
1408	NDA/MAL/HDP/9437	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MEDOFLORAN	TERBINAFINE HYDROCHLORIDE	250 MG	MEDOCHEMIE LTD-CENTRAL FACTORY A-1-10 CONSTANTINOUPOLEUS STREET	N/A	FACILITY NOT APPROVED FOR THIS LINE	RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	09/12/2020
1409	NDA/MAL/HDP/9438	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	URACTONUM	SPIRONOLACTONE	25 MG	MEDOCHEMIE LTD-CENTRAL FACTORY A-1-10 CONSTANTINOUPOLEUS STREET	N/A	FACILITY NOT APPROVED FOR THIS LINE	RETAINED	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	09/12/2020

1410	NDA/MAL/HDP/9449	JAMJOOM PHARMACEUTICALS COMPANY	MU PHARMACO -SMC LIMITED	ELICASAL	MOMETASONE FUROATE + SALICYLIC ACID	0.1% W/W + 5.0% W/W	N/A	JAMJOOM PHARMACEUTICALS CO.PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	N/A	NOT RETAINED	SAUDI ARABIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X30.0 G TUBE	18/12/2020
1411	NDA/MAL/HDP/9450	ACME FORMULATIONS LIMITED	PHARMA VILLE LIMITED	MIFESO	MIFEPRISTONE + MISOPROSTOL	200MG + 200MCG	N/A	ACME FORMULATION PVT. LTDROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X5.0 TABLET BLISTER	09/12/2020
1412	NDA/MAL/HDP/9495	MANEESH EXPORTS (EOU)	PLANET PHARMACEUTICALS UGANDA LTD	BOOSTIM-625	AMOXICILLIN TRIHYDRATE + DILUTED POTASSIUM CLAVULANATE	500 MG + 125 MG	N/A	MANEESH EXPORTS (EOU)PLOT D-16/7, TTC INDUSTRIAL AREA, MIDC TURBHE, NAVI MUMBAI – 400 703, DIST. THANE, MAHARASHTRA, INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	24/02/2021

1413	NDA/MAL/HDP/9496	CADILA HEALTHCARE LIMITED "ZYDUS TOWER" -	ABACUS PHARMA (AFRICA) LIMITED	OXYSPRAY	OXYMETAZOLINE HYDROCHLORIDE	0.05% W/V	CADILA HEALTHCARE LTD. PLOT NO. 417, 419 & 420, SARKHEJ-BAVLA N.H. NO. 8A, MORAIYA, TAL: SANAND, DIST. AHMEDABAD	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	OTHER SYSTEMIC SPRAYS WITHOUT GAS	1X1X15 ML Bottle	04/03/2021
1414	NDA/MAL/HDP/9500	POPULATION SERVICES INTERNATIONAL, UGANDA (PSIU)	POPULATION SERVICES INTERNATIONAL - UGANDA	MEURI	DESOGESTREL + ETHINYLESTRADIOL	150MCG + 30MCG	N/A	MYLAN LABORATORIES LIMITEDPLOT NO. 20 & 21, PHARMEZ, SARKHEJ - BAVLA, NATIONAL HIGHWAY NO. 8 - A, NEAR VILLAGE - MATODA, TAL - SANAND, DIST., AHMEDABAD - 382213	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X28.0 TABLET BLISTER	24/02/2021
1415	NDA/MAL/HDP/9509	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS UGANDA LTD	TOBIDERM	BETAMETHASONE DIPROPIONATE + GENTAMICIN SULFATE + TOLNAFTATE + IODOCHLORHYDROXYQUINOLINE	(0.643 MG + 1.0 MG + 10 MG + 10 MG)/G	N/A	KREMOINT PHARMA PVT LTD PLANT IIB-8, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST) DIST. THANE 421506	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	24/02/2021

1416	NDA/MAL/HDP/9510	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS UGANDA LTD	GEODERM	BETAMETHASONE DIPROPIONATE + GENTAMICIN SULFATE + CLOTRIMAZOLE	(0.5 MG + 1.0 MG + 10.0 MG)/G	N/A	KREMOINT PHARMA PVT LTD PLANT IIB-8, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST) DIST. THANE 421506	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE,1.0X30.0 G TUBE	24/02/2021
1417	NDA/MAL/HDP/9516	ORCHIDIA PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FORTYMOX	MOXIFLOXACIN HYDROCHLORIDE	0.5%W/V	N/A	ORCHIDIA PHARMACEUTICAL INDUSTRIESAL OBOUR CITY INDUSTRIAL ZONE, AREA 14, 15 - PLOT NO. 12011 - CAIRO - EGYPT	N/A	NOT RETAINED	EGYPT	OPHTHALMIC LIQUIDS	1.0X1.0X10.0 ML CONTAINER	24/02/2021
1418	NDA/MAL/HDP/9517	ORCHIDIA PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEVXAL	NEPAFENAC	0.1% W/V	N/A	ORCHIDIA PHARMACEUTICAL INDUSTRIESAL OBOUR CITY INDUSTRIAL ZONE, AREA 14, 15 - PLOT NO. 12011 - CAIRO - EGYPT	N/A	NOT RETAINED	EGYPT	OPHTHALMIC SUSPENSIONS	1.0X1.0X5.0 ML CONTAINER	24/02/2021

1419	NDA/MAL/HDP/9524	STRIDES PHARMA SCIENCE LIMITED	DELMAW ENTERPRISES LIMITED	TENOFOVIR DISOPROXIL FUMARATE / LAMIVUDINE/ DOLUTEGRAVIR TABLETS	TENOFOVIR DISOPROXIL FUMARATE + LAMIVUDINE + DOLUTEGRAVIR SODIUM	300 MG + 300 MG + 50 MG	STRIDES SHASUN LIMITED-NO. 36/7, SURAGAJAKKANAHALLI, INDLAVADI CROSS, ANEKAL TALUK, BENGALURU, KARNATA	N/A	FACILITY NAME CHANGED TO STRIDES PHARMA SCIENCE LIMITED; APPLICANT REQUIRED TO APPLY FOR VARIATION FOR CHANGE OF NAME	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE	24/02/2021
1420	NDA/MAL/HDP/9527	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD	HEALTHCARE LTD.	PARASYP	PARACETAMOL	120 MG/5 ML	AL FAZAL PHARMA INDUSTRIES (PVT) LTD-PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN	N/A	GMP EXPIRED ON 16/10/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS, HARD GELATIN CAPSULES, OINTMENTS/CREAMS/GELS	NOT RETAINED	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE	24/02/2021
1421	NDA/MAL/HDP/9528	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ONDANSETRON ORAL DISPERSIBLE TABLETS	ONDANSETRON	8MG	ATHENA DRUG DELIVERY SOLUTIONS PVT LTD ,.-PLOT A-1 TO A-5, MIDC CHEMICAL ZONE, AMBERNATH (W) THANE	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, CAPSULES (PELLETS IN CAPSULES), SACHETS (PELLETS/GRANULES)	RETAINED	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X10.0 TABLET BLISTER	24/02/2021

1422	NDA/MAL/HDP/9530	PFIZER LABORATORIES	LABOREX UGANDA LIMITED	ZAVICEFTA	CEFTAZIDIME PENTAHYDRATE + AVIBACTAM SODIUM	(2G +0.5 G)/VIAL	GLAXOSMITHKLINE MANUFACTURING S.P.A-VIA A.FLEMING,2-37135 VERONA-	N/A	GMP EXPIRED ON THE 31/01/2022 FOR CEPHALOSPORIN: SMALL VOLUME PARENTERALS	RETAINED	ITALY	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X20.0 ML VIAL	24/02/2021
1423	NDA/MAL/HDP/9536	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	LAXMAG	POLYETHYLENE GLYCOL + SODIUM CHLORIDE + SODIUM HYDROGEN CARBONATE + POTASSIUM CHLORIDE	(13.125 G + 350.7 MG + 178.5 MG + 46.6 MG)/SACHET	STRIDES SHASUN LIMITED-NO. 36/7, SURAGAJAKKANAHALLI, INDLAVADI CROSS, ANEKAL TALUK, BENGALURU, KARNATA	N/A	FACILITY NAME CHANGED TO STRIDES PHARMA SCIENCE LIMITED; APPLICANT REQUIRED TO APPLY FOR VARIATION FOR CHANGE OF NAME	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X10.0X13.72 G SACHET	24/02/2021
1424	NDA/MAL/HDP/9540	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TENGLYN	TENELIGLIPTIN HEMIPENTAHYDROBROMIDE HYDRATE	20MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	24/02/2021

1425	NDA/MAL/ HDP/9546	STRIDES PHARMA SCIENCE LIMITED	DELMAW ENTERPRISES LIMITED	ALU 80/480	ARTEMETHER + LUMEFANTRINE	80MG + 480MG	STRIDES SHASUN LIMITED-NO. 36/7, SURAGAJAKKANA HALLI, INDLAVADI CROSS, ANEKAL TALUK, BENGALURU, KARNATA	N/A	FACILITY NAME CHANGED TO STRIDES PHARMA SCIENCE LIMITED; APPLICANT REQUIRED TO APPLY FOR VARIATION FOR CHANGE OF NAME	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X6.0 IMPLANT BLISTER	24/02/2021
1426	NDA/MAL/ HDP/9550	OCTOBER PHARMA-	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BRONCHO PRO	AMBROXOL HYDROCHLORIDE	7.5MG/ML	OCTOBER PHARMA 1ST INDUSTRIAL ZONE, STREET 25 PLOT 190, 6TH OCTOBER CITY CAIRO, ARAB REPUBLIC OF EGYPT	N/A	GMP EXPIRED ON 28/9/2023 FOR NON-BETA LACTAM: ORAL TABLETS ORAL CAPSULES ORAL LIQUIDS (SYRUP & SUSPENSION) TOPICAL SOLUTIONS	NOT RETAINED	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X30.0 ML BOTTLE	24/02/2021
1427	NDA/MAL/ HDP/9577	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZURIG 40	FEBUXOSTAT	40 MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/06/2021

1428	NDA/MAL/HDP/9587	GOODMAN INTERNATIONAL LTD	GOODMAN INTERNATIONAL LTD	TAFIXYL™ 500 MG	TRANEXAMIC ACID	500 MG	N/A	LABIANA PHARMACEUTICALS, S.L.U.C/CASANOVA, 27-31, 08757 CORBERA DE LLOBREGAT (BARCELONA)	N/A	NOT RETAINED	SPAIN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X20.0 TABLET BLISTER	02/06/2021
1429	NDA/MAL/HDP/9594	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	N/A	GMP EXPIRED ON 2/11/2023 FOR NON-BETA LACTAM: LARGE VOLUME LIQUIDS (ASEPTICALLY PREPARED), TABLETS	RETAINED	POLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/06/2021
1430	NDA/MAL/HDP/9595	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	N/A	GMP EXPIRED ON 2/11/2023 FOR NON-BETA LACTAM: LARGE VOLUME LIQUIDS (ASEPTICALLY PREPARED), TABLETS	RETAINED	POLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/06/2021

1431	NDA/MAL/HDP/9596	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	N/A	GMP EXPIRED ON 2/11/2023 FOR NON-BETA LACTAM: LARGE VOLUME LIQUIDS (ASEPTICALLY PREPARED), TABLETS	RETAINED	POLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	02/06/2021
1432	NDA/MAL/HDP/9604	AMRING FARMA S.R.L	LABOREX UGANDA LIMITED	PROPOFOL AMRING	PROPOFOL	10 MG/ML	BAXTER PHARMACEUTICALS INDIA PRIVATE LIMITEDCHACHARWADI - VASANA, AHMEDABAD, IN 382213	N/A	GMP EXPIRED ON 14/12/2023 FOR Non-Beta Lactam: Small Volume Parenterals (vials and ampoules) Small Volume Parenterals (emulsions and aqueous solutions in glass bottles)	NOT RETAINED	INDIA	PARENTERAL ORDINARY OTHER INFUSIONS	1.0X5.0X20.0 ML VIAL	02/06/2021
1433	NDA/MAL/HDP/9605	SAKAR HEALTHCARE LIMITED -	ROYAL PHARMA 2011 LIMITED	PENTOKAR	PANTOPRAZOLE SODIUM SESQUIHYDRATE	40 MG/VIAL	N/A	SAKAR HEALTH CARE PVT LTD-10/13 CHONGODAR SARKHEJ BAVLA ROAD DIST AHEMABAD 382213 GUJARATI	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X40.0 MG VIAL	02/06/2021

1434	NDA/MAL/HDP/9618	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EMCAP 500	CAPECITABINE	500 MG	MSN LABORATORIES PRIVATE LIMITED-UNIT II, SY. NO. 1277 & 1319 TO 1324, NANDIGAMA (VILLAGE & MANDAL), RANDAREDDY	N/A	ADDRESS OF THIS FACLITY IS DIFFERENT FROM THE ONE PREVIOUSLY INSPECTED (SY. NO 1277 & 1319-1324, MAHABUBNAGAR, DIST TELANGANA 509216 INDIA). ADDRESS TO BE VERIFIED AFTER GMP INSPECTION	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	02/06/2021
1435	NDA/MAL/HDP/9619	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROMIDE PLUS	TROPICAMIDE + PHENYLEPHRINE HYDROCHLORIDE	0.8% W/V + 5%W/V	N/A	AUROLAB LIMITEDNO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU INDIA	N/A	NOT RETAINED	INDIA	OPHTHALMIC LIQUIDS	1.0X1.0X5.0 ML CONTAINER	02/06/2021
1436	NDA/MAL/HDP/9622	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED	SURGIPHARM (U) LIMITED	VITALIPID NOVUM ADULT	VITAMIN A + VITAMIN D2 + VITAMIN E + VITAMIN K1	330 IU + 20 IU + 1 IU + 15 µG/ML	N/A	FRESENIUS KABI ABRAPSGATAN 7, 751 74 UPPSALA - SWEDEN	N/A	NOT RETAINED	SWEDEN	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0 ML AMPOULE	02/06/2021
1437	NDA/MAL/HDP/9623	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED	SURGIPHARM (U) LIMITED	VITALIPID NOVUM INFANT	VITAMIN A + VITAMIN D2 + VITAMIN E + VITAMIN K1	230 IU + 40 IU + 0.7 IU + 20 µG/ML	N/A	FRESENIUS KABI ABRAPSGATAN 7, UPPSALA, SE-751 74	N/A	NOT RETAINED	SWEDEN	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0 ML AMPOULE	02/06/2021

1438	NDA/MAL/HDP/9625	ACME FORMULATION PVT. LTD.	POPULATION SERVICES INTERNATIONAL - UGANDA	AVERTISO	MISOPROSTOL	200 MCG	N/A	ACME FORMULATION PVT. LTDROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X4.0 TABLET BLISTER	02/06/2021
1439	NDA/MAL/HDP/9629	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DECOZAL	XYLOMETAZOLINE HYDROCHLORIDE	0.5 MG/ML	AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	N/A	GMP EXPIRED ON 28/09/2023 FOR NON-BETA LACTAM: STERILE EYE DROPS (ASEPTICALLY PREPARED) STERILE EYE OINTMENTS (ASEPTICALLY PREPARED) NON-STERILE NASAL DROPS NON-STERILE METERED DOSE NASAL SPRAYS OINTMENTS, CREAMS & LOTIONS	RETAINED	JORDAN	NASAL SYSTEMIC METERED-DOSE LIQUIDS	1.0X1.0X10.0 ML BOTTLE	02/06/2021
1440	NDA/MAL/HDP/9644	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS UGANDA LTD	HYDROMAX	HYDROCORTISONE	1.0 % W/W	N/A	KREMOINT PHARMA PVT LTD PLANT IIB-8, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST) DIST. THANE 421506	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	02/06/2021

1441	NDA/MAL/HDP/9646	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	AZEPTIL	TRANEXAMIC ACID	100 MG/ML	MEDOCHEMIE LTD-CENTRAL FACTORY A-1-10 CONSTANTINOUPOLEUS STREET	N/A	FACILITY NOT APPROVED FOR THIS LINE	RETAINED	CYPRUS	PARENTERAL ORDINARY AMPOULES	1.0X10.0X5.0 ML AMPOULE	02/06/2021
1442	NDA/MAL/HDP/9647	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MABRON	TRAMADOL HYDROCHLORIDE	100 MG/2ML	MEDOCHEMIE LTD-CENTRAL FACTORY A-1-10 CONSTANTINOUPOLEUS STREET	N/A	FACILITY NOT APPROVED FOR THIS LINE	RETAINED	CYPRUS	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	02/06/2021
1443	NDA/MAL/HDP/9653	LABORATE PHARMACEUTICALS INDIA LIMITED	HEALTHCARE LTD.	FERROUS SULPHATE WITH FOLIC ACID TABLETS	FERROUS SULPHATE + FOLIC ACID	60 MG + 0.6 MG	N/A	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	02/06/2021
1444	NDA/MAL/HDP/9659	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED	SURGIPHARM (U) LIMITED	VOLUVEN	POLY (O-2-HYDROXYETHYL) STARCH (HES 130/0.4)	60 G/1000 ML	FRESENIUS KABI DEUTSCHLAND GMBH-FRESENIUSSTRASSE 1, D-61169, FRIEDBER	FRESENIUS KABI MANUFACTURING SA (PTY) LTD,,-6 GLOBAL ROAD, KORSTEN, PORT ELIZABETH, 6014	PRODUCT LINE (LARGE VOLUME PARENTERALS) WAS NOT INCLUDED IN THE GMP APPLICATION FORM FOR RE-INSPECTION.	NOT RETAINED	SOUTH AFRICA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BAG	02/06/2021

1445	NDA/MAL/HDP/9668	LABORATE PHARMACEUTICALS INDIA LIMITED	HEALTHCARE LTD.	AZILAB-200	AZITHROMYCIN DIHYDRATE	200MG/5ML	N/A	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X1.0X30.0 ML CONTAINER + 30 ML WFI IN LDPE CONTAINER	02/06/2021
1446	NDA/MAL/HDP/9671	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	RISOPINE	CARBAMAZEPINE	200 MG	N/A	SUNRISE INTERNATIONAL LABS LTDPLOT NO. 100, LANE-5, SECTOR-II, PHASE-II, IDA, CHERLAPALLY INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	02/06/2021
1447	NDA/MAL/HDP/9673	SANDOZ GMBH, KUNDL	KIMSY MEDS LTD	DOXORUBICIN 100 MG/50ML	DOXORUBICIN HYDROCHLORIDE	100 MG/50ML	N/A	EBEWE PHARMA GES.M.B.H. NFG.KGMONDSEESTRABE 11 4866 UNTERACH AM ATTERSEE - AUSTRIA	N/A	NOT RETAINED	AUSTRIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X50.0 ML VIAL	02/06/2021
1448	NDA/MAL/HDP/9674	SANDOZ GMBH, KUNDL	KIMSY MEDS LTD	DOXORUBICIN 50 MG/25ML	DOXORUBICIN HYDROCHLORIDE	50 MG/25ML	N/A	EBEWE PHARMA GES.M.B.H. NFG.KGMONDSEESTRABE 11 4866 UNTERACH AM ATTERSEE - AUSTRIA	N/A	NOT RETAINED	AUSTRIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X25.0 ML VIAL	02/06/2021

1449	NDA/MAL/HDP/9676	SANDOZ GMBH, KUNDL	KIMSY MEDS LTD	DOCETAXEL 10 MG/ML	DOCETAXEL	160 MG/16 ML	N/A	EBEWE PHARMA GES.M.B.H. NFG.KGMONDSEESTRABE 11 4866 UNTERACH AM ATTERSEE - AUSTRIA	N/A	NOT RETAINED	AUSTRIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X8.0 ML VIAL	02/06/2021
1450	NDA/MAL/HDP/9681	SYNOKEM PHARMACEUTICALS LIMITED	ROYAL PHARMA 2011 LIMITED	MISSROL-200	MISOPROSTOL	200MCG	SYNOKEM PHARMACEUTICALS LTD-PLOT NO.-35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL)	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM (HUMAN): TABLETS, HARD GELATIN CAPSULES, ORAL LIQUIDS, HORMONES: TABLETS	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP,10.0X1.0X10.0 TABLET BLISTER	02/06/2021
1451	NDA/MAL/HDP/9682	SYNOKEM PHARMACEUTICALS LIMITED	ROYAL PHARMA 2011 LIMITED	ROTRAMIC	TRANEXAMIC ACID	500 MG	SYNOKEM PHARMACEUTICALS LTD-PLOT NO.-35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL)	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM (HUMAN): TABLETS, HARD GELATIN CAPSULES, ORAL LIQUIDS, HORMONES: TABLETS	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	02/06/2021

1452	NDA/MAL/HDP/9683	GLOBELA PHARMA PVT. LTD.	ROYAL PHARMA 2011 LIMITED	CAPTOGLO	CAPTOPRIL	25 MG	GLOBELA PHARMA PVT.LTD. 357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, ORAL POWDER IN SACHETS AND BOTTLES. ONCOLOGY: TABLETS, HARD GELATIN CAPSULES	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1X10X10 TABLET Strip,	23/06/2021
1453	NDA/MAL/HDP/9684	CELLTRION, INC	MELO GROUP AFRICA LIMITED	LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS, 300 MG/300 MG	LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE	300 MG + 300 MG	N/A	CELLTRION PHARM, INC.82, 2 SANDAN-RO, OCHANG-EUP, CHEONGWON-GU, CHEONGJU-SI – SOUTH KOREA	N/A	NOT RETAINED	SOUTH KOREA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	02/06/2021

1454	NDA/MAL/HDP/9685	CELLTRION, INC	MELO GROUP AFRICA LIMITED	DOLUTEGRAVIR, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS, 50 MG/300 MG/300 MG	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE	50 MG + 300 MG + 300 MG	N/A	CELLTRION PHARM, INC.82, 2 SANDAN-RO, OCHANG-EUP, CHEONGWON-GU, CHEONGJU-SI – SOUTH KOREA AIZANT DRUG RESEARCH SOLUTIONS PVT LTDSY. NO 172 &. 173, APPAREL PARK ROAD, DULAPALLY VILLAGE, QUTHBULLAPUR MANDAL, RR DIST., HYDERABAD- 500 100, TELANGANA	N/A	NOT RETAINED	SOUTH KOREA INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET CONTAINER, 1.0X90.0 TABLET CONTAINER	02/06/2021
1455	NDA/MAL/HDP/9688	FREDUN PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	FREDNISOL TABLETS	PREDNISOLONE	5MG	N/A	FREDUN PHARMACEUTICALS LIMITED14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PALGHAR (E), DIST: PALGHAR-401 404	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER, 1.0X2.0X5.0X10.0 TABLET BLISTER	19/07/2021

1456	NDA/MAL/HDP/9713	I CARE PHARMA LIMITED	SUPER MEDIC LTD	AZOL 400	ALBENDAZOLE	400MG	WEST COAST PHARMACEUTICAL WORKS LTD-1143,MELDI ESTATE,NR PRASANG PARTY PLOT,GOTA, AHMEDEBAD	MEDICO REMEDIES PVT LTD,.-8 & 9 DEWAN AND SONS, UDYOG NAGAR, PALGHAR, DIST. THANE-401404, MAHARSHITRA	GMP EXPIRED ON THE 21/09/2009 FOR NBL TABS-HUMAN N VET, NBL ORAL LIQIUDS-HUMAN N VET, NBL CAPS, NBL ORS, NBL CREAMS N OINTMENTS AND GELS	RETAINED	INDIA	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X1.0 TABLET BLISTER	15/09/2021
1457	NDA/MAL/HDP/9717	GETZ PHARMA PVT LIMITED	MU PHARMA CO -SMC LIMITED	ESOME	ESOMEPRAZOLE	40MG	N/A	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	N/A	NOT RETAINED	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER	29/09/2021
1458	NDA/MAL/HDP/9719	GETZ PHARMA PVT LIMITED	MU PHARMA CO -SMC LIMITED	ESOME	ESOMEPRAZOLE	20MG	N/A	GETZ PHARMA (PVT) LIMITED29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	N/A	NOT RETAINED	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER	29/09/2021
1459	NDA/MAL/HDP/9727	Y.S.P. INDUSTRIES (M) SDN. BHD.	ROYAL PHARMA 2011 LIMITED	CLARIMYCIN	CLARITHROMYCIN	500MG	N/A	Y.S.P INDUSTRIES (M) SDN BHN.LOT 3,5 & 7, JALAN P/7, SECTION 13	N/A	NOT RETAINED	MALAYSIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	05/10/2021

1460	NDA/MAL/HDP/9733	SWISS PARENTERALS PVT. LTD.	SHREEJI CARE LIMITED	KEMIN	KETAMINE HYDROCHLORIDE	50MG/ML	N/A	SWISS PARENTERALS PVT LTD ..809, KERALA INDUSTRIAL ESTAE, GIDC NEAR BAVLA, AHMEDABAD 382220, GUJARAT	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X10.0 ML VIAL	05/10/2021
1461	NDA/MAL/HDP/9734	SANDOZ GMBH, KUNDL	KIMSY MEDS LTD	5-FLUOROURACIL 500MG/10ML	5-FLUOROURACIL	500 MG/10 ML	N/A	EBEWE PHARMA GES.M.B.H. NFG.KGMONDSEESTRABE 11 4866 UNTERACH AM ATTERSEE - AUSTRIA	N/A	NOT RETAINED	AUSTRIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X10.0 ML VIAL	05/10/2021
1462	NDA/MAL/HDP/9735	SANOFI AVENTIS KENYA	SURGIPHARM (U) LIMITED	FEXINIDAZOLE WINTHROP	FEXINIDAZOLE	600MG	ALCAMI CAROLINAS CORPORATION1726 NORTH 23RD STREET WILMING	N/A	GMP EXPIRED ON 13/10/2023 FOR NON-BETA LACTAM: TABLETS	NOT RETAINED	UNITED STATES	ORAL SOLID ORDINARY TABLETS	1.0X2.0X12.0 TABLET BLISTER,1.0X1.0X14.0 TABLET PACK [A PACK CONTAINS (1*8 + 1*6) TABLET	05/10/2021
1463	NDA/MAL/HDP/9746	SANDOZ GMBH, KUNDL	KIMSY MEDS LTD	5-FLUOROURACIL 1000MG/20ML	5-FLUOROURACIL	1000 MG/20 ML	N/A	EBEWE PHARMA GES.M.B.H. NFG.KGMONDSEESTRABE 11 4866 UNTERACH AM ATTERSEE - AUSTRIA	N/A	NOT RETAINED	AUSTRIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X20.0 ML VIAL	05/10/2021

1464	NDA/MAL/HDP/9750	LIPTIS EGYPT FOR PHARMACEUTICALS AND MEDICAL PRODUCTS	GOODMAN INTERNATIONAL LTD	VAXATO 15 MG	RIVAROXABAN	15MG	N/A	LIPTIS EGYPY FOR PHARMACEUTICALS AND MEDICAL PRODUCTSPLOT NO. 2/B, 6TH INDUSTRIAL ZONE, 6TH OF OCTOBER CITY	N/A	NOT RETAINED	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	05/10/2021
1465	NDA/MAL/HDP/9751	LIPTIS EGYPT FOR PHARMACEUTICALS AND MEDICAL PRODUCTS	GOODMAN INTERNATIONAL LTD	VAXATO 20 MG	RIVAROXABAN	20 MG	N/A	LIPTIS EGYPY FOR PHARMACEUTICALS AND MEDICAL PRODUCTSPLOT NO. 2/B, 6TH INDUSTRIAL ZONE, 6TH OF OCTOBER CITY	N/A	NOT RETAINED	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	05/10/2021
1466	NDA/MAL/HDP/9752	LIPTIS EGYPT FOR PHARMACEUTICALS AND MEDICAL PRODUCTS	GOODMAN INTERNATIONAL LTD	ATROZEMB 10 MG/10 MG	ATORVASTATIN + EZETIMIDE	10 MG + 10 MG	N/A	LIPTIS EGYPY FOR PHARMACEUTICALS AND MEDICAL PRODUCTSPLOT NO. 2/B, 6TH INDUSTRIAL ZONE, 6TH OF OCTOBER CITY	N/A	NOT RETAINED	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	05/10/2021

1467	NDA/MAL/HDP/9753	LIPTIS EGYPT FOR PHARMACEUTICALS AND MEDICAL PRODUCTS	GOODMAN INTERNATIONAL LTD	ATROZEMB 20 MG/10 MG	ATORVASTATIN + EZETIMIBE	20 MG + 10 MG	N/A	LIPTIS EGYPY FOR PHARMACEUTICALS AND MEDICAL PRODUCTSPLOT NO. 2/B, 6TH INDUSTRIAL ZONE, 6TH OF OCTOBER CITY	N/A	NOT RETAINED	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	05/10/2021
1468	NDA/MAL/HDP/9764	RAINE INDUSTRIES	HEALTH LINK PHARMACY LIMITED	ROLXIN 90/720	DIHYDROARTEMISININ + PIPERAQUINE PHOSPHATE	(90 MG + 720 MG)/60 ML	EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMA CITY SELAQUI DEHRAD	N/A	FACILITY NOT APPROVED TO MANUFACTURE NBL ORAL POWDERS	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X1.0X60.0 ML BOTTLE,1.0X1.0X80.0 ML BOTTLE	05/10/2021
1469	NDA/MAL/HDP/9768	LABORATE PHARMACEUTICALS INDIA LIMITED	HEALTHCARE LTD.	MALAREST	QUININE DIHYDROCHLORIDE	600MG/2ML	N/A	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	N/A	NOT RETAINED	FRANCE	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0X2.0 ML AMPOULE	05/10/2021

1470	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	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, ORAL POWDER IN SACHETS AND BOTTLES. ONCOLOGY: TABLETS, HARD GELATIN CAPSULES	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	11/10/2021
1471	NDA/MAL/HDP/9787	SYNOKEM PHARMACEUTICALS LIMITED	ROYAL PHARMA 2011 LIMITED	SURE-72	LEVONORGESTREL	1.5MG	SYNOKEM PHARMACEUTICALS LTD- PLOT NO.-35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL)	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM (HUMAN): TABLETS, HARD GELATIN CAPSULES, ORAL LIQUIDS, HORMONES: TABLETS	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X1.0 TABLET BLISTER	05/10/2021

1472	NDA/MAL/HDP/9788	AFRICURE PHARMACEUTICALS (INDIA) PVT. LTD	AFRICURE PHARMACEUTICALS U LIMITED	CHLOROSIM-250	CHLORAMPHENICOL	250MG	N/A	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA.	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	05/10/2021
1473	NDA/MAL/HDP/9795	INOSAN BIOPHARMA, S.A.	LABOREX UGANDA LIMITED	INOSERP	POLYVALENT F(AB')2 IMMUNOGLOBULIN FRAGMENTS (EQUINE) - SNAKE ANTIVENOM	1000MG/VIAL	VETERIA LABS S.A. (INOSAN BIOPHARMA S.A.)-LUCERNA, PLOT NO.7.COL - JUAREZ CP 06600,DEL CUAUHTEMOC	N/A	GMP OF FACILITY EXPIRED ON THE 14/02/2023 FOR BIOLOGICAL IMMUNOLOGICAL PRODUCTS-POLYVALENT SNAKE ANTI-VENOMS	NOT RETAINED	MEXICO	PARENTERAL RETARD DRY VIALS	1.0X1.0 VIAL PACK	05/10/2021
1474	NDA/MAL/HDP/9798	ORCHIDIA PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OZOLAMIDE	DORZOLAMIDE HYDROCHLORIDE	22.26 MG/ML	N/A	ORCHIDIA PHARMACEUTICAL INDUSTRIESAL OBOUR CITY INDUSTRIAL ZONE, AREA 14, 15 - PLOT NO. 12011 - CAIRO - EGYPT	N/A	NOT RETAINED	EGYPT	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	05/10/2021

1475	NDA/MAL/HDP/9800	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYDALIS 10	TADALAFIL	10MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	05/10/2021
1476	NDA/MAL/HDP/9805	INTERNATIONAL PARTNERSHIP FOR MICROBICIDES SOUTH AFRICA NON-PROFIT COMPANY	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DAPIRING	DAPIVIRINE	25MG/RING	N/A	QPHARMA ABAGNESLUNDSVAGEN 27, MALMO, 21215 - SWEDEN	N/A	NOT RETAINED	SWEDEN	VAGINAL OTHER SPECIAL FORMS	1.0X1.0X25.0 MG RING	05/10/2021
1477	NDA/MAL/HDP/9806	SANDOZ GMBH, KUNDL	KIMSY MEDS LTD	DOCETAXEL 160 MG/16 ML	DOCETAXEL	160 MG/16 ML	N/A	EBEWE PHARMA GES.M.B.H. NFG.KGMONDSEESTRABE 11 4866 UNTERACH AM ATTERSEE - AUSTRIA	N/A	NOT RETAINED	AUSTRIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X16.0 ML VIAL	05/10/2021
1478	NDA/MAL/HDP/9822	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ONDANSETRON ORAL DISPERSIBLE TABLETS	ONDANSETRON	4MG	ATHENA DRUG DELIVERY SOLUTIONS PVT LTD ,.- PLOT A-1 TO A-5, MIDC CHEMICAL ZONE, AMBERNATH (W) THANE	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: TABLETS, CAPSULES (PELLETS IN CAPSULES), SACHETS (PELLETS/GRANULES)	RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	05/10/2021

1479	NDA/MAL/HDP/9832	SAGA LABORATORIES	ABACUS PHARMA (AFRICA) LIMITED	FEBEX	FERROUS FUMARATE + VITAMIN B12 + FOLIC ACID + DIBASIC CALCIUM PHOSPHATE	300MG + 15MCG + 1.5MG + 100MG	N/A	SAGA LIFESCIENCES LIMITEDSURVEY NO. 198/2 & 198/3, CHACHRAWADI VASNA, TA-SANAND, DIST. AHMEDABAD - 382210, INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	05/10/2021
1480	NDA/MAL/HDP/9840	SANDOZ GMBH, KUNDL	KIMSY MEDS LTD	SANDOZ® CAPECITABINE 150MG	CAPECITABINE	150MG	SALUTAS PHARMA GMBH-OTTO-VON-GUERICKE ALLEE-1, 39179 BARLEBEN	HETERO LABS LIMITED (UNIT VI)-APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOOBNAGER DISTRICT ANDHRA PRADESH-509301	GMP EXPIRED ON THE 12/11/2022 FOR HARD GELATIN CAPSULES AND TABLETS; SAMPLES SUBMITTED AT THE TIME OF REGISTRATION HAVE EXPIRED. CLIENT REQUIRED TO SUBMIT FRESH SAMPLES.	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X6.0X10.0 TABLET BLISTER	05/10/2021

1481	NDA/MAL/HDP/9841	SANDOZ GMBH, KUNDL	KIMSY MEDS LTD	SANDOZ® CAPECITABINE 500MG	CAPECITABINE	500MG	SALUTAS PHARMA GMBH-OTTO-VON-GUERICKE ALLEE-1, 39179 BARLEBEN	HETERO LABS LIMITED (UNIT VI)-APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOOBNAGER DISTRICT ANDHRA PRADESH-509301	GMP EXPIRED ON THE 12/11/2022 FOR HARD GELATIN CAPSULES AND TABLETS; SAMPLES SUBMITTED AT THE TIME OF REGISTRATION HAVE EXPIRED. CLIENT REQUIRED TO SUBMIT FRESH SAMPLES.	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X12.0X10.0 TABLET BLISTER	08/12/2021
1482	NDA/MAL/HDP/9846	GLOBELA PHARMA PVT. LTD.	TATA UGANDA LIMITED	SQUAM	DIHYDROARTEMISININ + PIPERAQUINE PHOSPHATE	400MG + 320MG	GLOBELA PHARMA PVT.LTD. 357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, ORAL POWDER IN SACHETS AND BOTTLES. ONCOLOGY: TABLETS, HARD GELATIN CAPSULES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1X1X9 TABLET Blister,	16/12/2021

1483	NDA/MAL/HDP/9862	SQUARE PHARMACEUTICALS LTD.PABNA UNIT	GAMA PHARMACEUTICALS (U) LIMITED	DERMASOL-N CREAM	CLOBETASOL PROPIONATE + NEOMYCIN SULFATE + NYSTATIN	(0.5 MG + 5 MG + 100,000 UNITS)/ GRAM	N/A	SQUARE PHARMACEUTICALS LTD.SQUARE ROAD SALGARIA PABNA	N/A	NOT RETAINED	BANGLADESH	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	08/12/2021
1484	NDA/MAL/HDP/9868	PHARMA BAVARIA INTERNACIONAL PORTUGAL	GOODMAN INTERNATIONAL LTD	CADEN 6MG/2ML	ADENOSINE	6MG/2ML	N/A	VALDEPHARMPARC INDUSTRIEL D'INCARVILLE, PARC DE LA FRINGALE, CS10606, 27100 VAL DE REUIL - FRANCE	N/A	NOT RETAINED	FRANCE	PARENTERAL ORDINARY VIALS	1.0X1.0X6.0X2.0 ML VIAL	08/12/2021
1485	NDA/MAL/HDP/9869	PHARMA BAVARIA INTERNACIONAL(PBI) PORTUGUAL	GOODMAN INTERNATIONAL LTD	FOSMOL	FOSFOMYCIN TROMETAMOL	3000 MG	N/A	LABIANA PHARMACEUTICALS, S.L.U.C/CASANOVA, 27-31, 08757 CORBERA DE LLOBREGAT (BARCELONA)	N/A	NOT RETAINED	SPAIN	ORAL SOLID ORDINARY GRANULES	1.0X3000.0 MG SACHET,1.0X2.0X3000.0 MG SACHET	08/12/2021
1486	NDA/MAL/HDP/9870	PHARMA BAVARIA INTERNATIONAL GMBH -	GOODMAN INTERNATIONAL LTD	TAFIXYL	TRANEXAMIC ACID	500MG/5ML	N/A	LABIANA PHARMACEUTICALS, S.L.U.C/CASANOVA, 27-31, 08757 CORBERA DE LLOBREGAT (BARCELONA)	N/A	NOT RETAINED	SPAIN	PARENTERAL ORDINARY I V AMPOULES	1.0X1.0X5.0X5.0 ML AMPOULE	08/12/2021

1487	NDA/MAL/HDP/9879	LABORATE PHARMACEUTICALS INDIA LIMITED	HEALTHCARE LTD.	AMILAB-500	AMIKACIN SULFATE	500MG/2ML	N/A	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X2.0 ML VIAL	08/12/2021
1488	NDA/MAL/HDP/9880	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	LEFLOXIN 750	LEVOFLOXACIN HEMIHYDRATE	750MG	N/A	FREDUN PHARMACEUTICALS LIMITED14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PALGHAR (E), DIST: PALGHAR-401 404	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BOTTLE	08/12/2021
1489	NDA/MAL/HDP/9884	LABORATE PHARMACEUTICALS INDIA LIMITED	HEALTHCARE LTD.	FOLILAB	FOLIC ACID,	5MG	N/A	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	08/12/2021

1490	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	N/A	GMP EXPIRED ON 28/09/2023 FOR NON-BETA LACTAM: STERILE EYE DROPS (ASEPTICALLY PREPARED) STERILE EYE OINTMENTS (ASEPTICALLY PREPARED) NON-STERILE NASAL DROPS NON-STERILE METERED DOSE NASAL SPRAYS OINTMENTS, CREAMS & LOTIONS	RETAINED	JORDAN	NASAL TOPICAL METERED-DOSE LIQUIDS	1.0X1.0X30.0 ML BOTTLE	08/12/2021
1491	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	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, ORAL POWDER IN SACHETS AND BOTTLES. ONCOLOGY: TABLETS, HARD GELATIN CAPSULES	RETAINED	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

1492	NDA/MAL/HDP/9898	LINCOLN PARENTERAL LIMITED	METRO PHARMACEUTICALS LIMITED	NOSIL 0.1%	XYLOMETAZOLINE HYDROCHLORIDE	0.1%W/V	LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL	LINCOLN PARENTERAL LTD11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	FACILITY NOT APPROVED TO MANUFACTURE THIS PRODUCT LINE	RETAINED	INDIA	NASAL TOPICAL DROPS	1.0X1.0X10.0 ML BOTTLE	08/12/2021
1493	NDA/MAL/HDP/9905	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BISOLOL H 10/6.25	BISOPROLOL FUMARATE + HYDROCHLOROTHIAZIDE	10MG +6.25 MG	CADILA HEALTHCARE LIMITED - KUNDAIM INDUSTRIAL ESTATE,PLOT NO 203-	N/A	A VARIATION FOR CHANGE OF NAME HAS NOT BEEN APPROVED. NAME OF FACILITY CHANGED TO ZYDUS LIFESCIENCES	RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	08/12/2021
1494	NDA/MAL/HDP/9907	LEGIT MEDEQ 2007 LIMITED	LEGIT MEDEQ 2007 LIMITED	ONDAZEN	ONDANSETRON HYDROCHLORIDE DIHYDRATE	8MG/4ML	N/A	ZEN PHARMA PVT LTD75/1, GIDC. VAPI-396 195 GUJARAT,	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X4.0 ML AMPOULE	11/12/2021
1495	NDA/MAL/HDP/9912	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	IBUREN SUSPENSION	IBUPROFEN	100MG/5ML	N/A	RENE INDUSTRIES LTDPLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	SAMPLES SUBMITTED AT THE TIME OF REGISTRATION HAVE EXPIRED. CLIENT REQUIRED TO SUBMIT FRESH SAMPLES.	RETAINED	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X60.0 ML BOTTLE	08/12/2021

1496	NDA/MAL/HDP/9914	SQUARE PHARMACEUTICALS LTD.	GAMA PHARMACEUTICALS (U) LIMITED	MUCOSPEL	BROMHEXINE HYDROCHLORIDE	4MG/5ML	N/A	SQUARE PHARMACEUTICALS LIMITED.SQUARE ROAD, SALGARIA, PABNA	N/A	NOT RETAINED	BANGLADESH	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	08/12/2021
1497	NDA/MAL/HDP/9921	REGAL PHARMACEUTICALS LTD	REGAL PHARMA U LIMITED	SONATEC MOUTHWASH MENTHOL BREEZE	CETYLPYRIDINIUM CHLORIDE	0.05%W/V	N/A	REGAL PHARMACEUTICALS LTD PLOT NO. 7879/18, OFF BABA DOGO ROAD, RUARAKA - NAIROBI	SAMPLES SUBMITTED AT THE TIME OF REGISTRATION HAVE EXPIRED. CLIENT REQUIRED TO SUBMIT FRESH SAMPLES.	RETAINED	KENYA	ORAL TOPICAL LIQUIDS	1.0X250.0 ML BOTTLE	08/12/2021
1498	NDA/MAL/HDP/9927	LINCOLN PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	NYSTATIN	NYSTATIN	500,000 I.U	N/A	MEDICAMEN BIOTECH LTD .SP-1192 A&B PHASE IV INDUSTRIAL AREA BHIWADI 301019 DIST. ALWAR (RAJASTHAN) LINCOLN PHARMACEUTICALS LTD10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER	02/02/2022

1499	NDA/MAL/HDP/9935	APEX LABORATORIES PRIVATE LIMITED	NORVIK ENTERPRISES LIMITED	ZINCOFER CAPSULES	FERROUS FUMARATE + FOLIC ACID BP + CYANOCOBALAMIN + 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	N/A	GMP EXPIRED ON THE 10/9/2022 FOR NON-BETA LACTAM (HUMAN): TABLETS (COATED AND UNCOATED) SEMI SOLIDS (CREAMS AND OINTMENTS) HARD GELATIN CAPSULES	RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1X3X10 CAPSULE Blister,	31/03/2022
1500	NDA/MAL/HDP/9939	CELOGEN PHARMA PVT LTD	OMAB UGANDA LIMITED	MELOXICAM TABLETS 7.5 MG	MELOXICAM	7.5MG	N/A	CELOGEN GENERICS PVT. LIMITED646/1 & 2. AGRAWAL INDUSTRIAL ESTATE, SOMNATH ROAD, DABHEL, DAMAN (UT) – 396210 INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	24/03/2022
1501	NDA/MAL/HDP/9940	CELOGEN PHARMA PVT LTD	OMAB UGANDA LIMITED	MELOXICAM TABLETS 15MG	MELOXICAM	15MG	N/A	CELOGEN GENERICS PVT. LIMITED646/1 & 2. AGRAWAL INDUSTRIAL ESTATE, SOMNATH ROAD, DABHEL, DAMAN (UT) – 396210 INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	24/03/2022

1502	NDA/MAL/HDP/9949	LABORATE PHARMACEUTICALS INDIA LIMITED	HEALTHCARE LTD.	GENTAM	GENTAMICIN SULPHATE	80MG/2ML	N/A	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	N/A	NOT RETAINED	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	24/03/2022
1503	NDA/MAL/HDP/9977	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	EMTRICITABINE + TENOFOVIR DISOPROXIL FUMARATE TABLETS 200 MG/ 300 MG	EMTRICITABINE + TENOFOVIR DISOPROXIL FUMARATE	200MG + 300MG	N/A	LAURUS LABS LTD (UNIT 2)PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH,	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET CONTAINER, 1.0X90.0 TABLET CONTAINER	24/03/2022

1504	NDA/MAL/ HDP/9979	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	PRILIS 10	LISINOPRIL DIHYDRATE	10 MG	GLOBELA PHARMA PVT.LTD. 357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED AND UNCOATED), HARD GELATIN CAPSULES, ORAL POWDER IN SACHETS AND BOTTLES. ONCOLOGY: TABLETS, HARD GELATIN CAPSULES	NOT RETAINED	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10 .0 TABLET BLISTER	24/03/2022

1505	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	N/A	GMP EXPIRED ON THE 29/9/2023 FOR NON-BETA LACTAM: HARD GELATIN CAPSULES SOFT GELATIN CAPSULES TABLETS (COATED & UNCOATED) DRY POWDERS FOR SUSPENSION POWDERS PACKED IN SACHETS SMALL VOLUME PARENTERAL (ASEPTICALLY PREPARED LIQUIDS) SMALL VOLUME PARENTERAL – (ASEPTICALLY PREPARED POWDERS) EYE DROPS (ASEPTICALLY PREPARED) ORAL LIQUIDS NON-STERILE NASAL DROPS EXTERNAL SEMI-SOLIDS (CREAMS & GELS)	RETAINED	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X5.0X5.0 ML AMPOULE	24/03/2022

1506	NDA/MAL/HHP/10011	GRIFFON BIOMETRIX PVT.LTD	METRO PHARMACEUTICALS LIMITED	GRIFFON BALM	MENTHOL + CAMPHOR + GULTHERIA KA TEL + AJWAIN KA PHOOL + PIPPERMINT OIL + LAVANG KA TEL + DALCHINI TAIL	10%W/W+ 15%W/W+ 15%W/W+ 3%W/W+5 %W/W+5% W/W+5%W /W	N/A	ZOETIS MANUFACTURING AND RESEARCH SPAIN, S.LCTRA. DE CAMPRODIN, S/N, FINCA LA RIBA, VALL DE BIANYA, 17813, GIRONA	N/A	NOT RETAINED	SPAIN	TOPICAL EXTERNAL OINTMENTS	1.0X10.0 G BOTTLE	28/02/2022
1507	NDA/MAL/HHP/10020	KALBE INTERNATIONAL PTE LTD	ABACUS PHARMA (AFRICA) LIMITED	WOOD'S PEPPERMINT LOZENGES (ORIGINAL FLAVOUR)	MULTIPLE INGERDIENT	MULTIPLE INGERDIENT	N/A	PT.KALBE FARMA TBKJL.M.H.THAMRIN BLOK A3-1, KAWASAN INDUSTRI DELTA SILIKON,LIPPO CIKARANG,BEKASI-	N/A	NOT RETAINED	SINGAPORE	ORAL SOLID ORDINARY LOZENGES	1.0X15.0X6.0 LOZENGE SACHET	10/03/2022
1508	NDA/MAL/HHP/10021	KALBE INTERNATIONAL PTE LTD	ABACUS PHARMA (AFRICA) LIMITED	WOOD'S PEPPERMINT LOZENGES(CHERRY FLAVOUR)	MULTIPLE INGREDIENT	MULTIPLE INGREDIENT	N/A	PT.KALBE FARMA TBKJL.M.H.THAMRIN BLOK A3-1, KAWASAN INDUSTRI DELTA SILIKON,LIPPO CIKARANG,BEKASI-	N/A	NOT RETAINED	SINGAPORE	ORAL SOLID ORDINARY LOZENGES	1.0X15.0X6.0 LOZENGE SACHET	10/03/2022

1509	NDA/MAL/HHP/10022	KALBE INTERNATIONAL PTE LTD	ABACUS PHARMA (AFRICA) LIMITED	WOOD'S PEPPERMINT LOZENGES (ORANGE FLAVOUR)	MULTIPLE INGREDIENT	MULTIPLE INGREDIENT	N/A	PT.KALBE FARMA TBKJL.M.H.THAMRIN BLOK A3-1, KAWASAN INDUSTRI DELTA SILIKON,LIPPO CIKARANG,BEKASI-	N/A	NOT RETAINED	SINGAPORE	ORAL SOLID ORDINARY LOZENGES	1.0X15.0X6.0 LOZENGE SACHET	10/03/2022
1510	NDA/MAL/HHP/10025	GAYATRI AYUPHARMA PRIVATE LIMITED	VIDA AFRICA LTD	HERO PAIN BALM	MULTI INGREDIENT	MULTI INGREDIENT	N/A	GAYATRI AYUPHARMA PRIVATE LIMITED234/2/2, PATEL ESTATE, NIKOL ROAD, AHMEDABAD: 382 350, GUJARAT (INDIA)	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL OINTMENTS	1X10 ML Jar,	05/04/2022
1511	NDA/MAL/HHP/10409	CHETAN & DIPTI (C&D) PHARMA PVT LTD	KAMCARE PHARMA LIMITED	HERBOXIL LOZENGES	MENTHOL + EUCALYPTUS OIL	0.34%W/W + 0.24%W/W	N/A	LEAMARK HEALTHCARE PVT LTDSARKHEJ BAVLA HIGHWAY,MATODA 382213 AHMEDABAD GUJARAT	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X50.0X2.0 LOZENGE STRIP	12/10/2022

1512	NDA/MAL/HHP/10501	SYNOKEM PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GOPAYN RUB GEL	MULTI INGREDIENT	30G	SYNOKEM PHARMACEUTICALS LTD-PLOT NO.-35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL)	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM (HUMAN): TABLETS, HARD GELATIN CAPSULES, ORAL LIQUIDS, HORMONES: TABLETS	RETAINED	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	02/12/2022
1513	NDA/MAL/HHP/5505	VENUS REMIDIES LTD	HARLEYS UGANDA LIMITED	AMPUCARE HERBAL OIL			N/A	PLANET HERBS LIFESCIENCES LIMITED B-4 SARA INDUSTRIAL ESTATE, SELAQUI, DEHRADUN-248197, UTTARKHAND, INDIA	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X50.0 ML BOTTLE	01/07/2008
1514	NDA/MAL/HHP/5561	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	COLDDROP MEDICATED COUGH DROPS			N/A	MEHTA HERBALS PVT LTDAMRUTMANTHAN HOUSE, SADAR,RAJKOT,GUJARAT - 360 001,INDIA, RAJKOT, GUJARAT 360001, INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X1.0X100.0 LOZENGE CARTON	01/07/2009

1515	NDA/MAL/HHP/5571	ABACUS (A) PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	DRAGON LIQUID BALM			N/A	AMRUTANJAN HEALTH CARE LIMITEDPLOT NO 37,38&39, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR VILLAGE, THIRUPORUR TALUK, KANCHEEPURAM DISTRICT 603110, INDIA	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL OTHER OINTMENTS	1.0X10.0 ML CONTAINER, 1.0X5.0 ML CONTAINER	01/07/2004
1516	NDA/MAL/HHP/5576	CINCINNATI CHILDREN'S HOSPITAL	SHURIK LTD	NO SCAR CREAM	MULTI-INGREDIENT	MULTI-INGREDIENT	N/A	METHA UNANI PHARMACYMETHA UNANI PHARMACY G-524 LODHIKA, G.I.D.C METODA	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2007
1517	NDA/MAL/HHP/5593	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	SYDLER GRIPE WATER			N/A	SYDLER REMEDIES PVT LTD M-190, M.I.D.C, WALUJ, AURANGABAD 431 136 (M.S), INDIA.	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X120.0 ML BOTTLE	01/07/2010

1518	NDA/MAL/HHP/6850	WILSHIRE LABORATORIES (PVT) LTD	HEALTHCARE LTD.	BENZIM NATURAL SYRUP 120ML	MULTI-INGREDIENT	N/A	WILSHIRE LABORATORIES LIMITED-124/1-INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE, PAKISTAN	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: COATED AND UNCOATED TABLETS, HARD GELATIN CAPSULES, POWDERS FOR ORAL SUSPENSION, SMALL AND LARGE VOLUME PARENTERAL LIQUIDS, SMALL VOLUME POWDER FOR INJECTION	NOT RETAINED	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	03/12/2016

1519	NDA/MAL/HHP/6852	WILSHIRE LABORATORIES (PVT) LTD	HEALTHCARE LTD.	DE-FLU SYRUP 120ML	MULTIINGREDIENT	N/A	WILSHIRE LABORATORIES LIMITED-124/1-INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE, PAKISTAN	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: COATED AND UNCOATED TABLETS, HARD GELATIN CAPSULES, POWDERS FOR ORAL SUSPENSION, SMALL AND LARGE VOLUME PARENTERAL LIQUIDS, SMALL VOLUME POWDER FOR INJECTION	NOT RETAINED	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	03/12/2016

1520	NDA/MAL/HHP/6853	WILSHIRE LABORATORIES (PVT) LTD	HEALTHCARE LTD.	LIV-LONG TABLET	MULTIINGREDIENT	N/A	WILSHIRE LABORATORIES LIMITED-124/1-INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE, PAKISTAN	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: COATED AND UNCOATED TABLETS, HARD GELATIN CAPSULES, POWDERS FOR ORAL SUSPENSION, SMALL AND LARGE VOLUME PARENTERAL LIQUIDS, SMALL VOLUME POWDER FOR INJECTION	NOT RETAINED	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
1521	NDA/MAL/HHP/6863	KREMOINT PHARMA PVT.LTD	GOOD DAY PHARMACY LIMITED	KOFFENGES LOZENGES (HONEY & LEMON FLAVOUR)	MULTIINGREDIENT	N/A	N/A	KREMOINT PHARMA PVT LTD - RAGHAV ESTATE, K.S.S.I.D.C. INDUSTRIAL ESTATE AREA, SHIGGAON ROAD, SAVANUR 581118, DIST: HAVERI, KARNATAKA, INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X5.0X4.0 LOZENGE BLISTER,1.0X10.0X6.0 LOZENGE BLISTER	01/07/2017

1522	NDA/MAL/HHP/6915	GREAT INDIA INDUSTRIAL & PHARAMCEUTICALS LABORATORIES	MALIX PHARMA (U) LIMITED	GIPLA GRIPE WATER	GIPLA GRIPE WATER	135ML	N/A	GREAT INDIA 19 SUN MILL COMPOUND	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X135.0 ML BOTTLE	01/07/2014
1523	NDA/MAL/HHP/7946	SHEBAC PHARMA	NORVIK ENTERPRISES LIMITED	APONTIS	GULTIGENERIC	105G	N/A	AEROMAC (INDIA) INC12, MELDI ESTATE, GOTA AHMEDABAD - 382481, GUJARAT, INDIA	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL SPRAYS WITHOUT GAS	1.0X150.0 ML BOTTLE	01/07/2015
1524	NDA/MAL/HHP/7955	KREMOINT PHARMA PVT.LTD	PLANET PHARMACEUTICALS UGANDA LTD	DICLODAY ROLL-ON	AJOWAN KA PHOOL	0.5MG	N/A	KREMOINT PHARMA PVT LTDB-8,ADDITIONAL AMBERNATH MIDC, AMBERNATH (E),DIST: THANE 421506, INDIA	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL EMULSIONS	1.0X50.0 ML BOTTLE	03/12/2016
1525	NDA/MAL/HHP/7958	KREMOINT PHARMA PVT.LTD	GOOD DAY PHARMACY LIMITED	KOFFENGES(GINGER FLAVOUR)	CINNAMOMUM CAMPHORA	0.18MG	N/A	KREMOINT PHARMA PVT LTD - RAGHAV ESTATE, K.S.S.I.D.C. INDUSTRIAL ESTATE AREA, SHIGGAON ROAD, SAVANUR 581118, DIST: HAVERI, KARNATAKA, INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X5.0X4.0 LOZENGE BLISTER,1.0X10.0X6.0 LOZENGE BLISTER	01/07/2017

1526	NDA/MAL/HHP/7960	KREMOINT PHARMA PVT.LTD	GOOD DAY PHARMACY LIMITED	KOFFENGES(ORANGE FLAVOUR)	KARPURA	0.18MG	N/A	KREMOINT PHARMA PVT LTD - RAGHAV ESTATE, K.S.S.I.D.C. INDUSTRIAL ESTATE AREA, SHIGGAON ROAD, SAVANUR 581118, DIST: HAVERI, KARNATAKA, INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X5.0X4.0 LOZENGE BLISTER,1.0X10.0X6.0 LOZENGE BLISTER	01/07/2017
1527	NDA/MAL/HHP/7961	KREMOINT PHARMA PVT.LTD	GOOD DAY PHARMACY LIMITED	KOFFENGES LOZENGES MINT	CINNAMOMUM CAMPHORANEES AND EBERM (KARPURA)	0.18MG	N/A	KREMOINT PHARMA PVT LTD - RAGHAV ESTATE, K.S.S.I.D.C. INDUSTRIAL ESTATE AREA, SHIGGAON ROAD, SAVANUR 581118, DIST: HAVERI, KARNATAKA, INDIA	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X5.0X4.0 LOZENGE BLISTER,1.0X10.0X6.0 LOZENGE BLISTER	01/07/2017

1528	NDA/MAL/HHP/7974	WILSHIRE LABORATORIES (PVT) LTD	HEALTHCARE LTD.	APPERIZE SYRUP 120ML	MULTI-INGREDIENT	MULTI-INGREDIENT	WILSHIRE LABORATORIES (PVT) LTD-124/1 INDUSTRIAL AREA, KOT LAKHPAT LAHORE PAKISTAN	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: COATED AND UNCOATED TABLETS, HARD GELATIN CAPSULES, POWDERS FOR ORAL SUSPENSION, SMALL AND LARGE VOLUME PARENTERAL LIQUIDS, SMALL VOLUME POWDER FOR INJECTION	NOT RETAINED	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2017
1529	NDA/MAL/HHP/8070	LEXINE TECHNOCHEM PVT LTD	KPI HEALTHCARE LIMITED	KWIK PAIN RELIEVING CREAM	MULTINGREDIENT	N/A	N/A	LEXINE TECHNOCHEM PVT LTD.INDIA	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	28/07/2018

1530	NDA/MAL/HHP/8071	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MOOVE MASSAGE CREAM	MULTI-INGREDIENT	N/A	EVA PHARMA FOR PHARMA CEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	N/A	GMP EXPIRED ON 30/9/2023 FOR NON-BETA LACTAM: ORAL LIQUIDS FOR INTERNAL USE TABLETS (COATED AND UNCOATED) HARD GELATIN CAPSULES ORAL POWDER FOR SUSPENSION OINTMENTS, CREAMS AND GELS	NOT RETAINED	EGYPT	TOPICAL EXTERNAL LOTIONS	1.0X1.0X40.0 G TUBE	01/07/2017
1531	NDA/MAL/HHP/8215	AMRUTANJAN HEALTH CARE LTD	ABACUS PHARMA (AFRICA) LIMITED	AMRUTANJAN DRAGON BACK PAIN ROLL-ON	MULTINGREDIENT	N/A	N/A	AMRUTANJAN HEALTH CARE LIMITED - PLOT NO.14, INDUSTRIAL DEVELOPMENT AREA, UPPAL HYDERABAD - 500039, INDIA	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL LOTIONS	1.0X50.0 ML CONTAINER	01/07/2004

1532	NDA/MAL/HHP/8548	ARTURA PHARMACEUTICALS PVT LTD	SWASTIK PHARMACEUTICAL LTD	PEPSOL	ALPHA AMYLASE+PAPAIN+FUNGAL LIPASE+SIMETHICONE	100MG+100MG+25MG+30MG	ARTURA PHARMACEUTICALS PVT LTD PLOT NO. 1505 PORTIA ROAD SIRI CITY SEZ SATYAVEDU MANDAL CHITTOOR DISTRICT	N/A	GMP EXPIRED ON 19/10/2023 FOR NON-BETA LACTAM: TABLETS (COATED & UNCOATED), HARD GELATIN CAPSULES	NOT RETAINED	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	24/10/2017
1533	NDA/MAL/HHP/8552	AMRUTANJAN HEALTHCARE LIMITE	ABACUS PHARMA (AFRICA) LIMITED	AMRUTANJAN DRAGON BALM	MULTI-INGREDIENT	MULTI-INGREDIENT	N/A	AMRUTANJAN HEALTH CARE LIMITED PLOT NO.14, INDUSTRIAL DEVELOPMENT AREA, UPPAL HYDERABAD - 500039, INDIA PLOT NO.:37, 38 & 39, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR VILLAGE, THIRUPORUR TK, KANCHEEPURAM, DIST. – 603 110, TAMILNADU, INDIA	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X10.0 ML TUBE	24/11/2017

1534	NDA/MAL/HHP/8553	RAZA INTERNATIONAL	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HONEY CURE	MULTI-INGREDIENT	MULTI-INGREDIENT	N/A	OZONE COSMETICS & NATURAL PRODUCTS MANUFACTURING COMPANY√SHARA BADRAN, MARJ ALFARAS, INDUSTRIAL ZONE, MUSAWAA STREET. OZONE INDUSTRIAL COMPLEX. P.O. BOX : 1764. AMMAN 11953, JORDAN	N/A	NOT RETAINED	JORDAN	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE,1.0X15.0 G TUBE	13/07/2017

1535	NDA/MAL/HHP/8837	PILLAR PHARMA LIMITED	PILLAR LOGISTICS LIMITED	HEPTOVIT	PHYLLANTHUS NIRURI+ECLIPTA ALBA+BERBERIS ARISTATA+FUMARIA PARVIFLORA+BOERHAAVIA DIFFUSA+ZINGIBER OFFICINALE+PLUMBAGO ZEYLANICA+TINOSPORA CORDIFOLIA+ANDROGRAPHIS PANICULATA+PICRORRHIZA KURROA+PIPER LONGUM+(TERMINALIA CHEBULA,TERMINALIA BELERICA	20MG+15MG+6.66MG+10MG+5.88MG+5MG+3.33MG+4.16MG+5MG+6.25MG+8.33MG+75MG	N/A	MILENNIUM HERBAL CARE LTD12B, NIRMAL, 241/242, BACKBAY RECLAMATION, NARIMAN POINT, MUMBAI 400 021	N/A	NOT RETAINED	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	07/06/2018

1536	NDA/MAL/HHP/8899	LEXINE TECHNOCHEM PVT LTD	KPI HEALTHCARE LIMITED	LEXICOF HERBAL COUGH SYRUP	OCIMUM SANCTUM + ADHATODA VASICA +GLYCYRRHIZA GLABRA + CLERODENDRON SERRATUM +SOLANUM XANTHOCARPUM +TERMINALIA BELERICA +ZINGIBER OFFICINALE +PHYLLANTHUS EMBLICA + PIPER LONGUM + CURCUMA LONGA + MENTHA	250MG + 250MG + 100MG + 75MG + 75MG + 75MG + 50MG + 50MG + 50MG + 50MG + 6MG	N/A	LEXINE TECHNOCHEM PVT LTD SURVEY PLOT NO. 373, OPP. RAMAKAKA DERI CHHANI, VADODARA – 391704 GUJARAT, INDIA	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	14/03/2018

1537	NDA/MAL/HHP/8902	WILSHIRE LABORATORIES (PVT) LTD	HEALTHCARE LTD.	DE-TUZ SYRUP	MULTI-INGREDIENT	MULTI-INGREDIENT	WILSHIRE LABORATORIES (PVT) LTD-124/1 INDUSTRIAL AREA, KOT LAKHPAT LAHORE PAKISTAN	N/A	GMP EXPIRED ON 12/10/2023 FOR NON-BETA LACTAM: COATED AND UNCOATED TABLETS, HARD GELATIN CAPSULES, POWDERS FOR ORAL SUSPENSION, SMALL AND LARGE VOLUME PARENTERAL LIQUIDS, SMALL VOLUME POWDER FOR INJECTION	NOT RETAINED	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	28/06/2018
1538	NDA/MAL/HHP/8979	LEXINE TECHNOCHEM PVT LTD	KPI HEALTHCARE LIMITED	KWIK PAIN BALM	GAULTHERIA FRAGRANTISSIMA + MENTHOL	10 G + 14 G	N/A	LEXINE TECHNOCHEM PVT LTD SURVEY PLOT NO. 373, OPP. RAMAKAKA DERI CHHANI, VADODARA – 391704 GUJARAT, INDIA	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X10.0 G TUBE,1.0X22.0 G TUBE	14/03/2018

1539	NDA/MAL/HHP/9026	LEXINE TECHNOCHEM PVT LTD	KPI HEALTHCARE LIMITED	BABY CARE + GRIPE WATER 130ML	MULTI-INGREDIENT	MULTI-INGREDIENT	N/A	LEXINE TECHNOCHEM PVT LTD SURVEY PLOT NO. 373, OPP. RAMAKAKA DERI CHHANI, VADODARA – 391704 GUJARAT, INDIA	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X130.0 ML BOTTLE	01/07/2015
1540	NDA/MAL/HHP/9091	UNOSOURCE PHARMA LTD	MEDVIN PHARMA LIMITED	KOFCLEAN SYRUP (HERBAL COUGH SYRUP)	ADHATODA VASICA + GLYCYRRHIZA GLABRA + PIPER LONGUM + VITIS VINIFERA + OCIMUM SANTUM-	500MG + 200MG + 80MG + 80MG + 100MG	N/A	MAXCURE NUTRAVEDICS LTD PLOT NO.13 SEC-6A IIE,SIDCUL,RANIPUR, HARIDWAR-249 403, UTTRAKHAND	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	28/01/2019

1541	NDA/MAL/HHP/9185	REVITAL HEALTHCARE LTD	HEALTHCARE LTD.	GINSEMAX-F	VITAMIN A + VITAMIN B1 + VITAMIN B2 + VITAMIN B3 + VITAMIN B5 + VITAMIN B6 + VITAMIN B12 + VITAMIN C + VITAMIN D3 + VITAMIN E + FOLIC ACID + L-ARGININE + CALCIUM + PHOSPHORUS + FERROUS FUMARATE + ZINC + MAGNESIUM + POTASSIUM + MANGANESE + COPPER + IODINE	2500I.U+1MG+1.5MG+10MG+5MG+1MG+1MCG+50MG+200I.U+5MG+0.15MG+25MG+75MG+58MG+30MG+10MG+3MG+2MG+0.5MG+0.1MG	ZEE LABORATORIES LTD-BEHIND 47, INDUSTRIAL AREA, PAONTA SAHIB-173025 DISTT. SIRMOUR HIMACHAL PRADESH	N/A	FAILED GMP ON THE 10/6/2022	NOT RETAINED	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X15.0 CAPSULE BLISTER	22/05/2020

1542	NDA/MAL/HHP/9186	REVITAL HEALTHCARE LTD	HEALTHCARE LTD.	GINSEMAX	GINSENG EXTRACT+VITAMIN A+VITAMIN B1+VITAMIN B2+VITAMIN B3+VITAMIN B5+VITAMIN B6+VITAMIN B12+VITAMIN C+VITAMIN D3+VITAMIN E+FOLIC ACID+L-ARGININE+CALCIUM+PHOSPHORUS+FERROUS FUMARATE+ZINC+MAGNESIUM+POTASSIUM+MANGANESE+COPPE	42.5MG+2500I.U+1MG+1.5MG+10MG+5MG+1MG+1MCG+50MG+200I.U+5MG+0.15MG+25MG+75MG+58MG+30MG+10MG+3MG+2MG+0.5MG+0.5MG+0.1MG	ZEE LABORATORIES LTD-BEHIND 47, INDUSTRIAL AREA, PAONTA SAHIB-173025 DISTT. SIRMOUR HIMACHAL PRADESH	N/A	FACILITY FAILED GMP ON THE 10/6/2022	NOT RETAINED	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X15.0 CAPSULE BLISTER	22/05/2020
1543	NDA/MAL/HHP/9489	KALBE INTERNATIONAL PTE LTD	ABACUS PHARMA (AFRICA) LIMITED	WOOD'S HERBAL COUGH SYRUP	IVY LEAF EXTRACT + PHYLLANTHUS NIRRURI LEAVES EXTRACT + MINT LEAVES EXTRACT + HONEY	35MG + 35MG + 25MG + 3000MG	N/A	PT.KALBE FARMA TBKJL.M.H.THAMRIN BLOK A3-1, KAWASAN INDUSTRI DELTA SILIKON,LIPPO CIKARANG,BEKASI-	N/A	NOT RETAINED	INDONESIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	09/02/2021

1544	NDA/MAL/HHP/9558	REVITAL HEALTHCARE LTD	HEALTHCARE LTD.	DR.ZEE HERBAL VAPOREX	MENTHOL + EUCALYPTUS OIL + CINNAMON OIL + NUTMEG + CAMPHOR + CLOVE	5% + 3% + 1% + 1% + 2% + 5%	ZEE LABORATORIES LTD-BEHIND 47, INDUSTRIAL AREA, PAONTA SAHIB-173025 DISTT. SIRMOUR	N/A	FACILITY FAILED GMP ON THE 10/6/2022	NOT RETAINED	INDIA	NASAL TOPICAL OINTMENTS	1.0X25.0 G JAR	01/03/2021
1545	NDA/MAL/HHP/9700	GRIFFON BIOMETRIX PVT.LTD	METRO PHARMACEUTICALS LIMITED	TOTO GRIPE WATER	MULTI INGREDIENT	MULTI INGREDIENT	N/A	KESAR PHARMA PVT LTDPLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X120.0 ML BOTTLE	27/08/2021
1546	NDA/MAL/HHP/9702	GRIFFON BIOMETRIX PVT.LTD	METRO PHARMACEUTICALS LIMITED	GRIFFON STRONG BALM	MULTI INGREDIENT	MULTI INGREDIENT	N/A	RAJESH PHARMACEUTICALS7, DESHVALI,CHANDLODIYA ROAD,AHMEDABAD, GUJARAT 382 481	N/A	NOT RETAINED	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X9.0 ML BOTTLE	27/08/2021

1547	NDA/MAL/HHP/9833	REVITAL HEALTHCARE LTD	HEALTHCARE LTD.	OSTEOCURE GEL	MULTI-INGREDIENT	N/A	ZEE LABORATORIES LTD-BEHIND 47, INDUSTRIAL AREA, PAONTA SAHIB-173025 DISTT. SIRMOUR	N/A	FAILED GMP ON THE 10/6/2022	NOT RETAINED	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X100.0 G TUBE	26/10/2021
1548	NDA/MAL/VDP/10003	JUBAILI AGROTEC LIMITED	JUBAILI AGROTEC LIMITED	INFLANOR	DEXAMETHASONE SODIUM PHOSPHATE	2 MG/ML	HEBEI HOPE HARMONY PHARMACEUTICAL CO LTD-INDUSTRY DEVELOPMENT AREA, YUANSHI COUNTY, SHIJIAZHUANG CITY, HEBEI PROVINC	N/A	GMP EXPIRED ON 8/10/2023 FOR NON-BETA LACTAM: TABLETS, ORAL LIQUIDS, SMALL VOLUME PARENTERAL SOLUTIONS (AMPOULES & VIALS), ORAL SOLUBLE POWDERS IN SACHETS	RETAINED	CHINA	PARENTERAL ORDINARY VIALS	1.0X1.0X50.0 ML VIAL,1.0X1.0X100.0 ML VIAL	31/03/2022
1549	NDA/MAL/VDP/10359	ZOETIS BELGIUM SA	VET CENTRE UGANDA LIMITED	SYNULOX BOLUS 500MG	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	400MG + 100MG	HAUPT PHARMA LATINA S.R.L,-S.S. 156 MONTI LEPINI, KM 47.600, 04100 BORGO	N/A	FACILITY NOT APPROVED TO MANUFACTURE BETA LACTAMS	RETAINED	ITALY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X5.0X4.0 TABLET STRIP	09/09/2022

1550	NDA/MAL/VDP/10581	NEOGEN CHEMICALS(U) LTD	NEOGEN CHEMICALS (U) LTD	OXY-GEN®	OXYTETRACYCLINE HYDROCHLORIDE	3.15%W/V	HEBEI NEW CENTURY PHARMACEUTICAL CO., LTD.-N0. 189 TAIHANG STREET, SHIJIAZHUANG	N/A	FACILITY HAS NOT BEEN APPROVED TO MANUFACTURE LARGE VOLUME PARENTERALS	RETAINED	CHINA	PARENTERAL ORDINARY VIALS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X250.0 ML BOTTLE,1.0X1.0X500.0 ML BOTTLE	10/02/2023
1551	NDA/MAL/VDP/10587	INTERCHEMIE WENKEN "DE ADELAAR" B.V.	VET CENTRE UGANDA LIMITED	XYLA	XYLAZINE HYDROCHLORIDE	20MG/ML	INTERCHEMIE WERKEN "DE ADEKAAR" BV-METAAL WEG	N/A	PARENTERAL LINE WAS NOT INCLUDED IN THE APPLICATION OF GMP RE-INSPECTION	RETAINED	NETHERLANDS	PARENTERAL ORDINARY VIALS	1.0X1.0X50.0 ML BOTTLE	10/02/2023
1552	NDA/MAL/VDP/10594	HEBEI HOPE HARMONY PHARMACEUTICAL CO., LTD	JUBAILI AGROTEC LIMITED	VECTONOR®	SULPHAMONOMETHOXINE SODIUM + TRIMETHOPRIM	20% W/V + 4% W/V	HEBEI HOPE HARMONY PHARMACEUTICAL CO LTD-INDUSTRY DEVELOPMENT AREA, YUANSHI COUNTY, SHIJIAZHUANG CITY, HEBEI PROVINC	N/A	GMP EXPIRED ON 8/10/2023 FOR NON-BETA LACTAM: TABLETS, ORAL LIQUIDS, SMALL VOLUME PARENTERAL SOLUTIONS (AMPOULES & VIALS), ORAL SOLUBLE POWDERS IN SACHETS	RETAINED	CHINA	PARENTERAL ORDINARY VIALS	1.0X1.0X100.0 ML VIAL	08/02/2023

1553	NDA/MAL/VDP/10869	BAODING SUNLIGHT HERB MEDICAMENT CO.LTD	BD PHARMACEUTICALS LTD	MECTIN	IVERMECTIN	1%W/V	BAODING SUNLIGHT HERB MEDICAMENT CO. LTD-NO. 3881 GREAT WALL SOUTH STREET, QINGYUAN DISTRICT, BAODING CITY, HEBEI PROVINCE CHINA	N/A	APPLICATION FOR GMP RE-INSPECTION BEARS A DIFFERENT ADDRESS (NO.2, PING AN EAST ROAD, EAST ZONE, ECONOMIC DEVELOPMENT DISTRICT, GAOYANG COUNTY, BAODING CITY, HEBEI PROVINCE - CHINA). APPLICANT REQUIRED TO UPDATE MANUFACTURER'S DETAILS	RETAINED	CHINA	PARENTERAL ORDINARY VIALS	1.0X1.0X50.0 ML VIAL,1.0X1.0X100.0 ML VIAL	03/05/2023

1554	NDA/MAL/VDP/10871	ELANCO ANIMAL HEALTH(PTY)LTD	ULTRAVETIS UGANDA LIMITED	AVIPRO® 104 MG BACTERIN	MYCOPLASMA GALLISEPTICUM BACTERIN, R STRAIN	10^6.0 CCU PER DOSE	LOHMANN ANIMAL HEALTH INTERNATIONAL-PLOT 375 CHINA ROAD, WINSLOW, MAINE 04901, USA	N/A	GMP EXPIRED ON THE 21/2/2023 FOR BIOLOGICAL PRODUCTS-LIVE /INACTIVATED VIRAL AND BACTERIAL POULTRY VACCINES: SMALL VOLUME LIQUIDS (PACKAGED IN GLASS AMPOULES AND VIALS) – ASEPTICALLY PREPARED, LARGE VOLUME LIQUIDS (PACKAGED GLASS VIALS AND HDPE BOTTLES) – ASEPTICALLY PREPARED, SMALL VOLUME PARENTERAL LYOPHILIZED POWDERS (PACKAGED IN GLASS VIALS) – ASEPTICALLY PREPARED	RETAINED	UNITED STATES	PARENTERAL ORDINARY S C VIALS	1.0X500.0 ML BOTTLE (1000 DOSES)	17/08/2023

1555	NDA/MAL/ VDP/10995	VMD NV HOGE MAUW	ERAM UGANDA LIMITED	DOXYVETO-CITRIX 500 MG/G	DOXYCYCLINE HYCLATE	500 MG/G	VMD NV - HOGE MUW 900, 2370, ARENDO NK	LABORATORIES BIOVE' -3, RUE DE LORRAINE, F-62510 ARQUES	GMP EXPIRED ON THE 2/3/2019 FOR NBL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, ORAL LIQUIDS, POWDERS FOR ORAL SUSPENSION) BL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, POWDERS FOR ORAL SUSPENSION)	RETAINED	FRANCE	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X100.0 G JAR,1.0X100 0.0 G JAR	17/08/2023
1556	NDA/MAL/ VDP/1594	NORBROOK KENYA LTD	NORBROOK (U) LTD	PESTIGON	FIPRONIL	100MG	NORBRO OK LABORAT ORIES LTD-STATION WORKS, NEWRY, COUNTRY DOWN, BT35 6JP, NORTHER	N/A	FACILITY NOT LICENSED TO MANUFACTURE PRODUCT LINE	RETAINED	UNITED KINGDOM	TOPICAL EXTERNAL LIQUIDS	1.0X4.02 ML PIPETTE,1.0X 1.34 ML PIPETTE,1.0X 0.67 ML PIPETTE,1.0X 0.5 ML PIPETTE,1.0X 2.68 ML PIPETTE	01/07/2013

1557	NDA/MAL/VDP/2881	NORBROOK KENYA LTD	NORBROOK (U) LTD	DUODIP 50:5 %	CHLORPYRIFOS + CYPERMETHRIN	50%W/V + 5%W/V	NORBROOK LAB. LTDSTATION WORKS, NEWRY, COUNTRY DOWN, BT35 6JP NORTHERN	NORBROOK KENYA LIMITED.P.O BOX 1287,00606 OLD LIMURU ROAD KARURI NAIROBI,KENYA(REPACKAGING)	GMP EXPIRED ON THE 30/9/2023	RETAINED	KENYA	TOPICAL EXTERNAL LIQUIDS	1.0X250.0 ML BOTTLE,1.0X 100.0 ML BOTTLE,1.0X 20.0 ML BOTTLE,1.0X 5.0 L JERRYCAN,1.0X50.0 ML BOTTLE,1.0X	01/07/2013
1558	NDA/MAL/VDP/4435	V.M.D.N.V	ERAM UGANDA LIMITED	ENROVETO-20	ENROFLOXACIN	200MG/ML	VMD NV HOGE MAUW--HOGE MUW 900-B2370, ARENDONK	N/A	GMP EXPIRED ON THE 2/3/2019 FOR NBL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, ORAL LIQUIDS, POWDERS FOR ORAL SUSPENSION) BL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, POWDERS FOR ORAL SUSPENSION)	RETAINED	BELGIUM	ORAL LIQUID ORDINARY LIQUIDS	1.0X1000.0 ML BOTTLE,1.0X 100.0 ML BOTTLE	01/07/2010

1559	NDA/MAL/VDP/4443	V.M.D.N.V	ERAM UGANDA LIMITED	IVERVETO-1	IVERMECTIN	10MG/ML	VMD NV HOGE MAUW-HOGE MUW 900, 2370, ARENDONK	N/A	GMP EXPIRED ON THE 2/3/2019 FOR NBL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, ORAL LIQUIDS, POWDERS FOR ORAL SUSPENSION) BL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, POWDERS FOR ORAL SUSPENSION)	RETAINED	BELGIUM	PARENTERAL ORDINARY S C VIALS	1.0X1.0X50.0 ML BOTTLE,1.0X100.0 ML BOTTLE	01/07/2010

1560	NDA/MAL/VDP/4476	VMD NV HOGE MAUW	ERAM UGANDA LIMITED	DOXYVET-50S	DOXYCYCLINE	500MG/G	VMD NV HOGE MAUW-HOGE MUW 900, 2370, ARENDONK	N/A	GMP EXPIRED ON THE 2/3/2019 FOR NBL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, ORAL LIQUIDS, POWDERS FOR ORAL SUSPENSION) BL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, POWDERS FOR ORAL SUSPENSION)	RETAINED	BELGIUM	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X100.0 G BOTTLE,1.0X 1.0 KG JAR	01/07/2005
1561	NDA/MAL/VDP/4508	ASHISH LIFE SCIENCE PVT. LTD.	ASHISH LIFE SCIENCE UGANDA LIMITED	ASHOXY EGG FORMULA	OXYTETRACYCLINE HCL + VITAMINS; A + D3 +B2 +B12 + E +K3 + NICOTINAMIDE + CALCIUM PANTOTHENATE	6G + 225,000IU + 45000IU + 290MG + 220MCG + 100IU + 80MG + .35G + 465MG /100G	N/A	ASHISH LIFE SCIENCE PVT. LIMITED. J-137, MIDC, TARAPUR, BOISAR, THANE, INDIA	N/A	NOT RETAINED	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X100.0 G SACHET,1.0X 25.0 G SACHET	01/07/2015

1562	NDA/MAL/VDP/4514	KEPRO B.V	QUALITY CHEMICALS LTD - VET	TRISUL 80/400 WSP	TRIMETHOPRIM / SULPHADIAZINE SODIUM	80MG + 400MG	LELY PHARMA ZUIVERINGWEG 42 P.O BOX 2047 8203 AAL	N/A	GMP EXPIRED ON 2/11/2023 FOR NON-BETA LACTAM: TABLETS, POWDERS/GRANULES, PENICILLIN: TABLETS, POWDERS/GRANULES, CEPHALOSPORIN: TABLETS, POWDERS/GRANULES	RETAINED	NETHERLANDS	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1X100 G Sachet,	01/07/2016
1563	NDA/MAL/VDP/5655	ELANCO ANIMAL HEALTH CO. LTD,DIVISION OF ELI LILLY(SA) PTY,LTD	ULTRAVETIS UGANDA LIMITED	DENAGARD 10% FEED PREMIX	TIAMULIN HYDROGEN FUMARATE	10%W/W	M & H MANUFACTURING CO LTD41 SUKHUMVIT ROAD, PAKNAM, MUANG-SAMUTP	DIVPHARM MANUFACTURING & PACKAGING. AGVET PTY LTD,SOUTH AFRICA	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: ORAL POWDERS (VETERINARY PREMIXES)	NOT RETAINED	SOUTH AFRICA THAILAND	ORAL SOLID ORDINARY POWDERS	1.0X10.0 KG BAG	01/07/2010
1564	NDA/MAL/VDP/5670	COSMOS LTD	ERAM UGANDA LIMITED	WORMITA-150 TABLETS	ALBENDAZOLE	150MG	N/A	COSMOS LTD.RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 41433, NAIROBI	N/A	NOT RETAINED	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/1997

1565	NDA/MAL/VDP/5676	VMD NV	ERAM UGANDA LIMITED	DIAZIPRIM 48%	SULPHADIAZINE + TRIMETHOPRIM	400 MG + 80 MG	VMD NV HOGE MAUW-HOGE MUW 900, 2370, ARENDONK	N/A	GMP EXPIRED ON THE 2/3/2019 FOR NBL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, ORAL LIQUIDS, POWDERS FOR ORAL SUSPENSION) BL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, POWDERS FOR ORAL SUSPENSION)	RETAINED	BELGIUM	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X100.0 G SACHET	01/07/2000

1566	NDA/MAL/VDP/5678	ALFASAN INTERNATIONAL BV	ANIMAL SOLUTIONS LIMITED	ALFACYCLINE 20%	OXYTETRACYCLINE HYDROCHLORIDE	200MG/GM	LELY PHARMA ZUIVERINGWEG 42 P.O BOX 2047 8203 AAL	N/A	GMP EXPIRED ON 2/11/2023 FOR NON-BETA LACTAM: TABLETS, POWDERS/GRANULES, PENICILLIN: TABLETS, POWDERS/GRANULES, CEPHALOSPORIN: TABLETS, POWDERS/GRANULES; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	NETHERLANDS	ORAL SOLID ORDINARY POWDERS		01/07/1997

1567	NDA/MAL/VDP/5679	ALFASAN INTERNATIONAL	ANIMAL SOLUTIONS LIMITED	DICOX FORTE	AMPROLIUM +SULPHAQUINOXALINE+VIT K+VIT A	17.5G+1.5G +500MG+1.5 MEGA I.U	LELY PHARMA ZUIVERINGWEG 42 P O BOX 2047 8203 AA L	N/A	GMP EXPIRED ON 2/11/2023 FOR NON-BETA LACTAM: TABLETS, POWDERS/GRANULES, PENICILLIN: TABLETS, POWDERS/GRANULES, CEPHALOSPORIN: TABLETS, POWDERS/GRANULES; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	NETHERLANDS	ORAL SOLID ORDINARY POWDERS		01/07/2002

1568	NDA/MAL/VDP/5684	KELA LABORATORIES N.V	NILE SERVICES LTD	DIMINAKEL-23.6G	DIMINAZENE ACETURATE	2.36G	KELA LABORATORIES N.V-ST.LENAARTSEWEG 48, B-2320	N/A	GMP EXPIRED ON THE 22/5/2022 FOR NON-BETA LACTAM: TABLETS, SVP LIQUIDS IN VIALS, LVP LIQUIDS, ORAL LIQUIDS, ORAL DRY POWDERS FOR SUSPENSION HORMONES: SVP, LVP LIQUIDS PENICILLIN: SVP POWDERS IN VIALS (ASEPTICALLY FILLED), LVP LIQUIDS	NOT RETAINED	BELGIUM	OTHER SYSTEMIC POWDER	1.0X23.6 G SACHET,1.0X 2.36 G SACHET	01/07/2002

1569	NDA/MAL/ VDP/5693	VMD NV HOGE MAUW	ERAM UGANDA LIMITED	DIMINAVE TO	DIMINAZENE/ ANTIPYRINE	1.05G/1.31 G	VMD NV HOGE MAUW- HOGE MUW 900, 2370, ARENDO NK	N/A	GMP EXPIRED ON THE 2/3/2019 FOR NBL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, ORAL LIQUIDS, POWDERS FOR ORAL SUSPENSION) BL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, POWDERS FOR ORAL SUSPENSION)	NOT RETAINED	BELGIUM	NON-HUMAN USE SOLUBLE POWDERS	1.0X2.36 G SACHET,1.0X 23.6 G SACHET	01/07/1999

1570	NDA/MAL/ VDP/5697	VMD NV HOGE MAUW	ERAM UGANDA LIMITED	VMD OLIGOVIT PLUS	MULTI-INGREDIENT	MULTI-INGREDIENT	VMD NV HOGE MAUW--HOGE MUW 900-B2370, ARENDONK	N/A	GMP EXPIRED ON THE 2/3/2019 FOR NBL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, ORAL LIQUIDS, POWDERS FOR ORAL SUSPENSION) BL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, POWDERS FOR ORAL SUSPENSION)	NOT RETAINED	BELGIUM	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X100.0 G SACHET	01/07/2001

1571	NDA/MAL/ VDP/5699	VMD NV	ERAM UGANDA LIMITED	VMD SUPERVITA MINS POWDER	MULTI-VITAMIN	MULTI-INGREDIEN T	VMD NV HOGE MAUW-B2370, ARENDO K	N/A	GMP EXPIRED ON THE 2/3/2019 FOR NBL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, ORAL LIQUIDS, POWDERS FOR ORAL SUSPENSION) BL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, POWDERS FOR ORAL SUSPENSION)	NOT RETAINED	BELGIUM	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X100.0 G SACHET	01/07/2001

1572	NDA/MAL/VDP/5700	KELA LABORATORIES N.V	NILE SERVICES LTD	MULTIVITAMIN	MULTI-INGREDIENT	NA	KELA LABORATORIES N.V-ST.LENAARTSEWEG 48, B-2320	N/A	GMP EXPIRED ON THE 22/5/2022 FOR NON-BETA LACTAM: TABLETS, SVP LIQUIDS IN VIALS, LVP LIQUIDS, ORAL LIQUIDS, ORAL DRY POWDERS FOR SUSPENSION HORMONES: SVP, LVP LIQUIDS PENICILLIN: SVP POWDERS IN VIALS (ASEPTICALLY FILLED), LVP LIQUIDS	NOT RETAINED	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X100.0 ML VIAL	01/07/2003
1573	NDA/MAL/VDP/5701	BIMEDA CHEMICAL EXPORT	BIMEDA UGANDA LIMITED	DIPEN	DIHYDROSTREPTOMYCIN/ BENZYL PENICILLIN	200MG/ML	BIMEDA CHEMICALS EXPORT LTD.-IRELAND	CHONGQING FANGTONG ANIMAL PHARMACEUTICAL COMPANY LTD-BANQIAO INDUSTRIAL PARK RONGCHANG CHONGQUING	GMP FOR BIMEDA EXPIRED ON THE 9/6/2014 FOR STERILE INTRAMAMMARY PRODUCTS IN PRE-FILLED SYRINGES (BL & NBL) NBL LIQUIDS (ORAL LIQUIDS_DRENCHES & ECTOPARASITICIDES_ACARICIDES)	RETAINED	CHINA	NON-HUMAN USE LIQUIDS	1.0X100.0 ML BOTTLE	01/07/1997

1574	NDA/MAL/VDP/5717	KELA LABORATORIES N.V	NILE SERVICES LTD	TYLOXAN 20%	TYLOSIN TARTRATE	20%W/V	KELA LABORATORIES N.V .- ST.LENAARTSEWEG 48,	N/A	GMP EXPIRED ON THE 22/5/2022 FOR NON-BETA LACTAM: TABLETS, SVP LIQUIDS IN VIALS, LVP LIQUIDS, ORAL LIQUIDS, ORAL DRY POWDERS FOR SUSPENSION HORMONES: SVP, LVP LIQUIDS PENICILLIN: SVP POWDERS IN VIALS (ASEPTICALLY FILLED), LVP LIQUIDS	NOT RETAINED	BELGIUM	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/1997
1575	NDA/MAL/VDP/5733	BIMEDA CHEMICAL EXPORT	BIMEDA UGANDA LIMITED	ENDOSPEC 10%	ALBENDAZOLE	100MG/ML	BIMEDA CHEMICALS EXPORT LTD- BANQIAO INDUSTRIAL PARK RONGCHANG CHONGQING	MEDISEL (K) LTD- PLOT NO. 4953/1209, GENERAL KAGO ROAD, THIKA	GMP FOR BIMEDA EXPIRED ON THE 9/6/2014 FOR STERILE INTRAMAMMARY PRODUCTS IN PRE-FILLED SYRINGES (BL & NBL) NBL LIQUIDS (ORAL LIQUIDS_DRENCHES & ECTOPARASITICIDES_ACARICIDES)	RETAINED	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0 L BOTTLE,1.0X 500.0 ML BOTTLE,1.0X 125.0 ML BOTTLE,1.0X 5.0 L JERRYCAN	01/07/1997

1576	NDA/MAL/VDP/5746	KELA LABORATORIES N.V	NILE SERVICES LTD	PENSTREP 20/20	DIHYDROSTREPTOMYCIN+PROCAINE PENICILLIN	200MG+200MG	KELA LABORATORIES N.V .- ST.LENAARTSEWEG 48,	N/A	GMP EXPIRED ON THE 22/5/2022 FOR NON-BETA LACTAM: TABLETS, SVP LIQUIDS IN VIALS, LVP LIQUIDS, ORAL LIQUIDS, ORAL DRY POWDERS FOR SUSPENSION HORMONES: SVP, LVP LIQUIDS PENICILLIN: SVP POWDERS IN VIALS (ASEPTICALLY FILLED), LVP LIQUIDS	NOT RETAINED	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X100.0 ML VIAL,1.0X50.0 ML VIAL	01/07/2002

1577	NDA/MAL/VDP/5749	BIMEDA CHEMICAL EXPORT	BIMEDA UGANDA LIMITED	TETROXY CHICK FORMULA	MULTI-VITAMIN	MULTI-INGREDIENT	BIMEDA CHEMICALS EXPORT LIMITED-BROOM HILL ROAD, TALLAGHT, DUBLIN 24, IRELAND	N/A	GMP FOR BIMEDA EXPIRED ON THE 9/6/2014 FOR STERILE INTRAMAMMARY PRODUCTS IN PRE-FILLED SYRINGES (BL & NBL) NBL LIQUIDS (ORAL LIQUIDS_DRENCHES & ECTOPARASITICIDES_ACARICIDES); FACILITY NOT APPROVED FOR THE MANUFACTURE OF THE PRODUCT LINE	RETAINED	IRELAND	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X120.0 G SACHET	01/07/1997

1578	NDA/MAL/VDP/5751	BIMEDA CHEMICAL EXPORT	BIMEDA UGANDA LIMITED	TETROXY EGG FORMULA	MULTI-VITAMIN	MULTI-INGREDIENT	BIMEDA CHEMICALS EXPORT LIMITED-BROOM HILL ROAD, TALLAGHT, DUBLIN 24, IRELAND	N/A	GMP FOR BIMEDA EXPIRED ON THE 9/6/2014 FOR STERILE INTRAMAMMARY PRODUCTS IN PRE-FILLED SYRINGES (BL & NBL) NBL LIQUIDS (ORAL LIQUIDS_DRENCHES & ECTOPARASITICIDES_ACARICIDES); FACILITY NOT APPROVED FOR THE MANUFACTURE OF THE PRODUCT LINE	RETAINED	IRELAND	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X120.0 G SACHET	01/07/1997

1579	NDA/MAL/VDP/5752	BIMEDA CHEMICAL EXPORT	BIMEDA UGANDA LIMITED	TETROXY INJECTION	OXYTETRACYCLINE HYDROCHLORIDE	100MG/ML	BIMEDA CHEMICALS EXPORT LIMITED-BROOM HILL ROAD, TALLAGHT, DUBLIN 24, IRELAND	HEBEI BIMEDA PHARMACEUTICAL TECHNOLOGY CO. LIMITEDNO. 60 GANJIANG ROAD, SHIJIAZHUANG ECONOMIC AND TECHNOLOGY DEVELOPMENT ZONE, CHINA CHONGOING FANGTONG ANIMAL PHARMACEUTICALS CO. LTDBANQIAO INDUSTRIAL PARK, RONGCHANG, CHONGOING, CHINA	GMP FOR BIMEDA EXPIRED ON THE 9/6/2014 FOR STERILE INTRAMAMMARY PRODUCTS IN PRE-FILLED SYRINGES (BL & NBL) NBL LIQUIDS (ORAL LIQUIDS_DRENCHES & ECTOPARASITICIDES_ACARICIDES)	RETAINED	BULGARIA CHINA	PARENTERAL ORDINARY VIALS	1.0X100.0 ML VIAL,1.0X250.0 ML BOTTLE,1.0X500.0 ML BOTTLE,1.0X50.0 ML BOTTLE	01/07/1997

1580	NDA/MAL/VDP/5755	BIMEDA CHEMICAL EXPORT	BIMEDA UGANDA LIMITED	TETROXYLA	OXYTETRACYCLINE HYDROCHLORIDE	200MG/ML	BIMEDA CHEMICALS EXPORT LIMITED-BROOM HILL ROAD, TALLAGHT, DUBLIN 24, IRELAND	CHONGGING FANGTONG ANIMAL PHARMACEUTICAL CO. LTD-BANQIAO INDUSTRIAL PARK RONGCHANG CHONGQING CHINA	GMP FOR BIMEDA EXPIRED ON THE 9/6/2014 FOR STERILE INTRAMAMMARY PRODUCTS IN PRE-FILLED SYRINGES (BL & NBL) NBL LIQUIDS (ORAL LIQUIDS_DRENCHES & ECTOPARASITICIDES_ACARICIDES); FACILITY NOT APPROVED FOR THE MANUFACTURE OF THE PRODUCT LINE	RETAINED	CHINA	PARENTERAL ORDINARY VIALS	1.0X100.0 ML VIAL,1.0X500.0 ML BOTTLE,1.0X250.0 ML BOTTLE	01/07/1997

1581	NDA/MAL/VDP/5761	BIMEDA CHEMICAL EXPORT	BIMEDA UGANDA LIMITED	PARVEXON INJECTION	PARVAQUONE	150MG/ML	BIMEDA CHEMICALS EXPORT LIMITED-BROOM HILL ROAD, TALLAGHT, DUBLIN 24, IRELAND	BIOVET JOINT STOCK COMPANY -FINISHED DRUG FORMS DEPARTMENT 48 VASIL PETLESHKOV STREET PESHTERA 4550 HEBEI BIMEDA PHARMACEUTICAL TECHNOLOGY CO. LIMITEDNO. 60 GANJIANG ROAD, SHIJIAZHUANG ECONOMIC AND TECHNOLOGY DEVELOPMENT ZONE, CHINA	GMP FOR BIMEDA EXPIRED ON THE 9/6/2014 FOR STERILE INTRAMAMMARY PRODUCTS IN PRE-FILLED SYRINGES (BL & NBL) NBL LIQUIDS (ORAL LIQUIDS_DRENCHES & ECTOPARASITICIDES_ACARICIDES)	RETAINED	BULGARIA CHINA	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL,1.0X100.0 ML VIAL	01/07/1997

1582	NDA/MAL/VDP/5763	BIMEDA CHEMICAL EXPORT	BIMEDA UGANDA LIMITED	PARVEXON PLUS	PARVAQUONE + FRUSEMIDE	150MG + 55MG/ML	BIMEDA CHEMICALS EXPORT LIMITED-BROOM HILL ROAD, TALLAGHT, DUBLIN 24, IRELAND	BIOVET JOINT STOCK COMPANY -FINISHED DRUG FORMS DEPARTMENT 48 VASIL PETLESHKOV STREET PESHTERA 4550 HEBEI BIMEDA PHARMACEUTICAL TECHNOLOGY CO. LIMITEDNO. 60 GANJIANG ROAD, SHIJIAZHUANG ECONOMIC AND TECHNOLOGY DEVELOPMENT ZONE, CHINA	GMP FOR BIMEDA EXPIRED ON THE 9/6/2014 FOR STERILE INTRAMAMMARY PRODUCTS IN PRE-FILLED SYRINGES (BL & NBL) NBL LIQUIDS (ORAL LIQUIDS_DRENCHES & ECTOPARASITICIDES_ACARICIDES)	RETAINED	BULGARIA CHINA	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL,1.0X100.0 ML VIAL	01/07/2000
1583	NDA/MAL/VDP/5769	BREMER PHARMA GMBH	QUALITY CHEMICALS LTD - VET	FERRUM 10% + B12 INJECTION	MULTI-VITAMIN	MULT-INGREDIENT	BREMER PHARMA GMBH .-WERKSTRSSE 42 34414 WARBURG SCH	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: INTRAMAMMARY OINTMENTS, SMALL VOLUME PARENTERAL LIQUIDS, POWDERS IN SACHETS AND BOTTLES	NOT RETAINED	GERMANY	PARENTERAL ORDINARY I M VIALS	1.0X50.0 ML VIAL,1.0X100.0 ML VIAL	01/07/1997

1584	NDA/MAL/ VDP/5778	VMD NV	ERAM UGANDA LIMITED	OXYVETO 50 S POWDER	OXYTETRACY CLINE HCL	500MG/G	VMD NV-HOGE MAUW 900-B2370, ARENDO K	N/A	GMP EXPIRED ON THE 2/3/2019 FOR NBL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, ORAL LIQUIDS, POWDERS FOR ORAL SUSPENSION) BL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, POWDERS FOR ORAL SUSPENSION)	RETAINED	BELGIUM	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X100.0 G SACHET,1.0X 250.0 G SACHET,1.0X 500.0 G SACHET,1.0X 1000.0 G SACHET	01/07/2000

1585	NDA/MAL/VDP/5785	VMD NV	ERAM UGANDA LIMITED	AMINOVIT POWDER	MULTIVITAMIN	MULTI-INGREDIENT	VMD NV HOGE MAUW-B2370, ARENDOK	N/A	GMP EXPIRED ON THE 2/3/2019 FOR NBL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, ORAL LIQUIDS, POWDERS FOR ORAL SUSPENSION) BL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, POWDERS FOR ORAL SUSPENSION)	NOT RETAINED	BELGIUM	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X100.0 G SACHET	01/07/2000

1586	NDA/MAL/ VDP/5794	VMD NV HOGE MAUW	ERAM UGANDA LIMITED	FLUMEQ-50-S	FLUMEQUINE	500MG/G	VMD NV HOGE MAUW--HOGE MUW 900-B2370, ARENDONK	N/A	GMP EXPIRED ON THE 2/3/2019 FOR NBL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, ORAL LIQUIDS, POWDERS FOR ORAL SUSPENSION) BL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, POWDERS FOR ORAL SUSPENSION)	NOT RETAINED	BELGIUM	ORAL SOLID ORDINARY POWDERS	1.0X100.0 G SACHET	01/07/2005

1587	NDA/MAL/VDP/5804	BOEHRINGER INGELHEIM VETMEDICA GMBH, GERMANY	ERAM UGANDA LIMITED	FRONTLINE SPRAY	FIPRONIL	0.25%W/V	MERIAL SAS-4 CHEMIN DU CALQUET 31057 TOULOUSE CEDE	N/A	GMP EXPIRED ON THE 27/07/2021 FORNBL TOPICAL SOLUTIONS (ECTOPARASITICIDES) INJECTABLE POWDER IN SACHETS (ISOMETAMIDIUM POWDER FOR INJECTION-TRYPAMIDIUM) SOLUTIONS FOR INJECTION (ASEPTICALLY FILLED AND TERMINALLY STERILIZED SMALL VOLUME PARENTERALS AND LARGE VOLUME PARENTERALS)	RETAINED	FRANCE	TOPICAL EXTERNAL SPRAYS WITHOUT GAS	1.0X500.0 ML CANNISTER, 1.0X125.0 ML CANNISTER, 1.0X250.0 ML CANNISTER	01/07/1997

1588	NDA/MAL/ VDP/5806	KELA LABORATORIES N.V	NILE SERVICES LTD	OXY-KEL 10	OXYTETRACYCLINE HYDROCHLORIDE	100MG/ML	KELA LABORATORIES N.V .- ST.LENAARTSEWEG 48,	N/A	GMP EXPIRED ON THE 22/5/2022 FOR NON-BETA LACTAM: TABLETS, SVP LIQUIDS IN VIALS, LVP LIQUIDS, ORAL LIQUIDS, ORAL DRY POWDERS FOR SUSPENSION HORMONES: SVP, LVP LIQUIDS PENICILLIN: SVP POWDERS IN VIALS (ASEPTICALLY FILLED), LVP LIQUIDS	NOT RETAINED	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL,1.0X500.0 ML VIAL,1.0X250.0 ML VIAL,1.0X100.0 ML VIAL	01/07/2003

1589	NDA/MAL/VDP/5807	KELA LABORATORIES N.V	NILE SERVICES LTD	OXYKEL 20	OXYTETRACYCLINE HYDROCHLORIDE	200MG/ML	KELA LABORATORIES N.V .- ST.LENAARTSEWEG 48,	N/A	GMP EXPIRED ON THE 22/5/2022 FOR NON-BETA LACTAM: TABLETS, SVP LIQUIDS IN VIALS, LVP LIQUIDS, ORAL LIQUIDS, ORAL DRY POWDERS FOR SUSPENSION HORMONES: SVP, LVP LIQUIDS PENICILLIN: SVP POWDERS IN VIALS (ASEPTICALLY FILLED), LVP LIQUIDS	NOT RETAINED	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X100.0 ML VIAL,1.0X50.0 ML VIAL,1.0X250.0 ML VIAL	01/07/2002
1590	NDA/MAL/VDP/5809	BREMER PHARMA GMBH	QUALITY CHEMICALS LTD - VET	GENTAMAST	GENTAMYCIN SULPHATE	20MG/GM	BREMER PHARMA GMBH .- WERKSTRSSE 42 34414 WARBURG SCH	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: INTRAMAMMARY OINTMENTS, SMALL VOLUME PARENTERAL LIQUIDS, POWDERS IN SACHETS AND BOTTLES	NOT RETAINED	GERMANY	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X7.5 MG PRE- FILLED SYRINGE	01/07/1997

1591	NDA/MAL/VDP/5813	VMD NV	ERAM UGANDA LIMITED	AMPROLIUM-20S	AMPROLIUM HYDROCHLORIDE	200MG/G	VMD NV-HOGE MAUW 900-B2370, ARENDOK	N/A	GMP EXPIRED ON THE 2/3/2019 FOR NBL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, ORAL LIQUIDS, POWDERS FOR ORAL SUSPENSION) BL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, POWDERS FOR ORAL SUSPENSION)	RETAINED	BELGIUM	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X100.0 G SACHET	01/07/2000

1592	NDA/MAL/VDP/5826	VMD NV	ERAM UGANDA LIMITED	GENTAVETO -5	GENTAMYCIN SULPHATE	50MG/ML	VMD NV-HOGE MAUW 900-B2370, ARENDOK	N/A	GMP EXPIRED ON THE 2/3/2019 FOR NBL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, ORAL LIQUIDS, POWDERS FOR ORAL SUSPENSION) BL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, POWDERS FOR ORAL SUSPENSION)	RETAINED	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X100.0 ML BOTTLE	01/07/1998
1593	NDA/MAL/VDP/5866	BREMER PHARMA GMBH	QUALITY CHEMICALS LTD - VET	TETRACYCLINE 25%	TETRACYCLINE HYDROCHLORIDE	50MG/ML	BREMER PHARMA GMBH .-WERKSTRSSE 42 34414 WARBURG SCH	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: INTRAMAMMARY OINTMENTS, SMALL VOLUME PARENTERAL LIQUIDS, POWDERS IN SACHETS AND BOTTLES	NOT RETAINED	GERMANY	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X100.0 G SACHET	01/07/1997

1594	NDA/MAL/VDP/5867	NORBROOK LABORATORIES LTD	NORBROOK (U) LTD	NOROCLOX DC	CLOXACILLIN BENZATHINE	500MG	NORBROOK LABORATORIES LTD-STATION WORKS, NEWRY, COUNTRY DOWN, BT35 6JP, NORTHER	N/A	FACILITY NOT LICENSED TO MANUFACTURE PRODUCT LINE	RETAINED	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X4.5 G SACHET	01/07/2003
1595	NDA/MAL/VDP/5868	BREMER PHARMA GMBH	QUALITY CHEMICALS LTD - VET	SYNCHRO MATE	CLOPROSTENOL	0.25MG/ML	BREMER PHARMA GMBH .- WERKSTRSSE 42 34414 WARBURG SCH	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: INTRAMAMMARY OINTMENTS, SMALL VOLUME PARENTERAL LIQUIDS, POWDERS IN SACHETS AND BOTTLES	NOT RETAINED	GERMANY	PARENTERAL ORDINARY VIALS	1.0X20.0 ML BOTTLE	01/07/2001
1596	NDA/MAL/VDP/5870	BREMER PHARMA GMBH	QUALITY CHEMICALS LTD - VET	SUPERMEDTS TS 1	SULFADIAZINE/TRIMETHOPRIM	400MG/80MG	BREMER PHARMA GMBH .- WERKSTRSSE 42 34414 WARBURG SCH	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: INTRAMAMMARY OINTMENTS, SMALL VOLUME PARENTERAL LIQUIDS, POWDERS IN SACHETS AND BOTTLES	NOT RETAINED	GERMANY	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X100.0 G SACHET	01/07/1997

1597	NDA/MAL/VDP/5890	ELANCO ANIMAL HEALTH (PTY) LTD	KWEWAYO (U) VET PHARMACY LIMITED	BAYCOX	TOLTRAZURIL	2.5 % W/W	BAYER AG-D-51368 LEVERKUSEN	N/A	FACILITY NOT APPROVED FOR THIS LINE	RETAINED	GERMANY	ORAL LIQUID ORDINARY LIQUIDS	1.0X25.0 ML BOTTLE,1.0X 100.0 ML BOTTLE,1.0X 1.0 L BOTTLE	01/07/1997
1598	NDA/MAL/VDP/5898	BIMEDA CHEMICAL EXPORTS	BIMEDA UGANDA LIMITED	MULTIVITAMIN INJECTION	MULTIVITAMIN	MULTI-INGREDIENT	BIMEDA CHEMICALS EXPORT LTD-BANQIAO INDUSTRIAL PARK RONGCHANG CHONGQING	HEBEI BIMEDA PHARMACEUTICAL TECHNOLOGY CO. LIMITEDNO. 60 GANJIANG ROAD, SHIJIAZHUANG ECONOMIC AND TECHNOLOGY DEVELOPMENT ZONE, CHINA CHONGQING FANGTONG ANIMAL PHARMACEUTICAL CO. LTDNO.80 EAST PART OF CHANGZHOU ROAD BANQIAO INDUSTRIAL PARK RONGCHANG CHONGQING CHINA	GMP FOR BIMEDA EXPIRED ON THE 9/6/2014 FOR STERILE INTRAMAMMARY PRODUCTS IN PRE-FILLED SYRINGES (BL & NBL) NBL LIQUIDS (ORAL LIQUIDS_DRENCHES & ECTOPARASITICIDES_ACARICIDES)	RETAINED	BULGARIA CHINA	PARENTERAL ORDINARY I M VIALS	1.0X100.0 ML BOTTLE,1.0X 50.0 ML BOTTLE	01/07/1997

1599	NDA/MAL/VDP/5910	NORBROOK LABORATORIES LTD	NORBROOK (U) LTD	BETAMOX	AMOXYCILLIN TRIHYDRATE	150MG/ML	N/A	NORBROOK LABORATORIES LTDSTATION WORKS, NEWRY, COUNTRY DOWN, BT35 6JP, NORTHERN IRELAND-UK	N/A	NOT RETAINED	IRELAND	PARENTERAL ORDINARY VIALS	1.0X100.0 ML VIAL	01/07/2005
1600	NDA/MAL/VDP/5915	BIMEDA UGANDA LIMITED	BIMEDA UGANDA LIMITED	BIMATRAZ	AMITRAZ	12.5% W/V	BIMEDA CHEMICALS EXPORT LIMITED-BROOM HILL ROAD, TALLAGHT, DUBLIN 24, IRELAND	IMPACT CHEMICALS LIMITEDKC ARORA COMPLEX, MOMBASA ROAD, CHONGQING FANTONG ANIMAL PHARMACEUTICALSB ANQIAO INDUSTRIAL PARK RONGCHANG CHONGQING BIMEDA CHEMICALS EXPORT LIMITEDBROOM HILL ROAD, TALLAGHT, DUBLIN 24, IRELAND	GMP FOR BIMEDA EXPIRED ON THE 9/6/2014 FOR STERILE INTRAMAMMARY PRODUCTS IN PRE-FILLED SYRINGES (BL & NBL) NBL LIQUIDS (ORAL LIQUIDS_DRENCHES & ECTOPARASITICIDES_ACARICIDES)	RETAINED	CHINA KENYA	TOPICAL EXTERNAL LIQUIDS	1.0X1.0 L CONTAINER, 1.0X100.0 ML CONTAINER, 1.0X250.0 ML CONTAINER, 1.0X500.0 ML CONTAINER	01/07/1999

1601	NDA/MAL/VDP/5917	BIMEDA UGANDA LIMITED	BIMEDA UGANDA LIMITED	BIMECTIN INJECTION	IVERMECTIN	10MG/ML	BIMEDA CHEMICALS EXPORT LTD-BANQIAO INDUSTRIAL PARK RONGCHANG CHONGQING	CHONGQING FANGTONG ANIMAL PHARMACEUTICAL COMPANY LTD-BANQIAO INDUSTRIAL PARK RONGCHANG CHONGQUING HEBEI BIMEDA PHARMACEUTICAL TECHNOLOGY CO. LIMITEDNO. 60 GANJIANG ROAD, SHIJIAZHUANG ECONOMIC AND TECHNOLOGY DEVELOPMENT ZONE, CHINA	GMP FOR BIMEDA EXPIRED ON THE 9/6/2014 FOR STERILE INTRAMAMMARY PRODUCTS IN PRE-FILLED SYRINGES (BL & NBL) NBL LIQUIDS (ORAL LIQUIDS_DRENCHES & ECTOPARASITICIDES_ACARICIDES)	RETAINED	CHINA	PARENTERAL ORDINARY S C VIALS	1.0X500.0 ML VIAL,1.0X50.0 ML VIAL,1.0X20.0 ML VIAL,1.0X100.0 ML VIAL	01/07/1998

1602	NDA/MAL/VDP/5919	BIMEDA UGANDA LIMITED	BIMEDA UGANDA LIMITED	BIMOXYLLA INJECTION	AMOXYCILLIN TRIHYDRATE	150MG/ML	BIMEDA CHEMICALS EXPORT LIMITED-BROOM HILL ROAD, TALLAGHT, DUBLIN 24, IRELAND	N/A	GMP FOR BIMEDA EXPIRED ON THE 9/6/2014 FOR STERILE INTRAMAMMARY PRODUCTS IN PRE-FILLED SYRINGES (BL & NBL) NBL LIQUIDS (ORAL LIQUIDS_DRENCHES & ECTOPARASITICIDES_ACARICIDES); FACILITY NOT APPROVED FOR THE MANUFACTURE OF THE PRODUCT LINE	RETAINED	IRELAND	PARENTERAL ORDINARY VIALS	1.0X100.0 ML VIAL,1.0X50.0 ML VIAL	01/07/1997
1603	NDA/MAL/VDP/5922	BREMER PHARMA GMBH	QUALITY CHEMICALS LTD - VET	PIPERAZINE CITRATE	PIPERAZINE CITRATE	100GM	BREMER PHARMA GMBH .-WERKSTRSSE 42 34414 WARBURG SCH	N/A	GMP EXPIRED ON 1/10/2023 FOR NON-BETA LACTAM: INTRAMAMMARY OINTMENTS, SMALL VOLUME PARENTERAL LIQUIDS, POWDERS IN SACHETS AND BOTTLES	NOT RETAINED	GERMANY	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X100.0 G SACHET	01/07/1997

1604	NDA/MAL/VDP/5925	KELA LABORATORIES N.V	NILE SERVICES LTD	KELAMECTIN 1%	IVERMECTIN	1%W/V	KELA LABORATORIES N.V-ST.LENAARTSEWEG 48, B-2320	N/A	GMP EXPIRED ON THE 22/5/2022 FOR NON-BETA LACTAM: TABLETS, SVP LIQUIDS IN VIALS, LVP LIQUIDS, ORAL LIQUIDS, ORAL DRY POWDERS FOR SUSPENSION HORMONES: SVP, LVP LIQUIDS PENICILLIN: SVP POWDERS IN VIALS (ASEPTICALLY FILLED), LVP LIQUIDS	NOT RETAINED	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL	01/07/2004
1605	NDA/MAL/VDP/5928	NORBROOK LABORATORIES LTD	NORBROOK (U) LTD	LIFE AID EXTRA	MINERAL SUPPLEMENT	MULTI-INGREDIENT	NORBROOK LABORATORIES LTD-STATION WORKS, NEWRY, COUNTRY DOWN, BT35 6JP, NORTHER	N/A	FACILITY NOT LICENSED TO MANUFACTURE PRODUCT LINE	RETAINED	UNITED KINGDOM	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X100.0 G SACHET	01/07/2000

1606	NDA/MAL/VDP/5929	KEPRO B.V	QUALITY CHEMICALS LTD - VET	KEPROCERYL WSP	MULTI-INGREDIENT	MULTI-INGREDIENT	LELY PHARMA ZUIVERINGWEG 42 P O BOX 2047 8203 AA L	N/A	GMP EXPIRED ON 2/11/2023 FOR NON-BETA LACTAM: TABLETS, POWDERS/GRANULES, PENICILLIN: TABLETS, POWDERS/GRANULES, CEPHALOSPORIN: TABLETS, POWDERS/GRANULES; NO APPLICATION FOR RENEWAL OF REGISTRATION HAS BEEN SUBMITTED	RETAINED	NETHERLANDS	ORAL LIQUID ORDINARY UNIT DOSE POWDERS	3 G Sachet, 1X30 G Sachet	01/07/1997
1607	NDA/MAL/VDP/5937	CEVA SANTE ANIMALE	VERI BRANDS U LTD	VECTOCID	DELTAMETHRIN	50G/L	CEVA SANTE ANIMALE TUNISIA-91 RUE DE CAMBODGE,	N/A	FACILITY AWAITS PHYSICAL INSPECTION	RETAINED	TUNISIA	TOPICAL EXTERNAL LIQUIDS	1.0X100.0 ML CANNISTER, 1.0X1000.0 ML CANNISTER, 1.0X20.0 ML CONTAINER	01/07/2007
1608	NDA/MAL/VDP/5940	NORBROOK LABORATORIES	NORBROOK (U) LTD	LEVACIDE	LEVAMISOLE HCL	7.5%W/V	NORBROOK LABORATORIES LTDSTATION WORKS, NEWRY, COUNTRY DOWN, BT35 6JP	N/A	FACILITY NOT LICENSED TO MANUFACTURE THE PRODUCT LINE	NOT RETAINED	IRELAND	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0 L BOTTLE	01/07/2003

1609	NDA/MAL/VDP/5945	CEVA SANTE ANIMALE	VERI BRANDS U LTD	VERIBEN	DIAMINAZENE DIACETURATE	445MG/G	CEVA SANTE ANIMALE 10 AVENUE DE LA BALLASTIERE 33500 LIBOURNE	CEVA SANTE ANIMALE .ZI-TRES LE BOIS 22600-LOUDEAC	GMP EXPIRED ON 28/9/2023 FOR NON-BETA LACTAM: SVP SOLUTIONS AND SUSPENSIONS LYOPHILIZED POWDERS (POWDERS/GRANULES FOR INJECTION) REPRODUCTIVE HORMONAL DEVICES , BETA LACTAM (PENICILLIN): SVP SOLUTIONS AND SUSPENSIONS LYOPHILIZED POWDERS (POWDERS/GRANULES FOR INJECTION) , SECONDARY PACKAGING: VACCINES	RETAINED	FRANCE	OTHER SYSTEMIC SPECIAL SOLIDS	1.0X2.36 G SACHET	01/07/1997

1610	NDA/MAL/VDP/5948	CEVA SANTE ANIMALE	VERI BRANDS U LTD	VERIDIUM	ISOMETAMIDIUM HCL	125MG,1G	CEVA SANTE ANIMALE 10 AVENUE DE LA BALLASTIERE 33500 LIBOURNE	CEVA SANTE ANIMALE .ZI-TRES LE BOIS 22600-LOUDEAC	GMP EXPIRED ON 28/9/2023 FOR NON-BETA LACTAM: SVP SOLUTIONS AND SUSPENSIONS LYOPHILIZED POWDERS (POWDERS/GRANULES FOR INJECTION) REPRODUCTIVE HORMONAL DEVICES , BETA LACTAM (PENICILLIN): SVP SOLUTIONS AND SUSPENSIONS LYOPHILIZED POWDERS (POWDERS/GRANULES FOR INJECTION) , SECONDARY PACKAGING: VACCINES	RETAINED	FRANCE	OTHER SYSTEMIC POWDER	1.0X10.0X125.0 MG SACHET,1.0X10.0X1.0 G SACHET	01/07/1997

1611	NDA/MAL/VDP/5949	CEVA SANTE ANIMALE	VERI BRANDS U LTD	VIGOSINE	CARNITINE HYDROCHLORIDE	50MG/ML	CEVA SANTE ANIMALE 10 AVENUE DE LA BALLASTIERE 33500 LIBOURNE	N/A	GMP EXPIRED ON 28/9/2023 FOR NON-BETA LACTAM: SVP SOLUTIONS AND SUSPENSIONS LYOPHILIZED POWDERS (POWDERS/GRANULES FOR INJECTION) REPRODUCTIVE HORMONAL DEVICES , BETA LACTAM (PENICILLIN): SVP SOLUTIONS AND SUSPENSIONS LYOPHILIZED POWDERS (POWDERS/GRANULES FOR INJECTION) , SECONDARY PACKAGING: VACCINES	RETAINED	FRANCE	ORAL LIQUID ORDINARY LIQUIDS	1.0X250.0 ML BOTTLE,1.0X 1.0 L BOTTLE	01/07/1998
1612	NDA/MAL/VDP/5952	CEVA SANTE ANIMALE	VERI BRANDS U LTD	VETACOX S	SODIUM SULFADIMIDINE+DIAVERIDINE	80G+8G/100G	SANOFI SANTE NUTRITION ANIMALE-98767 LIBOURN	N/A	FACILITY NOT FOUND	NOT RETAINED	FRANCE	ORAL SOLID ORDINARY POWDERS	1.0X25.0 G SACHET,1.0X 100.0 G SACHET	01/07/1997

1613	NDA/MAL/VDP/5962	INTERVET SA (PTY) LTD	ERAM UGANDA LIMITED	TAKTIC	AMITRAZ	125G/L	COOPER K. BRANDS LTD -P.O. BOX 40596 00100 NAIROBI, KENYA. ON KAPTAGAT ROAD, OFF	N/A	NAME OF FACILITY CHANGED TO CKL. APPLICANT REQUIRED TO APPLY FOR A VARIATION FOR CHANGE OF NAME.	RETAINED	KENYA	TOPICAL EXTERNAL LIQUIDS	1.0X250.0 ML BOTTLE,1.0X 100.0 ML BOTTLE,1.0X 5.0 L JERRYCAN,1.0X20.0 L JERRYCAN,1.0X1.0 L BOTTLE,1.0X 40.0 ML BOTTLE,1.0X	01/07/1997
1614	NDA/MAL/VDP/5968	UNIVET LTD	BIMEDA UGANDA LIMITED	TRAMAZOLE	ALBENDAZOLE	10%W/V	UNIVET LTD-TULLYVIN, COOTEHILL, COUNTY CAVAN, IRELAND.	MEDISEL KENYA LTD --LR NO : 4953 / 1209, GENERAL KAGO ROAD, P.O. BOX 5401000, THIKA - KENYA	PRODUCT LINE NOT INCLUDED IN GMP APPLICATION FOR INSPECTION	RETAINED	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X5.0 L JERRYCAN,1.0X2.5 L JERRYCAN,1.0X120.0 ML BOTTLE,1.0X 1.0 L JERRYCAN	01/07/2000

1615	NDA/MAL/VDP/5969	BIMEDA CHEMICAL EXPORTS LTD	BIMEDA UGANDA LIMITED	BUPARVEX	BUPARVAQUONE	50MG/ML	BIMEDA CHEMICALS EXPORT LIMITED-BROOM HILL ROAD, TALLAGHT, DUBLIN 24, IRELAND	HEBEI BIMEDA PHARMACEUTICAL TECHNOLOGY CO. LIMITEDNO. 60 GANJIANG ROAD, SHIJIAZHUANG ECONOMIC AND TECHNOLOGY DEVELOPMENT ZONE, CHINA BIOVET JOINT STOCK COMPANY FINISHED DRUG FORMS DEPARTMENT 48 VASIL PETLESHKOV STREET PESHTERA 4550	GMP FOR BIMEDA EXPIRED ON THE 9/6/2014 FOR STERILE INTRAMAMMARY PRODUCTS IN PRE-FILLED SYRINGES (BL & NBL) NBL LIQUIDS (ORAL LIQUIDS_DRENCHES & ECTOPARASITICIDES_ACARICIDES); FACILITY NOT APPROVED FOR THE MANUFACTURE OF THE PRODUCT LINE	RETAINED	BULGARIA CHINA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML BOTTLE,1.0X40.0 ML BOTTLE,1.0X50.0 ML BOTTLE	01/07/2005

1616	NDA/MAL/VDP/6004	BIMEDA CHEMICAL EXPORT	BIMEDA UGANDA LIMITED	DELTAGUARD POUR	DELTAMETHRIN	1%W/V	CROSS VETPHARM GROUP LIMITED-BROOM HILL ROAD, TALLAGHT, DUBLIN 24, IRELAND	N/A	GMP EXPIRED ON 13/10/2023 FOR BETA LACTAM (PENICILLIN): STERILE INTRAMAMMARY PRODUCTS IN PREFILLED SYRINGES, NON-BETA LACTAM: STERILE INTRAMAMMARY PRODUCTS IN PREFILLED SYRINGES, NON-BETA LACTAM (ACARICIDES): ORAL LIQUIDS (DRENCHES), ECTOPARASITICIDES	RETAINED	IRELAND	TOPICAL EXTERNAL EMULSIONS	1.0X250.0 ML BOTTLE,1.0X 500.0 ML BOTTLE,1.0X 100.0 ML BOTTLE	01/07/1997

1617	NDA/MAL/VDP/6010	VMD NV HOGE MAUW	ERAM UGANDA LIMITED	COLIVETO-4800	COLISTINE SULPHATE	4.8 MILLION I.U/G	VMD NV HOGE MAUW-HOGE MUW 900, 2370, ARENDONK	N/A	GMP EXPIRED ON THE 2/3/2019 FOR NBL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, ORAL LIQUIDS, POWDERS FOR ORAL SUSPENSION) BL (LARGE VOLUME PARENTERAL INJECTIONS, SMALL VOLUME PARENTERAL INJECTIONS, POWDERS FOR ORAL SUSPENSION)	RETAINED	BELGIUM	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X100.0 G CONTAINER, 1.0X1.0 KG JAR	01/07/2005
1618	NDA/MAL/VDP/6019	NORBROOK LABORATORIES LTD	NORBROOK (U) LTD	ALAMYCIN AEROSOL	OXYTETRACYCLINE HYDROCHLORIDE	3.6%W/W	NORBROOK LABORATORIES LTD-STATION WORKS, NEWRY, COUNTRY DOWN, BT35 6JP, NORTHER	N/A	FACILITY NOT LICENSED TO MANUFACTURE PRODUCT LINE	RETAINED	IRELAND	NON-HUMAN USE SPRAYS WITHOUT GAS	1.0X140.0 G CANNISTER	01/07/1997

1619	NDA/MAL/VDP/6027	BIMEDA CHEMICAL EXPORTS	BIMEDA UGANDA LIMITED	CYPERGUARD	CYPERMETHRIN	10%W/V	BIMEDA CHEMICALS EXPORT LIMITED-BROOM HILL ROAD, TALLAGHT, DUBLIN 24, IRELAND	N/A	GMP FOR BIMEDA EXPIRED ON THE 9/6/2014 FOR STERILE INTRAMAMMARY PRODUCTS IN PRE-FILLED SYRINGES (BL & NBL) NBL LIQUIDS (ORAL LIQUIDS_DRENCHES & ECTOPARASITICIDES_ACARICIDES)	RETAINED	IRELAND	TOPICAL EXTERNAL EMULSIONS	1.0X250.0 ML BOTTLE,1.0X400.0 ML BOTTLE,1.0X1.0 L BOTTLE,1.0X100.0 ML BOTTLE	01/07/1998
1620	NDA/MAL/VDP/6087	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO	GLOBAL VET (U) LIMITED	TECTIN	IVERMECTIN	1%W/V	N/A	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.AL HASSAN INDUSTRIAL ESTATE –IRBID	N/A	NOT RETAINED	JORDAN	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL,1.0X100.0 ML VIAL	01/07/2014
1621	NDA/MAL/VDP/6892	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO	GLOBAL VET (U) LIMITED	BUTEX	BUPARVAQUONE	5%W/V	N/A	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.AL HASSAN INDUSTRIAL ESTATE –IRBID	N/A	NOT RETAINED	JORDAN	PARENTERAL ORDINARY VIALS	1.0X40.0 ML VIAL	01/07/2010

1622	NDA/MAL/VDP/6894	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.	GLOBAL VET (U) LIMITED	PRIMOVET	SULPHADIAZINE + TRIMETHOPRIM	400MG + 80MG	N/A	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.AL HASSAN INDUSTRIAL ESTATE –IRBID	N/A	NOT RETAINED	JORDAN	ORAL SOLID ORDINARY POWDERS	1.0X100.0 G SACHET	01/07/2010
1623	NDA/MAL/VDP/6896	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.	GLOBAL VET (U) LIMITED	ERYTHRATE	ERYTHROMYCIN THIOCYANATE	350MG/G	N/A	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.AL HASSAN INDUSTRIAL ESTATE –IRBID	N/A	NOT RETAINED	JORDAN	ORAL SOLID ORDINARY POWDERS	1.0X100.0 G SACHET,1.0X 500.0 G SACHET	01/07/2016
1624	NDA/MAL/VDP/6902	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.	GLOBAL VET (U) LIMITED	ERYTHRATE 20%	ERYTHROMYCIN THIOCYANATE	20%W/W	N/A	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.AL HASSAN INDUSTRIAL ESTATE –IRBID	N/A	NOT RETAINED	JORDAN	ORAL SOLID ORDINARY POWDERS	1.0X100.0 G SACHET	01/07/2016
1625	NDA/MAL/VDP/6903	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.	GLOBAL VET (U) LIMITED	GENTYLO	TYLOSIN TARTRATE + GENTAMICIN SULPHATE	250MG + 100MG/G	N/A	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.AL HASSAN INDUSTRIAL ESTATE –IRBID	N/A	NOT RETAINED	JORDAN	ORAL SOLID ORDINARY POWDERS	1.0X100.0 G SACHET,1.0X 500.0 G SACHET	01/07/2016

1626	NDA/MAL/VDP/6906	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.	GLOBAL VET (U) LIMITED	IVOSAN	IVERMECTIN + CLOSANTEL-NA	5MG +125MG /ML	N/A	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.AL HASSAN INDUSTRIAL ESTATE –IRBID	N/A	NOT RETAINED	JORDAN	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2016
1627	NDA/MAL/VDP/6908	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.	GLOBAL VET (U) LIMITED	TECTIN SUPER	IVERMECTIN + CLORSULON	10MG + 100MG/ ML	N/A	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.AL HASSAN INDUSTRIAL ESTATE –IRBID	N/A	NOT RETAINED	JORDAN	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL,1.0X100.0 ML VIAL	01/07/2016
1628	NDA/MAL/VDP/7032	HEBEI HOPE HARMONY PHARMACEUTICAL CO., LTD	JUBAILI AGROTEC LIMITED	BUPARVANOR	BUPARVAQUONE	5 % W/V	HEBEI HOPE HARMONY PHARMACEUTICAL CO. LTD-INDUSTRIAL AREA, YUANSHI TOWN, SHIJIAZHUANG CITY, HEBEI PROVINCE CHINA	N/A	GMP EXPIRED ON 8/10/2023 FOR NON-BETA LACTAM: TABLETS, ORAL LIQUIDS, SMALL VOLUME PARENTERAL SOLUTIONS (AMPOULES & VIALS), ORAL SOLUBLE POWDERS IN SACHETS	RETAINED	CHINA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X50.0 ML BOTTLE,1.0X20.0 ML BOTTLE,1.0X100.0 ML BOTTLE	29/11/2017

1629	NDA/MAL/VDP/7034	HEBEI HOPE HARMONY PHARMACEUTICAL CO., LTD	JUBAILI AGROTEC LIMITED	IVANOR	IVERMECTIN	1% W/V	HEBEI HOPE HARMONY PHARMACEUTICAL CO LTD-INDUSTRY DEVELOPMENT AREA, YUANSHI COUNTY, SHIJIAZHUANG CITY, HEBEI PROVINC	N/A	GMP EXPIRED ON 8/10/2023 FOR NON-BETA LACTAM: TABLETS, ORAL LIQUIDS, SMALL VOLUME PARENTERAL SOLUTIONS (AMPOULES & VIALS), ORAL SOLUBLE POWDERS IN SACHETS	RETAINED	CHINA	PARENTERAL ORDINARY VIALS	1.0X100.0 ML VIAL + 10ML VIAL AND 5ML SYRINGE,1.0 X50.0 ML VIAL + 5ML VIAL AND 5ML SYRINGE,1.0 X250.0 ML BOTTLE	29/11/2017
1630	NDA/MAL/VDP/7036	HEBEI HOPE HARMONY PHARMACEUTICAL CO., LTD	JUBAILI AGROTEC LIMITED	DIMINOR PLUS	DIMINAZENE DIACETURATE + ANTIPYRINE + VITAMIN B12	10.5G + 13.1G + 10MG / SACHET OF 23.6G, 1.05G + 1.31G + 1MG / SACHET OF 2.36G	HEBEI HOPE HARMONY PHARMACEUTICAL CO LTD-INDUSTRY DEVELOPMENT AREA, YUANSHI COUNTY, SHIJIAZHUANG CITY, HEBEI PROVINC	N/A	GMP EXPIRED ON 8/10/2023 FOR NON-BETA LACTAM: TABLETS, ORAL LIQUIDS, SMALL VOLUME PARENTERAL SOLUTIONS (AMPOULES & VIALS), ORAL SOLUBLE POWDERS IN SACHETS	RETAINED	CHINA	ORAL SOLID ORDINARY POWDERS	1.0X10.0X23.6 G SACHET,1.0X10.0X2.36 G SACHET	27/11/2018

1631	NDA/MAL/VDP/7038	HEBEI HOPE HARMONY PHARMACEUTICAL CO., LTD	JUBAILI AGROTEC LIMITED	VBNOR	VITAMIN B1 + VITAMIN B2 + VITAMIN B6 + NICOTINAMIDE + D-PANTHENOL	25MG + 2MG + 2.5MG + 50MG + 5MG /10ML	HEBEI HOPE HARMONY PHARMACEUTICAL CO LTD-INDUSTRY DEVELOPMENT AREA, YUANSHI COUNTY, SHIJIAZHUANG CITY, HEBEI PROVINC	N/A	GMP EXPIRED ON 8/10/2023 FOR NON-BETA LACTAM: TABLETS, ORAL LIQUIDS, SMALL VOLUME PARENTERAL SOLUTIONS (AMPOULES & VIALS), ORAL SOLUBLE POWDERS IN SACHETS	RETAINED	CHINA	PARENTERAL ORDINARY IM VIALS	1.0X1.0X100.0 ML VIAL,1.0X50.0X10.0 ML VIAL	27/11/2018
1632	NDA/MAL/VDP/7041	EAGLE VET TECH CO., LTD	EAGLEVET UGANDA LIMITED	COCCITOLTRAZOL	TOLTRAZURIL	25G/L	N/A	EAGLE VET TECH. CO. LTD235-34, CHUSA-RO, SHINAM-MYEON, YESAN-GUN CHUNGCHEONGNAM-DO, KOREA	N/A	NOT RETAINED	SOUTH KOREA	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML CONTAINER, 1.0X500.0 ML CONTAINER, 1.0X100.0 ML CONTAINER	27/03/2019
1633	NDA/MAL/VDP/7054	BOEHRINGER INGELHEIM VETMEDICA GMBH, GERMANY	ERAM UGANDA LIMITED	IMOPEST	INACTIVATED NEWCASTLE DISEASE VIRUS, ULSTER STRAIN	NOT LESS THAN 50 PD50 / 0.3ML	MERIAL SASRUE DE L'AVIATION-69800 SAINT-PRIEST	N/A	GMP EXPIRED ON THE 15/11/2020 FOR VETERINARY VACCINES ; • SMALL VOLUME PARENTERALS (SOLUTIONS AND LYOPHILIZED) • TABLETS.	RETAINED	FRANCE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	, 1X1000 Dose Bottle	29/03/2019

1634	NDA/MAL/VDP/7056	NORBROOK KENYA LTD	NORBROOK (U) LTD	EPRIZERO	EPRINOMECTIN	5MG/ML	NORBROOK LABS LTD FACTORY 3, 105 ARMAGH ROAD, NEWRY, BT35 6PU CO.; / FACTORY 1, STATION WORKS, NEWRY, BT35 6JP, CO DOWN NORTHERN IRELAND	NORBROOK LABS LTDFACTORY 4, CARNBANE INDUSTRIAL ESTATE, NEWRY BT35 6QQ, CO DOWN,	GMP OF FACTORY 3 EXPIRED ON THE 30/9/2023 FOR BETA LACTAM: LVP LIQUIDS, NON-BETA LACTAM: LARGE VOLUME PARENTERAL LIQUIDS SMALL VOLUME PARENTERAL LIQUIDS, LIQUIDS FOR EXTERNAL USE. FACTORY 1 NOT LICENSED TO MANUFACTURE THE PRODUCT LINE	RETAINED	UNITED KINGDOM	TOPICAL EXTERNAL LIQUIDS	1.0X5.0 L CONTAINER, 1.0X0.25 L CONTAINER, 1.0X2.5 L CONTAINER, 1.0X1.0 L CONTAINER, 1.0X1.0 L CONTAINER, 1.0X2.5 L CONTAINER	27/03/2019

1635	NDA/MAL/VDP/7060	BAODING SUNLIGHT HERB MEDICAMENT CO., LTD	BD PHARMACEUTICALS LTD	IVER PLUS	IVERMECTIN + CLORSULON	10MG/ML +100MG/ML	BAODING SUNLIGHT HERB MEDICAMENT CO. LTD-NO. 3881 GREAT WALL SOUTH STREET, QINGYUAN DISTRICT, BAODING CITY, HEBEI PROVINCE CHINA	N/A	APPLICATION FOR GMP RE-INSPECTION BEARS A DIFFERENT ADDRESS (NO.2, PING AN EAST ROAD, EAST ZONE, ECONOMIC DEVELOPMENT DISTRICT, GAOYANG COUNTY, BAODING CITY, HEBEI PROVINCE - CHINA). APPLICANT REQUIRED TO UPDATE MANUFACTURER'S DETAILS	NOT RETAINED	CHINA	PARENTERAL ORDINARY S C VIALS	1.0X100.0 ML VIAL	01/07/2017

1636	NDA/MAL/VDP/7061	BAODING SUNLIGHT HERB MEDICAMENT CO., LTD	BD PHARMACEUTICALS LTD	OXY-100	OXYTETRACYCLINE	100MG/ML	BAODING SUNLIGHT HERB MEDICAMENT CO. LTD-NO. 3881 GREAT WALL SOUTH STREET, QINGYUAN DISTRICT, BAODING CITY, HEBEI PROVINCE CHINA	N/A	APPLICATION FOR GMP RE-INSPECTION BEARS A DIFFERENT ADDRESS (NO.2, PING AN EAST ROAD, EAST ZONE, ECONOMIC DEVELOPMENT DISTRICT, GAOYANG COUNTY, BAODING CITY, HEBEI PROVINCE - CHINA). APPLICANT REQUIRED TO UPDATE MANUFACTURER'S DETAILS	NOT RETAINED	CHINA	PARENTERAL ORDINARY VIALS	1.0X100.0 ML VIAL,1.0X500.0 ML BOTTLE	01/07/2017

1637	NDA/MAL/VDP/7171	BOEHRINGER INGELHEIM VETMEDICA GMBH, GERMANY	ERAM UGANDA LIMITED	FRONTLINE PLUS DOG X-LARGE	FIPRONIL + (S)-METHOPRENE	10% W/V+ 9% W/V	MERIAL-4 CHEMIN DU CALQUET 31000 TOULOUSE	N/A	GMP EXPIRED ON THE 27/07/2021 FORNBL TOPICAL SOLUTIONS (ECTOPARASITICIDES) INJECTABLE POWDER IN SACHETS (ISOMETAMIDIUM POWDER FOR INJECTION-TRYPAMIDIUM) SOLUTIONS FOR INJECTION (ASEPTICALLY FILLED AND TERMINALLY STERILIZED SMALL VOLUME PARENTERALS AND LARGE VOLUME PARENTERALS)	RETAINED	FRANCE	TOPICAL EXTERNAL LIQUIDS	1.0X1.0X3.0 X4.02 ML PIPETTE	27/11/2018

1638	NDA/MAL/VDP/7174	BOEHRINGER INGELHEIM VETMEDICA GMBH, GERMANY	ERAM UGANDA LIMITED	FRONTLINE PLUS CAT	FIPRONIL + (S)-METHOPRENE	10% W/V+ 12% W/V	MERIAL-4 CHEMIN DU CALQUET 31000 TOULOUSE	N/A	GMP EXPIRED ON THE 27/07/2021 FORNBL TOPICAL SOLUTIONS (ECTOPARASITICIDES) INJECTABLE POWDER IN SACHETS (ISOMETAMIDIUM POWDER FOR INJECTION-TRYPAMIDIUM) SOLUTIONS FOR INJECTION (ASEPTICALLY FILLED AND TERMINALLY STERILIZED SMALL VOLUME PARENTERALS AND LARGE VOLUME PARENTERALS)	RETAINED	FRANCE	TOPICAL EXTERNAL LIQUIDS	1.0X1.0X3.0 X0.5 ML PIPETTE	27/11/2018
1639	NDA/MAL/VDP/7398	EAGLE VET TECH CO., LTD	EAGLEVET UGANDA LIMITED	EAGLE TYLOSIN 200 INJECTION	TYLOSIN TARTRATE	200MG/ML	N/A	EAGLE VET TECH CO. LTD235-34, CHUSA-RO, SHINAM-MYUN, YESAN-GUN, CHUNGCHEONGNAM-DO, KOREA	N/A	NOT RETAINED	SOUTH KOREA	PARENTERAL ORDINARY IM VIALS	1.0X100.0 ML VIAL	01/07/2017

1640	NDA/MAL/VDP/7400	EAGLE VET TECH CO., LTD	EAGLEVET UGANDA LIMITED	OXYVET-LA INJECTION	OXYTETRACYCLINE DIHYDRATE	200MG/ML	N/A	EAGLE VET TECH. CO. LTD235-34, CHUSA-RO, SHINAM-MYEON, YESAN-GUN CHUNGCHEONGNAM-DO, KOREA	N/A	NOT RETAINED	SOUTH KOREA	PARENTERAL ORDINARY VIALS	1.0X100.0 ML VIAL	01/07/2017
1641	NDA/MAL/VDP/7532	LAPROVET –HUNGERARY PHARMACEUTICALS LTD	EVERVICTORY LIMITED	AVI IBD INTER	LIVE INFECTIOUS BURSAL DISEASE VACCINE - STRAIN LIBDV	$\geq 10^3$ $TCID_{50}$/DOSE.	LAPROVET HUNGARY .- BUDAPEST 1107, HOROG U 32-34 HUNGARY	N/A	GMP EXPIRED ON THE 30/5/2017 FOR LIVE FREEZE DRIED VIRAL VACCINES (VETERINARY) • INACTIVATED VIRAL VACCINES IN EMULSION (VETERINARY)	RETAINED	HUNGARY	PARENTERAL ORDINARY VIALS	1.0X500.0 DOSE VIAL,1.0X1000.0 DOSE VIAL	01/07/2016
1642	NDA/MAL/VDP/7568	MERIAL	ERAM UGANDA LIMITED	AVINEW NEO	NEWCASTLE DISEASE VIRUS, VG/GA-AVINEW STRAIN	NOT LESS THAN 5.5 LOG EID50 / DOSAGE UNIT	MERIAL-4 CHEMIN DU CALQUET 31000 TOULOUSE	N/A	GMP EXPIRED ON THE 15/11/2020 FOR VETERINARY VACCINES ; • SMALL VOLUME PARENTERALS (SOLUTIONS AND LYOPHILIZED) • TABLETS.	RETAINED	FRANCE	ORAL LIQUID ORDINARY OTHER SOLID SPECIAL FORMS	1.0X1.0X10.0X1000.0 DOSE BLISTER,1.0X1.0X10.0X2000.0 DOSE BLISTER	29/01/2019

1643	NDA/MAL/VDP/7570	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO	GLOBAL VET (U) LIMITED	DOXY TYLOVET PLUS	DOXYCYCLINE HYCLATE+TYLOSIN TARTRATE+VITAMIN A ACETATE+ CHOLECALCIFEROL+VITAMIN E +RIBOFLAVIN + CYANOCOBALAMIN + CALCIUM PANTHOTHENATE +NICOTINAMIDE +VITAMIN K3 + ASCORBIC ACID +THIAMINE HYDROCHLORIDE +PYRIDOXINE HYDROCHLORIDE	200MG +100MG + 750I.U + 300I.U + 3MG + 6MG + 0.015MG + 15MG + 30MG + 3MG + 30MG + 3MG + 3MG	N/A	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.-BUILDING NO.:150, KING ABDELLAHA II ST.AMMAN-JORDAN	N/A	NOT RETAINED	JORDAN	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X100.0 G SACHET,1.0X 500.0 G SACHET	31/01/2018

1644	NDA/MAL/ VDP/7580	ELANCO ANIMAL HEALTH (PTY) LTD	KWEWAYO (U) VET PHARMACY LIMITED	DOXYMYCIN	DOXYCYCLINE +SODIUM SULPHACETAMIDE	0.5G +2.5G	BAYER ANIMAL HEALTH (PTY) LTD .-16 WILLOW TON ROAD PIETERMARITZBURG 3201	N/A	GMP EXPIRED ON THE 17/09/2011 FOR NBL TABS, NBL POWDERS FOR ORAL SOLUTIONS/SUSPENSION, NBL ORAL LIQUID SOLUTION AND SUSPENSION, ECTOPARASITICIDES AND EXTERNAL PREPARATIONS, CREAMS AND OINTMENTS, NBL PARENETRAL PREPARATION	RETAINED	SOUTH AFRICA	ORAL SOLID ORDINARY POWDERS	1.0X50.0 G CONTAINER	01/07/2011

1645	NDA/MAL/VDP/7654	BAODING SUNLIGHT HERB MEDICAMENT CO., LTD	BD PHARMACEUTICALS LTD	ALBEN-100	ALBENDAZOLE	10%W/V	BAODING SUNLIGHT HERB MEDICAMENT CO. LTD-NO. 3881 GREAT WALL SOUTH STREET, QINGYUAN DISTRICT, BAODING CITY, HEBEI PROVINCE CHINA	N/A	APPLICATION FOR GMP RE-INSPECTION BEARS A DIFFERENT ADDRESS (NO.2, PING AN EAST ROAD, EAST ZONE, ECONOMIC DEVELOPMENT DISTRICT, GAOYANG COUNTY, BAODING CITY, HEBEI PROVINCE - CHINA). APPLICANT REQUIRED TO UPDATE MANUFACTURER'S DETAILS	NOT RETAINED	CHINA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X120.0 ML CONTAINER, 1.0X5000.0 ML CONTAINER, 1.0X1000.0 ML CONTAINER, 1.0X500.0 ML CONTAINER	01/07/2017

1646	NDA/MAL/VDP/7658	BAODING SUNLIGHT HERB MEDICAMENT CO., LTD	BD PHARMACEUTICALS LTD	ALBEN-25	ALBENDAZOLE	2.5%W/V	BAODING SUNLIGHT HERB MEDICAMENT CO. LTD-NO. 3881 GREAT WALL SOUTH STREET, QINGYUAN DISTRICT, BAODING CITY, HEBEI PROVINCE CHINA	N/A	APPLICATION FOR GMP RE-INSPECTION BEARS A DIFFERENT ADDRESS (NO.2, PING AN EAST ROAD, EAST ZONE, ECONOMIC DEVELOPMENT DISTRICT, GAOYANG COUNTY, BAODING CITY, HEBEI PROVINCE - CHINA). APPLICANT REQUIRED TO UPDATE MANUFACTURER'S DETAILS	NOT RETAINED	CHINA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X500.0 ML CONTAINER, 1.0X120.0 ML CONTAINER, 1.0X5000.0 ML CONTAINER, 1.0X1000.0 ML CONTAINER	01/07/2017

1647	NDA/MAL/VDP/7661	BAODING SUNLIGHT HERB MEDICAMENT CO., LTD	BD PHARMACEUTICALS LTD	ALBEN & IVER ORAL	ALBENDAZOLE+ IVERMECTIN	2.5%W/V + 0.1%W/V	BAODING SUNLIGHT HERB MEDICAMENT CO. LTD-NO. 3881 GREAT WALL SOUTH STREET, QINGYUAN DISTRICT, BAODING CITY, HEBEI PROVINCE CHINA	N/A	APPLICATION FOR GMP RE-INSPECTION BEARS A DIFFERENT ADDRESS (NO.2, PING AN EAST ROAD, EAST ZONE, ECONOMIC DEVELOPMENT DISTRICT, GAOYANG COUNTY, BAODING CITY, HEBEI PROVINCE - CHINA). APPLICANT REQUIRED TO UPDATE MANUFACTURER'S DETAILS	NOT RETAINED	CHINA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0 ML CONTAINER	01/07/2017
1648	NDA/MAL/VDP/7672	EAGLE VET TECH CO., LTD	EAGLEVET UGANDA LIMITED	DEXAPOWER	DEXAMETHASONE	2MG/ML	N/A	EAGLE VET TECH CO. LTD.235-34, CHUSA-RO, SHINAM MYUN, YESAN-KUN, CHUNGCHONGNAM-DO	N/A	NOT RETAINED	SOUTH KOREA	PARENTERAL ORDINARY VIALS	1.0X100.0 ML VIAL,1.0X50.0 ML VIAL	01/07/2017

1649	NDA/MAL/VDP/7676	HEBEI KEXING PHARMACEUTICAL CO., LTD.	JUBAILI AGROTEC LIMITED	IVANOR PLUS	IVERMECTIN + CLOSANTEL SODIUM	1%W/V + 10%W/V	HEBEI HOPE HARMONY PHARMACEUTICAL CO LTD-INDUSTRY DEVELOPMENT AREA, YUANSHI COUNTY, SHIJIAZHUANG CITY, HEBEI PROVINC	HEBEI KEXING PHARMACEUTICALS CO. LTDNO.114 CHANGSHENG STREET, LUQUAN DEVELOPMENT ZONE, SHIJIAZHUANG CITY, HEBEI, CHINA.	GMP EXPIRED ON 8/10/2023 FOR NON-BETA LACTAM: TABLETS, ORAL LIQUIDS, SMALL VOLUME PARENTERAL SOLUTIONS (AMPOULES & VIALS), ORAL SOLUBLE POWDERS IN SACHETS	RETAINED	CHINA	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL,1.0X100.0 ML VIAL,1.0X250.0 ML VIAL	01/07/2017
1650	NDA/MAL/VDP/7685	EAGLE VET TECH CO., LTD	EAGLEVET UGANDA LIMITED	NEW-PACPRIM	TRIMETHOPRIM + SULFAMETHOXAZOLE	40G+200G/KG	N/A	EAGLE VET TECH CO. LTD.235-34, CHUSA-RO, SHINAM MYUN, YESAN-KUN, CHUNGCHONGNAM-DO	N/A	NOT RETAINED	SOUTH KOREA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X100.0 G SACHET,1.0X500.0 G SACHET	01/07/2017
1651	NDA/MAL/VDP/7694	INTERCHEMIE WENKEN "DE ADELAAR" B.V.	VET CENTRE UGANDA LIMITED	LIMOXIN-100	OXYTETRACYCLINE	10%V/V	INTERCHIEME WENKEN "DE ADELAAR" B.V.-HORSTERWEG 26A 5811 AC CASTENE	N/A	APPLICANT REQUIRED TO UPDATE MANUFACTURER'S DETAILS	RETAINED	NETHERLANDS	PARENTERAL ORDINARY VIALS	1.0X100.0 ML VIAL	01/07/1999

1652	NDA/MAL/VDP/7697	BAODING SUNLIGHT HERB MEDICAMENT CO., LTD	BD PHARMACEUTICALS LTD	PEN-STREP	PENICILLIN G PROCAINE + DIHYROSTREPTOMYCIN SULFATE	200,000 IU + 200MG/ML	BAODING SUNLIGHT HERB MEDICAMENT CO. LTD-NO. 3881 GREAT WALL SOUTH STREET, QINGYUAN DISTRICT, BAODING CITY, HEBEI PROVINCE CHINA	N/A	APPLICATION FOR GMP RE-INSPECTION BEARS A DIFFERENT ADDRESS (NO.2, PING AN EAST ROAD, EAST ZONE, ECONOMIC DEVELOPMENT DISTRICT, GAOYANG COUNTY, BAODING CITY, HEBEI PROVINCE - CHINA). APPLICANT REQUIRED TO UPDATE MANUFACTURER'S DETAILS	NOT RETAINED	CHINA	PARENTERAL ORDINARY VIALS	1.0X100.0 ML VIAL	01/07/2017
1653	NDA/MAL/VDP/7723	NILE SERVICES LTD	NILE SERVICES LTD	TYPHOCOSTAR	SULFAQUINOXALINE SODIUM + TRIMETHOPRIM	536.5MG + 165MG/ G	N/A	CHONGQING FANGTONG ANIMAL PHARMACEUTICAL CO. LTDNO.80 EAST PART OF CHANGZHOU ROAD BANQIAO INDUSTRIAL PARK RONGCHANG CHONGQING CHINA	N/A	NOT RETAINED	CHINA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X100.0 G SACHET	28/05/2019

1654	NDA/MAL/VDP/8179	CEVA SANTE ANIMALE	VERI BRANDS U LTD	ENZAPROST T	DINOPROST	5MG/ML	CEVA SANTE ANIMALE-10 AVENUE DE LA BALLASTIERE 33500 LIBOURNE FRANCE	N/A	GMP EXPIRED ON 28/9/2023 FOR NON-BETA LACTAM: SVP SOLUTIONS AND SUSPENSIONS LYOPHILIZED POWDERS (POWDERS/GRANULES FOR INJECTION) REPRODUCTIVE HORMONAL DEVICES , BETA LACTAM (PENICILLIN): SVP SOLUTIONS AND SUSPENSIONS LYOPHILIZED POWDERS (POWDERS/GRANULES FOR INJECTION) , SECONDARY PACKAGING: VACCINES	RETAINED	FRANCE	PARENTERAL ORDINARY VIALS	1.0X30.0 ML VIAL,1.0X50.0 ML VIAL	01/07/2014
1655	NDA/MAL/VDP/8181	UNIVET LTD	BIMEDA UGANDA LIMITED	CURAFLUKE	FENBENDAZOLE+RAFOXANIDE	5%W/V+5%W/V	UNIVET LTD-TULLYVIN, COOTEHILL, COUNTY CAVAN, IRELAND.	MEDISEL KENYA LTD --LR NO : 4953 / 1209, GENERAL KAGO ROAD, P.O. BOX 5401000, THIKA - KENYA	PRODUCT LINE NOT INCLUDED IN GMP APPLICATION FOR INSPECTION	RETAINED	KENYA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0 L JERRYCAN	01/07/2017

1656	NDA/MAL/VDP/8256	HEBEI HOPE HARMONY PHARMACEUTICAL CO., LTD	JUBAILI AGROTEC LIMITED	ALBENOR 2500	ALBENDAZOLE	2500MG	HEBEI HARMONY PHARMACEUTICAL CO. LTD-INDUSTRIAL ZOO YUANSHI TOWN SHIJIAZHUANG CITY HEBEI PROVINCE	N/A	GMP EXPIRED ON 8/10/2023 FOR NON-BETA LACTAM: TABLETS, ORAL LIQUIDS, SMALL VOLUME PARENTERAL SOLUTIONS (AMPOULES & VIALS), ORAL SOLUBLE POWDERS IN SACHETS	RETAINED	CHINA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X20.0 BOLUS BLISTER	28/03/2018
1657	NDA/MAL/VDP/8257	ELANCO ANIMAL HEALTH CO. LTD,DIVISION OF ELI LILLY(SA) PTY,LTD	ULTRAVETIS UGANDA LIMITED	ESB3	SULFACLOZINE SODIUM MONOHYDRATE	300 G/KG	SHANGHAI NOVARTIS ANIMAL HEALTH CO., LTD-1 CHANGZHONG ROAD, FENGXIAN	N/A	FACILITY NAME CHANGED TO ELANCO. APPLICANT REQUIRED TO APPLY FOR A VARIATION	NOT RETAINED	CHINA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X250.0 G SACHET,1.0X 50.0 G SACHET,1.0X 20.0 G SACHET,1.0X 100.0 G SACHET	28/03/2018
1658	NDA/MAL/VDP/8259	EAGLE VET TECH CO., LTD	EAGLEVET UGANDA LIMITED	ENPROTIL	ENROFLOXACIN	100G/L	N/A	EAGLE VET TECH CO. LTD.235-34, CHUSA-RO, SHINAM MYUN, YESAN-KUN, CHUNGCHONGNAM-DO	N/A	NOT RETAINED	SOUTH KOREA	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE,1.0X 500.0 ML BOTTLE	28/03/2018

1659	NDA/MAL/VDP/8260	HEBEI HOPE HARMONY PHARMACEUTICAL CO., LTD	JUBAILI AGROTEC LIMITED	TETRANOR 10	OXYTETRACYCLINE HYDROCHLORIDE	10%W/V	HEBEI HARMONY PHARMACEUTICAL CO. LTD-INDUSTRIAL ZOO YUANSHI TOWN SHIJIAZHUANG CITY HEBEI PROVINCE	N/A	GMP EXPIRED ON 8/10/2023 FOR NON-BETA LACTAM: TABLETS, ORAL LIQUIDS, SMALL VOLUME PARENTERAL SOLUTIONS (AMPOULES & VIALS), ORAL SOLUBLE POWDERS IN SACHETS	RETAINED	CHINA	PARENTERAL ORDINARY VIALS	1.0X250.0 ML VIAL,1.0X500.0 ML VIAL,1.0X100.0 ML VIAL	28/03/2018
1660	NDA/MAL/VDP/8261	HEBEI HOPE HARMONY PHARMACEUTICAL CO., LTD	JUBAILI AGROTEC LIMITED	P-STREPNOR	PROCAINE PENICILLIN + DIHYDROSTREPTOMYCIN SULPHATE	200MG + 250MG/ML	HEBEI HOPE HARMONY PHARMACEUTICAL CO.,LTD - INDUSTRY AREA,YUANSHI COUNTY, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA	N/A	GMP EXPIRED ON 8/10/2023 FOR NON-BETA LACTAM: TABLETS, ORAL LIQUIDS, SMALL VOLUME PARENTERAL SOLUTIONS (AMPOULES & VIALS), ORAL SOLUBLE POWDERS IN SACHETS	RETAINED	CHINA	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL,1.0X100.0 ML VIAL,1.0X250.0 ML VIAL	28/03/2018

1661	NDA/MAL/VDP/8262	BAODING SUNLIGHT HERB MEDICAMENT CO.LTD	BD PHARMACEUTICALS LTD	MULTIVIT	VITAMINS [A + D3 +E +B1 + B2 + B6 +B12 + C] + D-PANTHENOL + NICOTINAMIDE + D-BIOTIN	3000I.U + 2000I.U +4MG + 10MG +1MG +5MG +10MCG + 1MG + 10MG + 12.5MG + 10MCG	BAODING SUNLIGHT HERB MEDICAMENT CO. LTD-NO. 3881 GREAT WALL SOUTH STREET, QINGYUAN DISTRICT, BAODING CITY, HEBEI PROVINCE CHINA	N/A	APPLICATION FOR GMP RE-INSPECTION BEARS A DIFFERENT ADDRESS (NO.2, PING AN EAST ROAD, EAST ZONE, ECONOMIC DEVELOPMENT DISTRICT, GAOYANG COUNTY, BAODING CITY, HEBEI PROVINCE - CHINA). APPLICANT REQUIRED TO UPDATE MANUFACTURER'S DETAILS	NOT RETAINED	CHINA	PARENTERAL ORDINARY VIALS	1.0X100.0 ML VIAL	01/07/2017
1662	NDA/MAL/VDP/8269	HEBEI HOPE HARMONY PHARMACEUTICAL CO., LTD	JUBAILI AGROTEC LIMITED	ALBENOR 2.5%	ALBENDAZOLE	2.5%W/V	HEBEI HARMONY PHARMACEUTICAL CO. LTD-INDUSTRIAL ZOO YUANSHI TOWN SHIJIAZHUANG CITY HEBEI PROVINCE	N/A	GMP EXPIRED ON 8/10/2023 FOR NON-BETA LACTAM: TABLETS, ORAL LIQUIDS, SMALL VOLUME PARENTERAL SOLUTIONS (AMPOULES & VIALS), ORAL SOLUBLE POWDERS IN SACHETS	RETAINED	CHINA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X500.0 ML CONTAINER, 1.0X1000.0 ML CONTAINER, 1.0X100.0 ML CONTAINER, 1.0X5.0 L CONTAINER	28/03/2018

1663	NDA/MAL/VDP/8270	HEBEI HOPE HARMONY PHARMACEUTICAL CO., LTD	JUBAILI AGROTEC LIMITED	TETRANOR 20 L.A	OXYTETRACYCLINE DIHYDRATE	20%W/V	HEBEI HARMONY PHARMACEUTICAL CO. LTD-INDUSTRIAL ZOO YUANSHI TOWN SHIJIAZHUANG CITY HEBEI PROVINCE	N/A	GMP EXPIRED ON 8/10/2023 FOR NON-BETA LACTAM: TABLETS, ORAL LIQUIDS, SMALL VOLUME PARENTERAL SOLUTIONS (AMPOULES & VIALS), ORAL SOLUBLE POWDERS IN SACHETS	RETAINED	CHINA	PARENTERAL ORDINARY VIALS	1.0X250.0 ML VIAL,1.0X100.0 ML VIAL,1.0X500.0 ML VIAL	28/03/2018
1664	NDA/MAL/VDP/8271	HEBEI HOPE HARMONY PHARMACEUTICAL CO., LTD	JUBAILI AGROTEC LIMITED	TETRANOR 30 L.A	OXYTETRACYCLINE HYDROCHLORIDE	30%W/V	HEBEI HARMONY PHARMACEUTICAL CO. LTD-INDUSTRIAL ZOO YUANSHI TOWN SHIJIAZHUANG CITY HEBEI PROVINCE	N/A	GMP EXPIRED ON 8/10/2023 FOR NON-BETA LACTAM: TABLETS, ORAL LIQUIDS, SMALL VOLUME PARENTERAL SOLUTIONS (AMPOULES & VIALS), ORAL SOLUBLE POWDERS IN SACHETS	RETAINED	CHINA	PARENTERAL ORDINARY VIALS	1.0X100.0 ML VIAL,1.0X250.0 ML VIAL	28/03/2018

1665	NDA/MAL/ VDP/8360	FATRO S.P.A	GLOBAL VET (U) LIMITED	VAIOL-VAC	LIVE ATTENUATED AVIAN FOWLPOX VIRUS, HP-2 STRAIN-2	$\geq 10^4 EID_{50}$/ DOSE	FATRO S.P.AVIA MOLINO EMILI 2, MACLODI O (BS, ITALY)	N/A	GMP EXPIRED ON 10/12/2023 FOR Non-Beta Lactam (Vet): Veterinary Vaccines (Live Vaccines, Freeze dried vaccines, Inactivated Vaccines and Marek Virus Vaccine) under the following dosage forms; 1. Small Volume Parenterals - Solutions and Lyophilised powders in Single and Multidoses 2. Large Volume Parenterals - Solutions and Lyophilised powders in Single and Multidoses 3. Solutions and Suspensions 4. Freeze Dried Powders	NOT RETAINED	ITALY	ORAL LIQUID ORDINARY DROPS	1.0X10.0X10 00.0 DOSE VIAL	31/01/2018

1666	NDA/MAL/VDP/8361	HEBEI HOPE HARMONY PHARMACEUTICAL CO., LTD	JUBAILI AGROTEC LIMITED	FLOXINOR	ENROFLOXACIN	200MG/ML	HEBEI HOPE HARMONY PHARMACEUTICAL CO LTD-INDUSTRY DEVELOPMENT AREA, YUANSHI COUNTY, SHIJIAZHUANG CITY, HEBEI PROVINC	N/A	GMP EXPIRED ON 8/10/2023 FOR NON-BETA LACTAM: TABLETS, ORAL LIQUIDS, SMALL VOLUME PARENTERAL SOLUTIONS (AMPOULES & VIALS), ORAL SOLUBLE POWDERS IN SACHETS	RETAINED	CHINA	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE,1.0X 1000.0 ML BOTTLE	29/11/2017

1667	NDA/MAL/VDP/8362	FATRO S.P.A	GLOBAL VET (U) LIMITED	S.E.T-VAC	INACTIVATED CULTURE OF SALMONELLA ENTERITIDIS + INACTIVATED CULTURE OF SALMONELLA TYPHIMURIUM	1,000,000,000CFU/DOSE + 1,000,000,000CFU/DOSE	FATRO S.P.A.-VIA EMILIA 285, OZZANO EMILIA (BO, ITALY) FATRO S.P.A-VIA MOLINO EMILI 2, MACLODIO (BS, ITALY)	N/A	GMP EXPIRED ON 10/12/2023 FOR Non-Beta Lactam (Vet): Veterinary Vaccines (Live Vaccines, Freeze dried vaccines, Inactivated Vaccines and Marek Virus Vaccine) under the following dosage forms; 1. Small Volume Parenterals - Solutions and Lyophilised powders in Single and Multidoses 2. Large Volume Parenterals - Solutions and Lyophilised powders in Single and Multidoses 3. Solutions and Suspensions 4. Freeze Dried Powders	NOT RETAINED	ITALY	PARENTERAL ORDINARY VIALS	1.0X500.0 DOSE VIAL (250ML),1.0X1000.0 DOSE VIAL (500ML)	31/01/2018

1668	NDA/MAL/ VDP/8364	FATRO S.P.A	GLOBAL VET (U) LIMITED	BIO–VAC ND–IB	HITCHNER B1 STRAIN + MASSACHUSETTS H-120	HITCHNER B1 STRAIN - $\geq 10^{6.5}$ EID_{50}/DOSE + MASSACHUSETTS H-120 - $\geq 10^{3.5}$ EID_{50}/DOSE	FATRO S.P.AFATRO S.P.A VIA MOLINO EMILI, 225030 MACLODIO (BS) ITALY	N/A	GMP EXPIRED ON 10/12/2023 FOR Non-Beta Lactam (Vet): Veterinary Vaccines (Live Vaccines, Freeze dried vaccines, Inactivated Vaccines and Marek Virus Vaccine) under the following dosage forms; 1. Small Volume Parenterals - Solutions and Lyophilised powders in Single and Multidoses 2. Large Volume Parenterals - Solutions and Lyophilised powders in Single and Multidoses 3. Solutions and Suspensions 4. Freeze Dried Powders	NOT RETAINED	ITALY	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X1000.0 DOSE VIAL	29/11/2017

1669	NDA/MAL/ VDP/8368	FATRO S.P.A	GLOBAL VET (U) LIMITED	IBA-VAC	LIVE ATTENUATED VIRUS OR GUMBORO DISEASE, 1/65PV STRAIN	$\geq 10^3 EID_{50}$/ DOSE	FATRO S.P.AVIA MOLINO EMILI 2, MACLODI O (BS, ITALY)	N/A	GMP EXPIRED ON 10/12/2023 FOR Non-Beta Lactam (Vet): Veterinary Vaccines (Live Vaccines, Freeze dried vaccines, Inactivated Vaccines and Marek Virus Vaccine) under the following dosage forms; 1. Small Volume Parenterals - Solutions and Lyophilised powders in Single and Multidoses 2. Large Volume Parenterals - Solutions and Lyophilised powders in Single and Multidoses 3. Solutions and Suspensions 4. Freeze Dried Powders	NOT RETAINED	ITALY	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1000.0 DOSE VIAL,1.0X25 00.0 DOSE VIAL,1.0X50 00.0 DOSE VIAL,1.0X10. 0X1000.0 DOSE VIAL,1.0X10. 0X2500.0 DOSE VIAL,1.0X10. 0X5000.0 DOSE VIAL	31/01/2018

1670	NDA/MAL/VDP/8371	FATRO S.P.A	GLOBAL VET (U) LIMITED	BIO-VAC LA SOTA	NEWCASTLE DISEASE VIRUS (STRAIN LA SOTA)	10^6.5 EID50/DOSE	FATRO S.P.AVIA MOLINO EMILI 2, MACLODIO (BS, ITALY)	N/A	GMP EXPIRED ON 10/12/2023 FOR Non-Beta Lactam (Vet): Veterinary Vaccines (Live Vaccines, Freeze dried vaccines, Inactivated Vaccines and Marek Virus Vaccine) under the following dosage forms; 1. Small Volume Parenterals - Solutions and Lyophilised powders in Single and Multidoses 2. Large Volume Parenterals - Solutions and Lyophilised powders in Single and Multidoses 3. Solutions and Suspensions 4. Freeze Dried Powders	NOT RETAINED	ITALY	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X1.0X1000.0 DOSE VIAL,1.0X1.0X2500.0 DOSE VIAL,1.0X1.0X500.0 DOSE VIAL,1.0X10.0X1000.0 DOSE VIAL,1.0X10.0X2500.0 DOSE VIAL,1.0X10.0X5000.0 DOSE VIAL	31/01/2018

1671	NDA/MAL/VDP/8372	FATRO S.P.A	GLOBAL VET (U) LIMITED	BIO-MAREK HVT	FREEZE DRIED FC 126 STRAIN OF HERPES VIRUS OF TURKEY (HVT)	1500 PLAQUE FORMING UNITS/ DOSE	FATRO S.P.AVIA MOLINO EMILI 2, MACLODIO (BS, ITALY)	N/A	GMP EXPIRED ON 10/12/2023 FOR Non-Beta Lactam (Vet): Veterinary Vaccines (Live Vaccines, Freeze dried vaccines, Inactivated Vaccines and Marek Virus Vaccine) under the following dosage forms; 1. Small Volume Parenterals - Solutions and Lyophilised powders in Single and Multidoses 2. Large Volume Parenterals - Solutions and Lyophilised powders in Single and Multidoses 3. Solutions and Suspensions 4. Freeze Dried Powders	NOT RETAINED	ITALY	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 DOSE VIAL,1.0X2000.0 DOSE VIAL	31/01/2018

1672	NDA/MAL/ VDP/8387	FATRO S.P.A	GLOBAL VET (U) LIMITED	BI-VAC 2º	ATTENUATED AVIAN INFECTIOUS BRONCHITIS VIRUS, MASSACHUSETTS H-52 STRAIN	$\geq 10^4 EID_{50}$/ DOSE	FATRO S.P.AVIA MOLINO EMILI 2, MACLODIO (BS, ITALY)	N/A	GMP EXPIRED ON 10/12/2023 FOR Non-Beta Lactam (Vet): Veterinary Vaccines (Live Vaccines, Freeze dried vaccines, Inactivated Vaccines and Marek Virus Vaccine) under the following dosage forms; 1. Small Volume Parenterals - Solutions and Lyophilised powders in Single and Multidoses 2. Large Volume Parenterals - Solutions and Lyophilised powders in Single and Multidoses 3. Solutions and Suspensions 4. Freeze Dried Powders	NOT RETAINED	ITALY	ORAL LIQUID ORDINARY DRY SUSPENSIONS /SYRUPS/DROPS	1.0X10.0X1000.0 DOSE VIAL,1.0X10.0X2500.0 DOSE VIAL,1.0X10.0X5000.0 DOSE VIAL	31/01/2018

1673	NDA/MAL/VDP/8391	EAGLE VET TECH CO., LTD	EAGLEVET UGANDA LIMITED	VITAPOWER	MULTI-VITAMIN	MULTI-INGREDIENT	N/A	EAGLE VET TECH CO. LTD.35-34, CHUSA-RO, SHINAM-MYEON, YESAN-GUN, CHUNGCHEONGNAM-DO, KOREA	N/A	NOT RETAINED	SOUTH KOREA	PARENTERAL ORDINARY IM VIALS	1.0X100.0 ML BOTTLE	29/11/2017
1674	NDA/MAL/VDP/8398	HEBEI HOPE HARMONY PHARMACEUTICAL CO., LTD	JUBAILI AGROTEC LIMITED	ALBENOR 300	ALBENDAZOLE	300MG	HEBEI HOPE HARMONY PHARMACEUTICAL CO.,LTD - INDUSTRY AREA,YUANSHI COUNTY, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA	N/A	GMP EXPIRED ON 8/10/2023 FOR NON-BETA LACTAM: TABLETS, ORAL LIQUIDS, SMALL VOLUME PARENTERAL SOLUTIONS (AMPOULES & VIALS), ORAL SOLUBLE POWDERS IN SACHETS	RETAINED	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	29/11/2017

1675	NDA/MAL/VDP/8399	BIMEDA CHEMICAL EXPORTS	BIMEDA UGANDA LIMITED	AMINOVITAL	MULTIVITAMIN	MULTI-INGREDIENT	BIMEDA CHEMICALS EXPORT LIMITED-BROOM HILL ROAD, TALLAGHT, DUBLIN 24, IRELAND	MEDISEL (K) LTD-PLOT NO. 4953/1209, GENERAL KAGO ROAD, THIKA	GMP FOR BIMEDA EXPIRED ON THE 9/6/2014 FOR STERILE INTRAMAMMARY PRODUCTS IN PRE-FILLED SYRINGES (BL & NBL) NBL LIQUIDS (ORAL LIQUIDS_DRENCHES & ECTOPARASITICIDES_ACARICIDES)	RETAINED	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X500.0 ML BOTTLE,1.0X200.0 ML BOTTLE,1.0X1.0 L BOTTLE	01/07/1998
1676	NDA/MAL/VDP/8400	HEBEI HOPE HARMONY PHARMACEUTICAL CO., LTD	JUBAILI AGROTEC LIMITED	ALBENOR 10	ALBENDAZOLE	100MG/ML	HEBEI HOPE HARMONY PHARMACEUTICAL CO.,LTD - INDUSTRY AREA,YUANSHI COUNTY, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA	N/A	GMP EXPIRED ON 8/10/2023 FOR NON-BETA LACTAM: TABLETS, ORAL LIQUIDS, SMALL VOLUME PARENTERAL SOLUTIONS (AMPOULES & VIALS), ORAL SOLUBLE POWDERS IN SACHETS	RETAINED	CHINA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1000.0 ML BOTTLE,1.0X500.0 ML BOTTLE,1.0X100.0 ML BOTTLE,1.0X5000.0 ML JERRYCAN,1.0X125.0 ML BOTTLE	29/11/2017

1677	NDA/MAL/VDP/8532	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO	GLOBAL VET (U) LIMITED	TYLORATE	TYLOSIN	20%W/V	N/A	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.AL HASSAN INDUSTRIAL ESTATE –IRBID	N/A	NOT RETAINED	JORDAN	PARENTERAL ORDINARY VIALS	1.0X1.0X50.0 ML VIAL,1.0X1.0X100.0 ML VIAL	01/07/2011
1678	NDA/MAL/VDP/8535	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO	GLOBAL VET (U) LIMITED	MULTIVITAMIN INJ	VITAMINS A + D3 +E + B1 + B2 +B6 + B12 + NICOTINAMIDE + PANTOTHENOL	15,000IU + 1000IU + 20MG + 10MG + 5MG + 3MG + 50MCG + 35MG + 25MG	N/A	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.AL HASSAN INDUSTRIAL ESTATE –IRBID	N/A	NOT RETAINED	JORDAN	PARENTERAL ORDINARY VIALS	1.0X100.0 ML VIAL	01/07/2014
1679	NDA/MAL/VDP/8537	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO	GLOBAL VET (U) LIMITED	ENROCURE	ENROFLOXACIN	10%W/V	N/A	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.AL HASSAN INDUSTRIAL ESTATE –IRBID	N/A	NOT RETAINED	JORDAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X500.0 ML BOTTLE,1.0X1.0 L BOTTLE	01/07/2013
1680	NDA/MAL/VDP/8568	BOEHRINGER INGELHEIM VETMEDICA GMBH, GERMANY	ERAM UGANDA LIMITED	BIORAL H120 NEO	H120 STRAIN OF AVIAN INFECTIOUS BRONCHITIS VIRUS	AT LEAST 3.7 LOG TO THE BASE 10 OF EID50	MERIAL LABORATOIRE-PORTE DES ALPES–RUE DE L' AVIATION 69800 SAINT PRIEST FRANCE	N/A	GMP EXPIRED ON THE 15/11/2020 FOR VETERINARY VACCINES ; • SMALL VOLUME PARENTERALS (SOLUTIONS AND LYOPHILIZED) • TABLETS.	RETAINED	FRANCE	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X10.0X200.0 DOSE BOTTLE	30/05/2018

1681	NDA/MAL/VDP/8703	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO	GLOBAL VET (U) LIMITED	PIPERAMENTIC	PIPERAZINE	36%W/W	N/A	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.AL HASSAN INDUSTRIAL ESTATE –IRBID	N/A	NOT RETAINED	JORDAN	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X100.0 G SACHET,1.0X 500.0 G SACHET,1.0X 1.0 KG SACHET	01/07/2011
1682	NDA/MAL/VDP/8708	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO	GLOBAL VET (U) LIMITED	OXYTETRA VET	OXYTETRACY CLINE HYDROCHLOR IDE	5G/200ML	N/A	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.AL HASSAN INDUSTRIAL ESTATE –IRBID	N/A	NOT RETAINED	JORDAN	TOPICAL EXTERNAL PRESSURISED AEROSOLS	1.0X200.0 ML CANNISTER	01/07/2015
1683	NDA/MAL/VDP/8744	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO	GLOBAL VET (U) LIMITED	ALBEVET	ALBENDAZOL E	10%W/V	N/A	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.AL HASSAN INDUSTRIAL ESTATE –IRBID	N/A	NOT RETAINED	JORDAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0 L BOTTLE,1.0X 500.0 ML BOTTLE,1.0X 5.0 L BOTTLE	01/07/2014
1684	NDA/MAL/VDP/8745	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.	GLOBAL VET (U) LIMITED	ANTICOX	DICLAZURIL	10MG/ML	N/A	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO.AL HASSAN INDUSTRIAL ESTATE –IRBID	N/A	NOT RETAINED	JORDAN	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE,1.0X 500.0 ML BOTTLE	01/07/2014

1685	NDA/MAL/VDP/8942	CEVA SANTE ANIMALE	VERI BRANDS U LTD	CYSTORELIN	GONADORELIN (GNRH) DIACETATE TETRAHYDRATE	50MCG/ML	CEVA SANTE ANIMALE 10 AVENUE DE LA BALLASTIERE 33500 LIBOURNE FRANCE	N/A	GMP EXPIRED ON 28/9/2023 FOR NON-BETA LACTAM: SVP SOLUTIONS AND SUSPENSIONS LYOPHILIZED POWDERS (POWDERS/GRANULES FOR INJECTION) REPRODUCTIVE HORMONAL DEVICES , BETA LACTAM (PENICILLIN): SVP SOLUTIONS AND SUSPENSIONS LYOPHILIZED POWDERS (POWDERS/GRANULES FOR INJECTION) , SECONDARY PACKAGING: VACCINES	RETAINED	FRANCE	PARENTERAL ORDINARY VIALS	1.0X1.0X20.0 ML VIAL	25/07/2018
1686	NDA/MAL/VDP/9119	CEVA-PHYLAXIA VETERINARY BIOLOGICALS CO. LTD	VERI BRANDS U LTD	CEVAC NEW K VACCINE	INACTIVATED NEWCASTLE DISEASE VIRUS, LASOTA STRAIN	INDUCING NLT 4LOG2 HI TITRE OR NLT 50 PD50 IN CHALLENGE	N/A	CEVA- PHYLAXIA VETERINARY BIOLOGICALS CO. LTDSZALLAS UTCA 5, BUDAPEST, 1107 - HUNGARY	N/A	NOT RETAINED	HUNGARY	PARENTERAL ORDINARY VIALS	1.0X500.0 DOSE BOTTLE,1.0X1000.0 DOSE BOTTLE,1.0X3000.0 DOSE BOTTLE	27/08/2019

1687	NDA/MAL/VDP/9151	MEDMAC MANUFACTURER OF AGRICULTURAL CHEMICALS AND VETERINARY PRODUCTS LTD	KWEWAYO (U) VET PHARMACY LIMITED	PENOMYCIN	PENICILLIN G PROCAINE + DIHYDROSTREPTOMYCIN SULPHATE	200MG + 200MG / ML	N/A	HEBEI YUANZHENG PHARMACEUTICALS COMPANYNO.16 LIUYUAN ROAD CHANG'AN DISTRICT SHIJIAZHUANG CITY-050041, HEBEI PROVINCE	N/A	NOT RETAINED	CHINA	PARENTERAL ORDINARY VIALS	1.0X100.0 ML VIAL	21/11/2019
1688	NDA/MAL/VDP/9152	HEBEI HOPE HARMONY PHARMACEUTICAL CO., LTD	JUBAILI AGROTEC LIMITED	FLUKENOR	OXYCLOZANIDE + LEVAMISOLE + COBALT SULPHATE	3.5%W/V + 2%W/V + 0.4%W/V	HEBEI HOPE HARMONY PHARMACEUTICAL CO LTD-INDUSTRY DEVELOPMENT AREA, YUANSHI COUNTY, SHIJIAZHUANG CITY, HEBEI PROVINC	N/A	GMP EXPIRED ON 8/10/2023 FOR NON-BETA LACTAM: TABLETS, ORAL LIQUIDS, SMALL VOLUME PARENTERAL SOLUTIONS (AMPOULES & VIALS), ORAL SOLUBLE POWDERS IN SACHETS	RETAINED	CHINA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X125.0 ML BOTTLE,1.0X 500.0 ML BOTTLE,1.0X 1.0 L BOTTLE,1.0X 5.0 L BOTTLE	21/11/2019

1689	NDA/MAL/VDP/9153	HEBEI HOPE HARMONY PHARMACEUTICAL CO., LTD	JUBAILI AGROTEC LIMITED	I.D-NOR PLUS	IRON DEXTRAN + VITAMIN B12	100MG + 100MCG/ML	HEBEI HOPE HARMONY PHARMACEUTICAL CO LTD-INDUSTRY DEVELOPMENT AREA, YUANSHI COUNTY, SHIJIAZHUANG CITY, HEBEI PROVINCE - PEOPLE'S REPUBLIC OF CHINA	N/A	GMP EXPIRED ON 8/10/2023 FOR NON-BETA LACTAM: TABLETS, ORAL LIQUIDS, SMALL VOLUME PARENTERAL SOLUTIONS (AMPOULES & VIALS), ORAL SOLUBLE POWDERS IN SACHETS	RETAINED	CHINA	PARENTERAL ORDINARY VIALS	1.0X100.0 ML BOTTLE	21/11/2019

1690	NDA/MAL/VDP/9159	ELANCO ANIMAL HEALTH CO. LTD,DIVISION OF ELI LILLY(SA) PTY,LTD	ULTRAVETIS UGANDA LIMITED	AVIPRO® ND VISOTA	LIVE, NEWCASTLE DISEASE VACCINE, B1 TYPE, LASOTA STRAIN	NOT LESS THAN 10^5.5 EID50 / DOSE	LOHMANN ANIMAL HEALTH GMBH-374 CHINA ROAD, WINSLOW, MAINE 0491	N/A	GMP EXPIRED ON THE 21/2/2023 FOR BIOLOGICAL PRODUCTS-LIVE /INACTIVATED VIRAL AND BACTERIAL POULTRY VACCINES: SMALL VOLUME LIQUIDS (PACKAGED IN GLASS AMPOULES AND VIALS) – ASEPTICALLY PREPARED, LARGE VOLUME LIQUIDS (PACKAGED GLASS VIALS AND HDPE BOTTLES) – ASEPTICALLY PREPARED, SMALL VOLUME PARENTERAL LYOPHILIZED POWDERS (PACKAGED IN GLASS VIALS) – ASEPTICALLY PREPARED	NOT RETAINED	UNITED STATES	OTHER SYSTEMIC SPECIAL SOLIDS	1.0X10.0X1000.0 DOSE VIAL,1.0X10.0X2500.0 DOSE VIAL	21/11/2019

1691	NDA/MAL/ VDP/9160	ELANCO ANIMAL HEALTH CO. LTD,DIVISION OF ELI LILLY(SA) PTY,LTD	ULTRAVETIS UGANDA LIMITED	AVIPRO® POX CEO	FOWL POX VACCINE, LIVE VIRUS	NOT LESS THAN 10^2.0 EID50	LOHMANN ANIMAL HEALTH GMBH-374 CHINA ROAD, WINSLOW, MAINE 0491	N/A	GMP EXPIRED ON THE 21/2/2023 FOR BIOLOGICAL PRODUCTS-LIVE /INACTIVATED VIRAL AND BACTERIAL POULTRY VACCINES: SMALL VOLUME LIQUIDS (PACKAGED IN GLASS AMPOULES AND VIALS) – ASEPTICALLY PREPARED, LARGE VOLUME LIQUIDS (PACKAGED GLASS VIALS AND HDPE BOTTLES) – ASEPTICALLY PREPARED, SMALL VOLUME PARENTERAL LYOPHILIZED POWDERS (PACKAGED IN GLASS VIALS) – ASEPTICALLY PREPARED	NOT RETAINED	UNITED STATES	PARENTERAL ORDINARY VIALS	1.0X10.0X2500.0 DOSE VIAL	21/11/2019

1692	NDA/MAL/VDP/9161	ELANCO ANIMAL HEALTH CO. LTD,DIVISION OF ELI LILLY(SA) PTY,LTD	ULTRAVETIS UGANDA LIMITED	AVIPRO® ND-IB SOHOL	NEWCASTLE DISEASE, B1 TYPE, LASOTA STRAIN + INFECTIOUS BRONCHITIS, MASS. TYPE, HOLLAND STRAIN, LIVE VIRUS VACCINE	NOT LESS THAN 10^5.5 EID50 + NOT LESS THAN 10^2.7 EID50 / DOSE	LOHMANN ANIMAL HEALTH GMBH-374 CHINA ROAD, WINSLOW, MAINE 0491	N/A	GMP EXPIRED ON THE 21/2/2023 FOR BIOLOGICAL PRODUCTS-LIVE /INACTIVATED VIRAL AND BACTERIAL POULTRY VACCINES: SMALL VOLUME LIQUIDS (PACKAGED IN GLASS AMPOULES AND VIALS) – ASEPTICALLY PREPARED, LARGE VOLUME LIQUIDS (PACKAGED GLASS VIALS AND HDPE BOTTLES) – ASEPTICALLY PREPARED, SMALL VOLUME PARENTERAL LYOPHILIZED POWDERS (PACKAGED IN GLASS VIALS) – ASEPTICALLY PREPARED	NOT RETAINED	UNITED STATES	OTHER SYSTEMIC SPECIAL SOLIDS	1.0X10.0X2500.0 DOSE VIAL	21/11/2019

1693	NDA/MAL/VDP/9162	CEVA-PHYLAXIA VETERINARY BIOLOGICALS CO. LTD	VERI BRANDS U LTD	CEVAC UNIL	NEWCASTLE DISEASE VIRUS, STRAIN HITCHNER B1	NOT LESS THAN 10^5.5 EID50/DOSE	N/A	CEVA- PHYLAXIA VETERINARY BIOLOGICALS CO. LTDSZALLAS UTCA 5, BUDAPEST, 1107 - HUNGARY	N/A	NOT RETAINED	HUNGARY	OCULAR THERAPEUTIC SYSTEMS	1.0X500.0 DOSE VIAL,1.0X1000.0 DOSE VIAL,1.0X2000.0 DOSE VIAL,1.0X2500.0 DOSE VIAL,1.0X5000.0 DOSE VIAL	21/11/2019
1694	NDA/MAL/VDP/9164	BOEHRINGER INGELHEIM VETMEDICA GMBH, GERMANY	ERAM UGANDA LIMITED	BUR 706	LIVE,ATTENUATED, INFECTIOUS BURSAL DISEASE (GUMBORO DISEASE) VIRUS, STRAIN S706	EACH DOSE CONTAINS ≥10 4.0 CCID 50	MERIAL SAS-RUE DE L'AVIATION-69800 SAINT-PRIEST	N/A	GMP EXPIRED ON THE 15/11/2020 FOR VETERINARY VACCINES ; • SMALL VOLUME PARENTERALS (SOLUTIONS AND LYOPHILIZED) • TABLETS.	NOT RETAINED	FRANCE	ORAL LIQUID ORDINARY OTHER SOLID SPECIAL FORMS	1.0X5000.0 DOSE VIAL	21/11/2019
1695	NDA/MAL/VDP/9233	ELANCO ANIMAL HEALTH CO. LTD,DIVISION OF ELI LILLY(SA) PTY,LTD	ULTRAVETIS UGANDA LIMITED	AVIPRO IBD XTREME	LIVE (FREEZE-DRIED) (IBD) INFECTIOUS BURSAL DISEASE VIRUS, STRAIN V217, (WINTERFIELD DERIVED) OF CHICKEN EMBRYO ORIGIN	NOT LESS THAN 10^1.5 EID50/DOSE	N/A	ELANCO ANIMAL HEALTH GMBH ALSO KNOWN AS LOHMANN ANIMAL HEALTH GMBHHEINZ LOHMANN STRASSE 4, CUXHAVEN, 27472	N/A	NOT RETAINED	GERMANY	ORAL SOLID ORDINARY PELLETS	1.0X10.0X1000.0 DOSE VIAL	08/09/2020

1696	NDA/MAL/VDP/9235	ELANCO ANIMAL HEALTH CO. LTD,DIVISION OF ELI LILLY(SA) PTY,LTD	ULTRAVETIS UGANDA LIMITED	AVIPRO SALMONELLA DUO	LIVE ATTENUATED SALMONELLA ENTERITIDIS BACTERIA, STRAIN SM24/RIF12/SSQ + LIVE ATTENUATED SALMONELLA TYPHIMURIUM BACTERIA, STRAIN NAL2/RIF9/RTT	NOT LESS THAN 1×10^8 CFU/DOSE	LOHMANN ANIMAL HEALTH GMBH-374 CHINA ROAD, WINSLOW, MAINE 0491	N/A	GMP EXPIRED ON THE 21/2/2023 FOR BIOLOGICAL PRODUCTS-LIVE /INACTIVATED VIRAL AND BACTERIAL POULTRY VACCINES: SMALL VOLUME LIQUIDS (PACKAGED IN GLASS AMPOULES AND VIALS) – ASEPTICALLY PREPARED, LARGE VOLUME LIQUIDS (PACKAGED GLASS VIALS AND HDPE BOTTLES) – ASEPTICALLY PREPARED, SMALL VOLUME PARENTERAL LYOPHILIZED POWDERS (PACKAGED IN GLASS VIALS) – ASEPTICALLY PREPARED	NOT RETAINED	UNITED STATES	ORAL SOLID ORDINARY PELLETS	1.0X10.0X2000.0 DOSE VIAL	08/09/2020

1697	NDA/MAL/VDP/9242	BOEHRINGER INGELHEIM VETMEDICA GMBH, GERMANY	ERAM UGANDA LIMITED	GALLIVAC IB88 NEO	LIVE, INFECTIOUS BRONCHITIS CORONAVIRUS, STRAIN CR88121	4.0 LOG10EID50/DOSE	MERIAL SAS-RUE DE L'AVIATION-69800 SAINT-PRIEST	N/A	GMP EXPIRED ON THE 15/11/2020 FOR VETERINARY VACCINES ; • SMALL VOLUME PARENTERALS (SOLUTIONS AND LYOPHILIZED) • TABLETS.	RETAINED	FRANCE	ORAL SOLID ORDINARY EFFERVESCENT TABLETS	1.0X10.0X2000.0 DOSE BLISTER	08/09/2020
1698	NDA/MAL/VDP/9461	BASH PHARMA CO. LIMITED,	GAMA PHARMACEUTICALS (U) LIMITED	AVOMECTIN	IVERMECTIN	10MG/ML	BASH COMPANY LIMITED-SOBA INDUSTRIAL AREA, KHARTOUM-SUDAN PLOT NO.8 BLOCK 11	N/A	GMP EXPIRED ON THE 11/4/2021 FOR VETERINARY (NON-BETA LACTAM): ORAL POWDERS, ORAL LIQUIDS, SMALL & LARGE VOLUME PARENTERAL LIQUIDS (ASEPTICALLY PREPARED). HUMAN (NON-BETA LACTAM): STERILE EYE DROPS (ASEPTICALLY PREPARED)	NOT RETAINED	SUDAN	PARENTERAL ORDINARY VIALS	1.0X1.0X50.0 ML VIAL	09/12/2020

1699	NDA/MAL/ VDP/9466	ELANCO ANIMAL HEALTH CO. LTD,DIVISION OF ELI LILLY(SA) PTY,LTD	ULTRAVETIS UGANDA LIMITED	AVIPRO ND LASOTA	NEW CASTLE DISEASE VIRUS, B1 TYPE, LASOTA STRAIN LIVE	≥10^6.0TCID50 /DOSE	N/A	ELANCO ANIMAL HEALTH GMBH ALSO KNOWN AS LOHMANN ANIMAL HEALTH GMBHHEINZ LOHMANN STRASSE 4, CUXHAVEN, 27472	N/A	NOT RETAINED	GERMANY	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X1000.0 DOSE VIAL + (1*10*34 ML AVIPRO DILUDROP/ DILUENT)	09/12/2020

1700	NDA/MAL/VDP/9470	FATRO S.P.A,	GLOBAL VET (U) LIMITED	IBA-VAC ST	LIVE, FREEZE DRIED INFECTIOUS BURSAL DISEASE VIRUS (GUMBORO DISEASE VIRUS, WINTERFIELD 2512 STRAIN)	NOT LESS THAN 10^2 EID50/DOSE	FATRO S.P.A.VIA MOLINO EMILI, 2 MACLODIO (BS) 25030 - ITALY	N/A	GMP EXPIRED ON 10/12/2023 FOR Non-Beta Lactam (Vet): Veterinary Vaccines (Live Vaccines, Freeze dried vaccines, Inactivated Vaccines and Marek Virus Vaccine) under the following dosage forms; 1. Small Volume Parenterals - Solutions and Lyophilised powders in Single and Multidoses 2. Large Volume Parenterals - Solutions and Lyophilised powders in Single and Multidoses 3. Solutions and Suspensions 4. Freeze Dried Powders	NOT RETAINED	ITALY	NON-HUMAN USE SOLUBLE TABLETS	1.0X10.0X1000.0 DOSE VIAL	09/12/2020
1701	NDA/MAL/VDP/9475	ADWIA	GAMA PHARMACEUTICALS (U) LIMITED	IVEEN INJECTION	IVERMECTIN	10 MG/ML	N/A	ADWIA 1ST INDUSTRIAL ZONE, A1, 10TH OF RAMADAN CITY	N/A	NOT RETAINED	EGYPT	PARENTERAL ORDINARY VIALS	1.0X1.0X50.0 ML VIAL,1.0X1.0X100.0 ML VIAL	18/12/2020

1702	NDA/MAL/VDP/9531	ARAB VETERINARY INDUSTRIAL CO.	K.S. VET PHARMACY LIMITED	COCCIDIOPAN	SULPHAQUINOXALINE SODIUM + SULPHADIMIDINE SODIUM + SULPHADIAZINE SODIUM + VITAMIN K3 + VITAMIN A	(150 MG + 70 MG + 70 MG + 2 MG + 8000 I.U)/G	N/A	ARAB VETERINARY INDUSTRIAL COMPANY AVICOALQUDS ST-NAUR, AMMAN JORDAN, P.O BOX 150906	N/A	NOT RETAINED	JORDAN	ORAL LIQUID ORDINARY OTHER POWDERS/GRANULES	1.0X100.0 G SACHET,1.0X 200.0 G SACHET,1.0X 500.0 G SACHET,1.0X 1.0 KG SACHET	24/02/2021
1703	NDA/MAL/VDP/9532	ARAB VETERINARY INDUSTRIAL CO.	K.S. VET PHARMACY LIMITED	BACTECLEAN 50%	DOXYCYCLINE HYCLATE	500 MG/G	N/A	ARAB VETERINARY INDUSTRIAL COMPANY AVICOALQUDS ST-NAUR, AMMAN JORDAN, P.O BOX 150906	N/A	NOT RETAINED	JORDAN	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X200.0 G SACHET,1.0X 500.0 G CONTAINER, 1.0X1.0 KG CONTAINER, 1.0X100.0 G SACHET	24/02/2021
1704	NDA/MAL/VDP/9561	DYNTEC SPOL. S R. O	GLOBAL VET (U) LIMITED	CANVAC P	LIVE ATTENUATED CANINE PARVOVIRUS STRAIN ENTERITIDIS (PARVOVIRUS ENTERITIDIS CANIS ATTENUATUM)	10^2.1 - 10^3.6 HAU/DOSE	N/A	DYNTEC SPOL. S.R.O.PRAZSKA 328, 411 55 TEREZIN – CZECH REPUBLIC	N/A	NOT RETAINED	CZECH REPUBLIC	PARENTERAL ORDINARY DRY VIALS	1.0X6.0X1.0 DOSE VIAL + 1*6*1ML CLEAR GLASS VIAL DILUENT	24/02/2021
1705	NDA/MAL/VDP/9742	THE ARAB PESTICIDES AND VETERINARY DRUGS MFG. CO	GLOBAL VET (U) LIMITED	DOXYVET 500	DOXYCYCLINE HYCLATE	433.3MG/G	N/A	THE ARAB PESTICIDES & VETERINARY DRUGS MANUFACTURING CO.AL HASSAN INDUSTRIAL ESTATE, IRBID, P.O. BOOX 45, IRIBID, 21467	N/A	NOT RETAINED	JORDAN	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X100.0 G SACHET,1.0X 500.0 G SACHET,1.0X 1000.0 G SACHET	05/10/2021