

PROVISIONAL HUMAN HERBAL REGISTER - SEPTEMBER 2021

S/N	NDA REGISTRATION NUMBER	LICENSE HOLDER	LOCAL TECHNICAL REPRESENTATIVE	NAME OF DRUG	MANUFACTURER	COUNTRY OF MANUFACTURE	DOSAGE FORM	PACK SIZE	REGISTRATION DATE
1	NDA/MAL/HHP/3115	SHURIK LTD	SHURIK LTD	RHINO BALM	MEHTA UNANI PHARMACY & CO LTD-INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G CONTAINER,1.0X10.0 G CONTAINER	11/7/2018
2	NDA/MAL/HHP/5498	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	FIGURIN	AJANTA PHARMA LTD 31-0-AJANTA PHARMA LTD 31-0 MIDC INDUSTRIAL AREACHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X6.0X10.0 CAPSULE BLISTER	7/1/2000
3	NDA/MAL/HHP/5500	CHARAK PHARMA PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	APTIZOOM SYRUP	CHARAK PHARMA PVT. LTD,-PLOT NO. 371, SAYLI RAKHOLI ROAD, SILVASSA-396 230, D.T. OF DADRA & NAGAR HAVELI. INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE	7/1/2000
4	NDA/MAL/HHP/5503	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	AMODEX OINTMENT	POOJA DRUGS-POOJA DRUGS	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X25.0 G JAR	7/1/2000
5	NDA/MAL/HHP/5505	VENUS REMIDIES LTD	HARLEYS UGANDA LIMITED	AMPUCARE HERBAL OIL	PLANET HERBS LIFESCIENCES LIMITED -B-4 SARA INDUSTRIAL ESTATE, SELAQUI, DEHRADUN-248197, UTTARKHAND, INDIA	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X50.0 ML BOTTLE	7/1/2008

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6	NDA/MAL/HHP/5518	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	PENODEX OINTMENT	MEHTA UNANI PHARMACY & CO LTD-INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G CONTAINER	7/1/2007
7	NDA/MAL/HHP/5519	AJANTA PHARMA LTD 31-0	ABACUS PHARMA (AFRICA) LIMITED	APDYL-H, HERBAL COUGH SYRUP	SAVERA PHARMACEUTICALS PVT LTD --H-39 & 40, M.I.D.C, WALUJ, AURANGABAD, INDIA. AJANTA PHARMA LTD - -31-0 M.I.D.C. INDUSTRIAL AREA CHIKALTHANA-AURANGABAD 431210 DIST AURANGABAD	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE	7/1/2004
8	NDA/MAL/HHP/5528	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	AQUAREST	288,SIDCO ESTATE-AMBATTUR, CHENNAI 600098, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY POWDERS	1.0X10.0X765.0 MG SACHET	7/1/2009
9	NDA/MAL/HHP/5532	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	ATMANANTHAN COLD RUB	META UNANI PHARMACY & CO PVT-G 5524, GIDC, LODHIKA METODA, DIST RAJKOT, GUJARATI	INDIA	NASAL TOPICAL LIQUID INHALATIONS	1.0X12.0X1.0 G ROD	7/1/2009
10	NDA/MAL/HHP/5536	ABACUS PHARMA LTD	JEET PHARMACEUTICALS LIMITED	MENTHO PLUS PAIN BALM	EMAMI LTD-EMAMI LIMITED COLLEGE NAGAR ABHOYPUR, GUWAHATI 781031, ASSAM INDIA / EMAMI LIMITED PLOT NO 200 SANJAN -AMAGOAN ROAD DONGARI TALASARI	INDIA	NASAL TOPICAL OINTMENTS	1.0X24.0X3.5 ML VIAL,1.0X1.2 G JAR,1.0X4.0 G JAR,1.0X9.0 G JAR,1.0X30.0 G JAR	7/1/2004
11	NDA/MAL/HHP/5546	CHARAK PHARMA PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	PAEDRITONE SYRUP	CHARAK PHARMA PVT LTD,-EVERGREEN INDUSTRIAL ESTATE, SHAUTI MILL LANE, MUMBAI-400011 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/1/2015

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12	NDA/MAL/HHP/5547	SHURIK LTD	SHURIK LTD	MENTHOSIL COUGH DROP	MEHTA HERBALS PVT LTD-INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X35.0X2.0 LOZENGE STRIP	7/1/2001
13	NDA/MAL/HHP/5549	HIMALAYA DRUG COMPANY.	EUROPA HEALTHCARE (U) LTD	BONISAN LIQUID	HIMALAYA DRUG COMPANY-27256287 INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X120.0 ML BOTTLE	7/1/2000
14	NDA/MAL/HHP/5550	CHARAK PHARMA PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	GUM TONE GEL	CHARAK PHARMA PVT LTD,-EVERGREEN INDUSTRIAL ESTATE, SHAUTI MILL LANE, MUMBAI-400011 INDIA	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X50.0 G TUBE	7/1/2015
15	NDA/MAL/HHP/5553	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	MENTHOXYL DOUBLE ACTION HERBAL COUGH LOZENGES	LEAMARK HEALTHCAREPVT LTD-SARKHEJ- BAVLA HIGHWAY MATODA AHMEDABAD	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X10.0X2.0 LOZENGE STRIP,1.0X50. 0X2.0 LOZENGE STRIP	7/1/2009
16	NDA/MAL/HHP/5557	BETA HEALTH CARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	NEW BETA GRIPE WATER	SYDLER REMEDIES PVT LTD-M-190 MIDC WALUJ AURANGABAD 431136 BETA HEALTHCARE INTERNATIONAL LTD--PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA,NAIROBI,KENYA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X120.0 ML BOTTLE,1.0X1 00.0 ML BOTTLE	7/1/2014
17	NDA/MAL/HHP/5559	SHURIK LTD	SHURIK LTD	STAR SKIN OINTMENT	MEHTA UNANI PHARMACY & CO LTD-INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X12.0 G TUBE	7/1/2001

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18	NDA/MAL/HHP/5560	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	STAMINA	AJANTA PHARMA LTD-31-0, M.I.D.C. CHIKALTHANA, CHIKALTHANA, AURANGABAD, MAHARASHTRA STATE, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	7/1/2000
19	NDA/MAL/HHP/5561	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	COLDDROP MEDICATED COUGH DROPS	MEHTA HERBALS PVT LTD-AMRUTMANTHAN HOUSE, SADAR,RAJKOT,GUJARAT - 360 001,INDIA, RAJKOT, GUJARAT 360001, INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X1.0X100.0 LOZENGE CARTON	7/1/2009
20	NDA/MAL/HHP/5565	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	DENTEX TOOTHACE	POOJA DRUGS-POOJA DRUGS	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X5.0 ML BOTTLE	7/1/2000
21	NDA/MAL/HHP/5570	PANACEA BIOTEC PHARMA LTD	VITACARE LIMITED	SITCOM	PANACEA BIOTEC PHARMA LIMITED-MALPURI BADDI, DISTRICT SOLAN, HIMACHAL PRADESH-173205 - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	7/1/2013
22	NDA/MAL/HHP/5571	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	DRAGON LIQUID BALM	AMRUTANJAN HEALTH CARE LIMITED-PLOT NO 37,38&39, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR VILLAGE, THIRUPORUR TALUK, KANCHEEPURAM DISTRICT 603110, INDIA	INDIA	TOPICAL EXTERNAL OTHER OINTMENTS	1.0X10.0 ML CONTAINER,1.0X5.0 ML CONTAINER	7/1/2004
23	NDA/MAL/HHP/5572	CHARAK PHARMA PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	VIGOMAX FORTE	CHARAK PHARMA PVT LTD-JAURASI ROAD,PAUTI VILLAGE,G.T ROAD,SAMALKHA-132 101 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X20.0 TABLET BLISTER	7/1/2011

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24	NDA/MAL/HHP/5574	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	NEW PINKOO GRIPE WATER	AJANTA PHARMA LIMITED-31-0 MIDC INDUSTRIAL AREA CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA STATE	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X120.0 ML BOTTLE	7/1/2009
25	NDA/MAL/HHP/5576	SHURIK LTD	SHURIK LTD	NO SCAR CREAM	METHA UNANI PHARMACY-METHA UNANI PHARMACY G-524 LODHIKA, G.I.D.C METODA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	7/1/2007
26	NDA/MAL/HHP/5580	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	EUGICA SYRUP	DHG PHARMACEUTICALJOINT-STOCK COMPANY (DHG PHARMA)-NO. 288 BIS, NGUYEN VAN CN STREET, AN HOA WARD, NINHKIEN DISTRICT, CAN THO CITY	VIETNAM	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	7/1/2016
27	NDA/MAL/HHP/5587	CHARAK PHARMA PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	MANOLL SYRUP	CHARAK PHARMA PVT LTD-JAURASI ROAD,PAUTI VILLAGE,G.T ROAD,SAMALKHA-132 101 INDIA CHARAK PHARMA PVT. LTD,- PLOT NO. 371, SAYLI RAKHOLI ROAD, SILVASSA-396 230, D.T. OF DADRA & NAGAR HAVELI. INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X250.0 MG BOTTLE	7/1/2016
28	NDA/MAL/HHP/5588	CHARAK PHARMA PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	KOFOL (HONEY LEMON FLAVOUR)	CHARAK PHARMA PVT LTD,-EVERGREEN INDUSTRIAL ESTATE, SHAUTI MILL LANE, MUMBAI-400011 INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X3.0X4.0 LOZENGE STRIP	7/1/2014
29	NDA/MAL/HHP/5593	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	SYDLER GRIPE WATER	SYDLER REMEDIES PVT LTD -M-190, M.I.D.C, WALUJ, AURANGABAD 431 136 (M.S), INDIA.	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X120.0 ML BOTTLE	7/1/2010

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30	NDA/MAL/HHP/5597	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	TOOCHE DROPS	CIRON DRUGS AND PHARMACEUTICALS PVT LTD-N-118 M.I.D.C, TAAPUR,BOISAR,DIST.THANE MAHARASHTRA INDIA	INDIA	ORAL TOPICAL DROPS	1.0X10.0 ML BOTTLE	7/1/2014
31	NDA/MAL/HHP/5613	DR. KIM AYURVEDIC PHARMACY	J.P.IMPEX PHARMACY (U) LIMITED	SMOOTH COUGH DROPS	DR KIM AYURVEDIC PHARMACY-INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X100.0X2.0 LOZENGE STRIP	7/1/2005
32	NDA/MAL/HHP/5618	SHURIK LTD	SHURIK LTD	VYBRANT	VITAL CARE-INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	5.0X10.0 CAPSULE BLISTER	7/1/2000
33	NDA/MAL/HHP/5620	UNIQUE PHARMACEUTICAL LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	ZECUF COLD RUB	UNIQUE PHARMACEUTICAL LABORATORIES- PLOT NO. 4 PASE IV, GIDC PANOLI -394 116 GUJARAT INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G CONTAINER	7/1/2009
34	NDA/MAL/HHP/5623	UNIQUE PHARMACEUTICAL LABORATORIES	TATA UGANDA LIMITED	ZECUF HERBAL COUGH LOZENGES(FRUITY FLAVOUR)	UNIQUE PHARMACEUTICAL LABORATORIES. - SURVEY NO.101/2 AND 102/1,DAMAN INDUSTRIAL ESTATE, AIRPORT ROAD, KADAIYA, DAMAN-396 210 INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X5.0X4.0 LOZENGE STRIP	7/1/2005
35	NDA/MAL/HHP/5629	UNIQUE PHARMACEUTICAL LABORATORIES	TATA UGANDA LIMITED	ZECUF HERBAL COUGH LOZENGES(ORANGE FLAVOUR)	UNIQUE PHARMACEUTICAL LABORATORIES. - SURVEY NO.101/2 AND 102/1,DAMAN INDUSTRIAL ESTATE, AIRPORT ROAD, KADAIYA, DAMAN-396 210 INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X5.0X4.0 LOZENGE STRIP	7/1/2005

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36	NDA/MAL/HHP/5630	UNIQUE PHARMACEUTICAL LABORATORIES	TATA UGANDA LIMITED	ZECUF HERBAL COUGH REMEDY	UNIQUE PHARMACEUTICAL LABORATORIES -- PLOT NO. 215-219 AND 304 - 308 G.I.D.C. INDUSTRIAL AREA,PANOLI—394 116,INDIA.	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE	7/1/2000
37	NDA/MAL/HHP/5631	UNIQUE PHARMACEUTICAL LABORATORIES	TATA UGANDA LIMITED	ZECUF HERBAL COUGH LOZENGES(LEMON)	UNIQUE PHARMACEUTICAL LABORATORIES. - SURVEY NO.101/2 AND 102/1,DAMAN INDUSTRIAL ESTATE, AIRPORT ROAD, KADAIYA, DAMAN-396 210 INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X5.0X4.0 LOZENGE STRIP	7/1/2014
38	NDA/MAL/HHP/6848	CHARAK PHARMA PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	KOFOL (MINT)	LEAMARK HEALTHCARE PVT LTD-SARKHEJ BAVLA HIGHWAY,MATODA 382213 AHMEDABAD GUJARAT	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X3.0X4.0 LOZENGE BLISTER	7/1/2016
39	NDA/MAL/HHP/6850	WILSHIRE LABORATORIES (PVT) LTD	HEALTHCARE LTD.	BENZIM NATURAL SYRUP 120ML	WILSHIRE LABORATORIES LIMITED-124/1- INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE, PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	12/3/2016
40	NDA/MAL/HHP/6852	WILSHIRE LABORATORIES (PVT) LTD	HEALTHCARE LTD.	DE-FLU SYRUP 120ML	WILSHIRE LABORATORIES LIMITED-124/1- INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE, PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	12/3/2016
41	NDA/MAL/HHP/6853	WILSHIRE LABORATORIES (PVT) LTD	HEALTHCARE LTD.	LIV-LONG TABLET	WILSHIRE LABORATORIES LIMITED-124/1- INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE, PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2016

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42	NDA/MAL/HHP/6863	KREMOINT PHARMA PVT.LTD	GOOD DAY PHARMACY LIMITED	KOFFENGES LOZENGES (HONEY & LEMON FLAVOUR)	KREMOINT PHARMA PVT LTD - RAGHAV ESTATE, K.S.S.I.D.C. INDUSTRIAL ESTATE AREA, SHIGGAON ROAD, SAVANUR 581118, DIST: HAVERI, KARNATAKA, INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X5.0X4.0 LOZENGE BLISTER,1.0X10.0X6.0 LOZENGE BLISTER	12/1/2016
43	NDA/MAL/HHP/6915	GREAT INDIA INDUSTRIAL & PHARAMCEUTICALS LABORATORIES	MALIX PHARMA (U) LIMITED	GIPLA GRIPE WATER	GREAT INDIA -19 SUN MILL COMPOUND	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X135.0 ML BOTTLE	7/1/2014
44	NDA/MAL/HHP/7929	WOCKHARD LTD	STAR PHARMACEUTICALS LTD	MANIX HERBAL CAPSULES	TIRUPATI LIFESCIENCES-NAHAN ROAD, PAONTA SAHIB, DISTT. SIRMOUR HIMACHAL PRADESH-173025, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	7/1/2015
45	NDA/MAL/HHP/7931	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO. LTD	GAMA PHARMACEUTICALS (U) LIMITED	LIBLAB SYRUP	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO. LTD,-NA'UR PRINCE HASHEM BIN AL-HUSSEIN STREET, AMMAN, JORDAN.	JORDAN	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/1/2012
46	NDA/MAL/HHP/7934	STAR PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	SENSUR RUBEFACIENT	GLENMARK PHARMACEUTICAL LIMITED-61-62 COMPOUND, DEWAS NAKA, LASUDIA MORI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE	7/1/2015
47	NDA/MAL/HHP/7936	SQUARE HERBAL AND NUTRACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	GILOBA 60 CAPSULE	SQUARE HERBAL AND NUTRACEUTICALS LTD-48, MOHAKHALI COMMERCIAL AREA, DHAKA-1212	BANGLADESH	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X6.0 CAPSULE BLISTER	7/1/2013

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48	NDA/MAL/HHP/7937	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	SENSUR OIL	GLENMARK PHARMACEUTICAL LIMITED-61-62 COMPOUND, DEWAS NAKA, LASUDIA MORI	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X10.0 ML VIAL	7/1/2015
49	NDA/MAL/HHP/7938	SQUARE HERBAL AND NUTRACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	SILYBIN 140	SQUARE HERBAL AND NUTRACEUTICALS LTD-48 MOHAKHALI COMERCIAL AREA, DHAKA-1212	BANGLADESH	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	7/1/2013
50	NDA/MAL/HHP/7939	SQUARE HERBAL AND NUTRACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	GINTEX	SQUARE HERBAL AND NUTRACEUTICALS LTD-48, MOHAKHALI COMMERCIAL AREA, DHAKA-1212	BANGLADESH	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X6.0 CAPSULE STRIP	7/1/2014
51	NDA/MAL/HHP/7940	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	SENSUR LOTION	GLENMARK PHARMACEUTICAL LIMITED-61-62 COMPOUND, DEWAS NAKA, LASUDIA MORI SYDLER REMEDIES-PRIM-190, MIDC, WALUJ, AURANGABAD-431136, MAHARASHTRA, INDIA	INDIA	TOPICAL EXTERNAL OTHER CREAMS	1.0X50.0 ML BOTTLE	7/1/2015
52	NDA/MAL/HHP/7942	MEGA LIFESCSCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	EUGICA FORT	DHG PHARMACEUTICALJOINT-STOCK COMPANY (DHG PHARMA)-NO. 288 BIS, NGUYEN VAN CN STREET, AN HOA WARD, NINH KIEN DISTRICT, CAN THO CITY	THAILAND	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/2016
53	NDA/MAL/HHP/7946	SHEBAC PHARMA	NORVIK ENTERPRISES LIMITED	APONTIS	AEROMAC (INDIA) INC-12, MELDI ESTATE, GOTA AHMEDABAD -382481, GUJARAT, INDIA	INDIA	TOPICAL EXTERNAL SPRAYS WITHOUT GAS	1.0X150.0 ML BOTTLE	7/1/2015

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54	NDA/MAL/HHP/7947	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICALS LTD)	TATA UGANDA LIMITED	ZECUF HERBAL COUGH LOZENGES(HONEY LEMON)	UNIQUE PHARMACEUTICAL LABORATORIES. - SURVEY NO.101/2 AND 102/1,DAMAN INDUSTRIAL ESTATE, AIRPORT ROAD, KADAIYA, DAMAN-396 210 INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X5.0X4.0 LOZENGE STRIP	7/1/2014
55	NDA/MAL/HHP/7949	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICALS LTD)	TATA UGANDA LIMITED	ZECUF HERBAL COUGH (SUGAR FREE)	UNIQUE PHARMACEUTICAL LABORATORIES -- PLOT NO. 215-219 AND 304 - 308 G.I.D.C. INDUSTRIAL AREA,PANOLI—394 116,INDIA.	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X2.0X12.0 LOZENGE CONTAINER	7/1/2016
56	NDA/MAL/HHP/7950	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICALS LTD)	TATA UGANDA LIMITED	ZECUF HERBAL COUGH LOZENGES(RASPBERRY)	UNIQUE PHARMACEUTICAL LABORATORIES. - SURVEY NO.101/2 AND 102/1,DAMAN INDUSTRIAL ESTATE, AIRPORT ROAD, KADAIYA, DAMAN-396 210 INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X5.0X4.0 LOZENGE STRIP	7/1/2014
57	NDA/MAL/HHP/7954	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICALS LTD)	TATA UGANDA LIMITED	ZECUF HERBAL COUGH LOZENGES(PINEAPPLE)	UNIQUE PHARMACEUTICAL LABORATORIES. - SURVEY NO.101/2 AND 102/1,DAMAN INDUSTRIAL ESTATE, AIRPORT ROAD, KADAIYA, DAMAN-396 210 INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X5.0X4.0 LOZENGE STRIP	7/1/2014
58	NDA/MAL/HHP/7955	KREMOINT PHARMA PVT.LTD	PLANET PHARMACEUTICALS UGANDA LTD	DICLODAY ROLL-ON	KREMOINT PHARMA PVT LTD-B-8,ADDITIONAL AMBERNATH MIDC, AMBERNATH (E),DIST: THANE 421506, INDIA	INDIA	TOPICAL EXTERNAL EMULSIONS	1.0X50.0 ML BOTTLE	12/3/2016
59	NDA/MAL/HHP/7956	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICALS LTD)	TATA UGANDA LIMITED	ZECUF HERBAL (SUGAR FREE)	UNIQUE PHARMACEUTICAL LABORATORIES. - SURVEY NO.101/2 AND 102/1,DAMAN INDUSTRIAL ESTATE, AIRPORT ROAD, KADAIYA, DAMAN-396 210 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/1/2015

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60	NDA/MAL/HHP/7958	KREMOINT PHARMA PVT.LTD	GOOD DAY PHARMACY LIMITED	KOFFENGES(GINGER FLAVOUR)	KREMOINT PHARMA PVT LTD - -RAGHAV ESTATE, K.S.S.I.D.C. INDUSTRIAL ESTATE AREA, SHIGGAON ROAD, SAVANUR 581118, DIST: HAVERI, KARNATAKA, INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X5.0X4.0 LOZENGE BLISTER,1.0X10.0X6.0 LOZENGE BLISTER	12/1/2016
61	NDA/MAL/HHP/7959	BHARGAVA PHYTO LAB PVT. LTD	PLANET PHARMACEUTICALS UGANDA LTD	TONIPHIB	BHARGAVA PHYTO LAB PVT. LTD -E-1216, PHASE - 1, EXTN. GHATAL, BHIWADI INDUSTRIAL AREA, BHIWADI (RAJ.) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER	7/1/2015
62	NDA/MAL/HHP/7960	KREMOINT PHARMA PVT.LTD	GOOD DAY PHARMACY LIMITED	KOFFENGES(ORANGE FLAVOUR)	KREMOINT PHARMA PVT LTD - -RAGHAV ESTATE, K.S.S.I.D.C. INDUSTRIAL ESTATE AREA, SHIGGAON ROAD, SAVANUR 581118, DIST: HAVERI, KARNATAKA, INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X5.0X4.0 LOZENGE BLISTER,1.0X10.0X6.0 LOZENGE BLISTER	12/1/2016
63	NDA/MAL/HHP/7961	KREMOINT PHARMA PVT.LTD	GOOD DAY PHARMACY LIMITED	KOFFENGES LOZENGES MINT	KREMOINT PHARMA PVT LTD - -RAGHAV ESTATE, K.S.S.I.D.C. INDUSTRIAL ESTATE AREA, SHIGGAON ROAD, SAVANUR 581118, DIST: HAVERI, KARNATAKA, INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X5.0X4.0 LOZENGE BLISTER,1.0X10.0X6.0 LOZENGE BLISTER	12/1/2016
64	NDA/MAL/HHP/7962	GOOD DAY PHARMACY LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	KREMOINT BABY CARE GRIPE WATER	KREMOINT PHARMA PVT LTD---B-8 ADDITIONAL AMBERNATH MIDC OPP. ANAND NAGAR POLICE CHECK POST AMBERNATH (E) DIST THANE 421 506	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X135.0 ML BOTTLE	7/1/2015
65	NDA/MAL/HHP/7965	BHARGAVA PHYTO LAB PVT. LTD	PLANET PHARMACEUTICALS UGANDA LTD	CO-EX	BHARGAVA PHYTO LAB PVT. LTD -E-1216, PHASE - 1, EXTN. GHATAL, BHIWADI INDUSTRIAL AREA, BHIWADI (RAJ.) INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE	7/1/2017

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66	NDA/MAL/HHP/7966	BHARGAVA PHYTOLAB PVT LTD	PLANET PHARMACEUTICAL S UGANDA LTD	KIDFLAME	BHARGAVA PHYTOLAB PVT LTD-B-92, SECTOR - 2 , NOIDA – 201301, U.P. (INDIA)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X5.0 TABLET BLISTER	7/1/2015
67	NDA/MAL/HHP/7974	WILSHIRE LABORATORIES (PVT) LTD	HEALTHCARE LTD.	APPERIZE SYRUP 120ML	WILSHIRE LABORATORIES (PVT) LTD-124/1 INDUSTRIAL AREA, KOT LAKHPAT LAHORE PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	1/15/2019
68	NDA/MAL/HHP/8071	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MOOVE MASSAGE CREAM	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	TOPICAL EXTERNAL LOTIONS	1.0X1.0X40.0 G TUBE	7/1/2017
69	NDA/MAL/HHP/8094	BHARGAVA PHYTOLAB PVT. LTD	PLANET PHARMACEUTICAL S UGANDA LTD	POSTORAL	BHARGAVA PHYTOLAB PVT. LTD -E-1216, PHASE – 1, EXTN. GHATAL, BHIWADI INDUSTRIAL AREA, BHIWADI (RAJ.) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X15.0 TABLET BLISTER	7/1/2017
70	NDA/MAL/HHP/8215	AMRUTANJAN HEALTH CARE LTD	ABACUS PHARMA (AFRICA) LIMITED	AMRUTANJAN DRAGON BACK PAIN ROLL-ON	AMRUTANJAN HEALTH CARE LIMITED - -PLOT NO.14, INDUSTRIAL DEVELOPMENT AREA, UPPAL HYDERABAD - 500039, INDIA	INDIA	TOPICAL EXTERNAL LOTIONS	1.0X50.0 ML CONTAINER	7/1/2004
71	NDA/MAL/HHP/8220	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	NOCOLIC	AJANTA PHARMA LTD - -31-0 M.I.D.C. INDUSTRIAL AREA CHIKALTHANA- AURANGABAD 431210 DIST AURANGABAD	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X120.0 ML BOTTLE	7/1/2017

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72	NDA/MAL/HHP/8379	CHARAK PHARMA PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	M2 TONE TABLET	CHARAK PHARMA PVT LTD-INDUSTRIALESTATE, SHAUTI MILL LANE, MUMBAI-400011	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE	9/20/2017
73	NDA/MAL/HHP/8457	BHARGAVA PHYTO LAB PVT. LTD	PLANET PHARMACEUTICALS UGANDA LTD	GASTICA SYRUP	BHARGAVA PHYTO LAB PVT.LTD-E-1216 PHASE-1, EXTN. GHATAL,BHIWADI INDUSTRIAL AREA, BHIWADI(RAJ.) INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	7/1/2017
74	NDA/MAL/HHP/8505	CHARAK PHARMA PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	LIVOMYN SYRUP	CHARAK PHARMA PVT LTD-INDUSTRIALESTATE, SHAUTI MILL LANE, MUMBAI-400011	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X200.0 ML BOTTLE	2/2/2018
75	NDA/MAL/HHP/8506	CHARAK PHARMA PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	ALKA 5 SYRUP	CHARAK PHARMA PVT. LTD,-PLOT NO. 371, SAYLI RAKHOLI ROAD, SILVASSA-396 230, D.T. OF DADRA & NAGAR HAVELI. INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	2/2/2018
76	NDA/MAL/HHP/8508	CHARAK PHARMA PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	KOFOL SF SYRUP	CHARAK PHARMA PVT LTD-INDUSTRIALESTATE, SHAUTI MILL LANE, MUMBAI-400011	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	2/2/2018
77	NDA/MAL/HHP/8509	CHARAK PHARMA PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	EVANOVA CAPSULE	CHARAK PHARMA PVT LTD-INDUSTRIALESTATE, SHAUTI MILL LANE, MUMBAI-400011	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X20.0 CAPSULE BLISTER	11/29/2017

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78	NDA/MAL/HHP/8511	BHARGAVA PHYTOLAB PVT. LTD	PLANET PHARMACEUTICAL S UGANDA LTD	THUNDER-M	BHARGAVA PHYTOLAB PVT. LTD -E-1216, PHASE – 1, EXTN. GHATAL, BHIWADI INDUSTRIAL AREA, BHIWADI (RAJ.) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2017
79	NDA/MAL/HHP/8512	BHARGAVA PHYTOLAB PVT. LTD	PLANET PHARMACEUTICAL S UGANDA LTD	INFAB SYRUP	BHARGAVA PHYTOLAB PVT. LTD -E-1216, PHASE – 1, EXTN. GHATAL, BHIWADI INDUSTRIAL AREA, BHIWADI (RAJ.) INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	7/1/2017
80	NDA/MAL/HHP/8513	BHARGAVA PHYTOLAB PVT. LTD	PLANET PHARMACEUTICAL S UGANDA LTD	MENIPHIB	BHARGAVA PHYTOLAB PVT. LTD -E-1216, PHASE – 1, EXTN. GHATAL, BHIWADI INDUSTRIAL AREA, BHIWADI (RAJ.) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X20.0 TABLET BLISTER	7/1/2016
81	NDA/MAL/HHP/8548	ARTURA PHARMACEUTICALS PVT LTD	SWASTIK PHARMACEUTICAL LTD	PEPSOL	ARTURA PHARMACEUTICALS PVT LTD-PLOT NO. 1505 PORTIA ROAD SIRI CITY SEZ SATYAVEDU MANDAL CHITTOOR DISTRICT ANDHRA PRADESHI - 517 588 INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	10/24/2017
82	NDA/MAL/HHP/8552	AMRUTANJAN HEALTHCARE LIMITE	ABACUS PHARMA (AFRICA) LIMITED	AMRUTANJAN DRAGON BALM	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, TAMIL NADU	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X10.0 ML TUBE	11/24/2017
83	NDA/MAL/HHP/8553	RAZA INTERNATIONAL	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HONEY CURE	OZONE COSMETICS & NATURAL PRODUCTS MANUFACTURING COMPANYV- SHARA BADRAN, MARJ ALFARAS, INDUSTRIAL ZONE, MUSAWAA STREET. OZONE INDUSTRIAL COMPLEX. P.O. BOX : 1764. AMMAN 11953, JORDAN	JORDAN	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE,1.0X15.0 G TUBE	7/13/2017

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84	NDA/MAL/HHP/8556	MANKIND PHARMA LTD.	TATA UGANDA LIMITED	UNIORTHO-500	TIRUPATI LIFESCIENCES-NAHAN ROAD, PAONTA SAHIB, DISTT. SIRMOUR HIMACHAL PRADESH-173025, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER	11/10/2017
85	NDA/MAL/HHP/8557	MANKIND PHARMA LTD.	TATA UGANDA LIMITED	UNIORTHO-250	TIRUPATI LIFESCIENCES-NAHAN ROAD, PAONTA SAHIB, DISTT. SIRMOUR HIMACHAL PRADESH-173025, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER	11/10/2017
86	NDA/MAL/HHP/8837	PILLAR PHARMA LIMITED	PILLAR LOGISTICS LIMITED	HEPTOVIT	MILLENNIUM HERBAL CARE LTD-12B, NIRMAL, 241/242, BACKBAY RECLAMATION, NARIMAN POINT, MUMBAI 400 021	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	6/7/2018
87	NDA/MAL/HHP/8902	WILSHIRE LABORATORIES (PVT) LTD	HEALTHCARE LTD.	DE-TUZ SYRUP	WILSHIRE LABORATORIES (PVT) LTD-124/1 INDUSTRIAL AREA, KOT LAKHPAT LAHORE PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	7/1/2018
88	NDA/MAL/HHP/9090	I_CARE PHARMA LIMITED	AIVEEN (U) LIMITED	FATNILE	WEST COAST PHARMACEUTICAL WORKS LTD-1143,MELDI ESTATE,NR PRASANG PARTY PLOT,GOTA, AHMEDEBAD	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X4.0X15.0 CAPSULE BLISTER	1/28/2019
89	NDA/MAL/HHP/9091	UNOSOURCE PHARMA LTD	ESCORTS PHARMACEUTICALS LIMITED	KOFCLEAN SYRUP (HERBAL COUGH SYRUP)	MAXCURE NUTRAVEDICS LTD -PLOT NO.13 SEC-6A IIE,SIDCUL,RANIPUR,HARIDWAR-249 403, UTTRAKHAND	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	1/28/2019

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90	NDA/MAL/HHP/9093	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	COFTA EXTRA SYRUP	BETA HEALTHCARE INTERNATIONAL LTD - PLOT NO LR 209/6534 MOGADISHU ROAD	KENYA	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE	3/22/2019
91	NDA/MAL/HHP/9094	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	BETASIL HERBAL COUGH SYSRUP	BETA HEALTHCARE INTERNATIONAL LTD - PLOT NO LR 209/6534 MOGADISHU ROAD	KENYA	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE	3/22/2019
92	NDA/MAL/HHP/9095	WILSHIRE LABORATORIES (PVT) LTD	HEALTHCARE LTD.	X-TREME	WILSHIRE LABORATORIES (PVT) LTD-124/1 INDUSTRIAL AREA, KOT LAKHPAT LAHORE PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	4/23/2019
93	NDA/MAL/HHP/9099	HINUCON	BOOTS PHARMACEUTICALS LIMITED	CRAN MAX PRO SACHET	HINUCON -PLOT NO.12/1 SECTOR 15,KORANGI INDUSTRIAL AREA, KARACHI 9TH FLOOR PROGRESSIVE PLAZA,BEAUMONT ROAD,KARACHI,PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X10.0 SACHET CARTON	5/31/2019
94	NDA/MAL/HHP/9100	HINUCON	BOOTS PHARMACEUTICALS LIMITED	FIBO SACHET	HINUCON -PLOT NO.12/1 SECTOR 15,KORANGI INDUSTRIAL AREA, KARACHI 9TH FLOOR PROGRESSIVE PLAZA,BEAUMONT ROAD,KARACHI,PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X10.0 SACHET CARTON	5/31/2019
95	NDA/MAL/HHP/9101	HINUCON	BOOTS PHARMACEUTICALS LIMITED	FIBO SYRUP	HINUCON -PLOT NO.12/1 SECTOR 15,KORANGI INDUSTRIAL AREA, KARACHI 9TH FLOOR PROGRESSIVE PLAZA,BEAUMONT ROAD,KARACHI,PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	5/31/2019

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96	NDA/MAL/HHP/9102	HINUCON	BOOTS PHARMACEUTICALS LIMITED	EPTI SYRUP	HINUCON -PLOT NO.12/1 SECTOR 15,KORANGI INDUSTRIAL AREA, KARACHI 9TH FLOOR PROGRESSIVE PLAZA,BEAUMONT ROAD,KARACHI,PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	5/31/2019
97	NDA/MAL/HHP/9103	HINUCON	BOOTS PHARMACEUTICALS LIMITED	HILGAS SYRUP	HINUCON -PLOT NO.12/1 SECTOR 15,KORANGI INDUSTRIAL AREA, KARACHI 9TH FLOOR PROGRESSIVE PLAZA,BEAUMONT ROAD,KARACHI,PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	5/31/2019
98	NDA/MAL/HHP/9104	HINUCON	BOOTS PHARMACEUTICALS LIMITED	COLOREST DROPS	HINUCON -PLOT NO.12/1 SECTOR 15,KORANGI INDUSTRIAL AREA, KARACHI 9TH FLOOR PROGRESSIVE PLAZA,BEAUMONT ROAD,KARACHI,PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY DROPS	1.0X30.0 ML BOTTLE	5/31/2019
99	NDA/MAL/HHP/9105	HINUCON	BOOTS PHARMACEUTICALS LIMITED	RIMONA CAPSULES	HINUCON -PLOT NO.12/1 SECTOR 15,KORANGI INDUSTRIAL AREA, KARACHI 9TH FLOOR PROGRESSIVE PLAZA,BEAUMONT ROAD,KARACHI,PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	5/31/2019
100	NDA/MAL/HHP/9121	HINUCON	BOOTS PHARMACEUTICALS LIMITED	HILGAS INSTANT SACHET	HINUCON -PLOT NO.12/1 SECTOR 15,KORANGI INDUSTRIAL AREA, KARACHI 9TH FLOOR PROGRESSIVE PLAZA,BEAUMONT ROAD,KARACHI,PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X10.0 SACHET CARTON	3/11/2020
101	NDA/MAL/HHP/9122	HINUCON	BOOTS PHARMACEUTICALS LIMITED	COFERB DROPS	HINUCON -PLOT NO.12/1 SECTOR 15,KORANGI INDUSTRIAL AREA, KARACHI 9TH FLOOR PROGRESSIVE PLAZA,BEAUMONT ROAD,KARACHI,PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY DROPS	1.0X20.0 ML BOTTLE	3/11/2020

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102	NDA/MAL/HHP/9123	HINUCON	BOOTS PHARMACEUTICALS LIMITED	COFERB PLUS SYRUP	HINUCON -PLOT NO.12/1 SECTOR 15,KORANGI INDUSTRIAL AREA, KARACHI 9TH FLOOR PROGRESSIVE PLAZA,BEAUMONT ROAD,KARACHI,PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	3/11/2020
103	NDA/MAL/HHP/9125	HINUCON	BOOTS PHARMACEUTICALS LIMITED	RIMONA SACHET	HINUCON -PLOT NO.12/1 SECTOR 15,KORANGI INDUSTRIAL AREA, KARACHI 9TH FLOOR PROGRESSIVE PLAZA,BEAUMONT ROAD,KARACHI,PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X10.0 SACHET CARTON	3/11/2020
104	NDA/MAL/HHP/9126	HINUCON	BOOTS PHARMACEUTICALS LIMITED	CRANMAX AQUA SYRUP	HINUCON -PLOT NO.12/1 SECTOR 15,KORANGI INDUSTRIAL AREA, KARACHI 9TH FLOOR PROGRESSIVE PLAZA,BEAUMONT ROAD,KARACHI,PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	3/11/2020
105	NDA/MAL/HHP/9127	HINUCON	BOOTS PHARMACEUTICALS LIMITED	FIBO JAR	HINUCON -PLOT NO.12/1 SECTOR 15,KORANGI INDUSTRIAL AREA, KARACHI 9TH FLOOR PROGRESSIVE PLAZA,BEAUMONT ROAD,KARACHI,PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X175.0 G JAR	3/11/2020
106	NDA/MAL/HHP/9128	HINUCON	BOOTS PHARMACEUTICALS LIMITED	ELFERB SYRUP	HINUCON -PLOT NO.12/1 SECTOR 15,KORANGI INDUSTRIAL AREA, KARACHI 9TH FLOOR PROGRESSIVE PLAZA,BEAUMONT ROAD,KARACHI,PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	3/11/2020
107	NDA/MAL/HHP/9179	CHARAK PHARMA PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	ADDYZOA CAPSULES	CHARAK PHARMA PVT. LTD,-PLOT NO. 371, SAYLI RAKHOLI ROAD, SILVASSA-396 230, D.T. OF DADRA & NAGAR HAVELI. INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X20.0 CAPSULE BLISTER	1/29/2020

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108	NDA/MAL/HHP/9181	REDDYS PHARMA LIMITED	REDDYS PHARMA LIMITED	ZEBRA	GREAT INDIA INDUSTRIAL AND PHARMACEUTICAL LABORATORIES-19,SUN MILLS COMPD,MUMBAI 400 013	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X1 20.0 ML BOTTLE,1.0X1 35.0 ML BOTTLE	3/11/2020
109	NDA/MAL/HHP/9185	HEALTHCARE LTD.	HEALTHCARE LTD.	GINSEMEX-F	ZEE LABORATORIES LTD-BEHIND 47, INDUSTRIAL AREA, PAONTA SAHIB-173025 DISTT. SIRMOUR HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X15.0 CAPSULE BLISTER	5/22/2020
110	NDA/MAL/HHP/9254	UNIQUE PHARMACEUTICALS LABORATORIES	TATA UGANDA LIMITED	ZECUF HERBAL COUGH LOZENGES STRAWBERRY FLAVOUR	UNIQUE PHARMACEUTICAL LABORATORIES ;- SURVEY NO. 101/2 & 102/1, DAMAN INDUSTRIAL ESTATE, KAPAIYA, DAMAN 396210	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X5.0X4.0 LOZENGE STRIP	7/18/2020
111	NDA/MAL/HHP/9330	ECHO PHARMACY	ECHO PHARMACY (U) LIMITED	HEMOZEL CREAM	ALFA MANUFACTURING LLC-4701 NW. 77 AVENUE,MIAMI,FL 33166	UNITED STATES	TOPICAL EXTERNAL CREAMS	1.0X40.0 G TUBE	8/7/2020
112	NDA/MAL/HHP/9332	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	EUGICA IVY SYRUP	MEGA LIFESCIENCES PUBLIC CO. LTD-PLANT 1; 384 MOO 4, SOI 6, BANGPOO INDUSTRIAL ESTATE, PATTANA 3 ROAD, PHRAEKSA, MUEANG, SAMUTPRAKARN 10280 THAILAND	THAILAND	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	8/31/2020
113	NDA/MAL/HHP/9333	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	EUGICA MOUTH SPRAY	MEGA LIFESCIENCES PUBLIC CO. LTD-PLANT 1; 384 MOO 4, SOI 6, BANGPOO INDUSTRIAL ESTATE, PATTANA 3 ROAD, PHRAEKSA, MUEANG, SAMUTPRAKARN 10280 THAILAND	THAILAND	ORAL TOPICAL SPRAYS WITHOUT GAS	1.0X10.0 ML BOTTLE	8/31/2020

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114	NDA/MAL/HHP/9334	NABROS PHARMA PVT LTD.	SHREEJI PHARMACEUTICALS LIMITED	KOFANOL	NABROS PHARMA PVT LTD-SURVEY NO. 110/A/2, AMIT FARM JAIN UPASRAYA, NEAR COCACOLA FACTORY, NH NO. 8, KAJIPURA, DIST. KHEDA-387411, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X25.0X4.0 TABLET STRIP	9/17/2020
115	NDA/MAL/HHP/9335	SYDLER REMEDIES PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	EAZOL HERBAL COUGH LOZENGES (RASPBERRY FLAVOUR)	SYDLER REMEDIES-PRIM-190, MIDC, WALUJ, AURANGABAD-431136, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X5.0X4.0 LOZENGE STRIP	9/23/2020
116	NDA/MAL/HHP/9336	SYDLER REMEDIES PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	EAZOL HERBAL COUGH LOZENGES (MINT FLAVOUR)	SYDLER REMEDIES-PRIM-190, MIDC, WALUJ, AURANGABAD-431136, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X5.0X4.0 LOZENGE STRIP	9/23/2020
117	NDA/MAL/HHP/9337	SYDLER REMEDIES PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	EAZOL HERBAL COUGH LOZENGES (PINEAPPLE FLAVOUR)	SYDLER REMEDIES-PRIM-190, MIDC, WALUJ, AURANGABAD-431136, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X5.0X4.0 LOZENGE STRIP	9/23/2020
118	NDA/MAL/HHP/9338	SYDLER REMEDIES PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	EAZOL HERBAL COUGH LOZENGES (ORANGE FLAVOUR)	SYDLER REMEDIES-PRIM-190, MIDC, WALUJ, AURANGABAD-431136, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X5.0X4.0 LOZENGE STRIP	9/23/2020
119	NDA/MAL/HHP/9339	SYDLER REMEDIES PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	EAZOL HERBAL COUGH LOZENGES (STRAWBERRY FLAVOUR)	SYDLER REMEDIES-PRIM-190, MIDC, WALUJ, AURANGABAD-431136, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X5.0X4.0 LOZENGE STRIP	9/23/2020

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120	NDA/MAL/HHP/9341	SINO AFRICA MEDICALS AND HEALTHY LTD	SINO AFRICA MEDICINES & HEALTH LTD	LIANHUA QINGWEN CAPSULE	SHIJIAZHUANG YILING PHARMACEUTICAL CO.,LTD-NO. 238 TIANSHAN STREET, HIGH-TECH AREA, SHIJIAZHUANG, HEBEI PROVINCE	CHINA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X24.0 CAPSULE BLISTER	10/15/2020
121	NDA/MAL/HHP/9342	GAYATRI AYUPHARMA PRIVATE LIMITED	SONA PHARMACEUTICALS LIMITED	LOZETS- ORANGE	PRINCE SUPPLICO-PLOT NO. 90-A, G.I.D.C, CHITRA, BHAVNAGAR	INDIA	ORAL TOPICAL LOZENGES	1.0X2.0X12.0 LOZENGE BLISTER	11/5/2020
122	NDA/MAL/HHP/9343	GAYATRI AYUPHARMA PRIVATE LIMITED	SONA PHARMACEUTICALS LIMITED	LOZETS-WARM GINGER	PRINCE SUPPLICO-PLOT NO. 90-A, G.I.D.C, CHITRA, BHAVNAGAR	INDIA	ORAL TOPICAL LOZENGES	1.0X2.0X12.0 LOZENGE BLISTER	11/5/2020
123	NDA/MAL/HHP/9344	GAYATRI AYUPHARMA PRIVATE LIMITED	SONA PHARMACEUTICALS LIMITED	LOZETS- COOL MINT	PRINCE SUPPLICO-PLOT NO. 90-A, G.I.D.C, CHITRA, BHAVNAGAR	INDIA	ORAL TOPICAL LOZENGES	1.0X2.0X12.0 LOZENGE BLISTER	11/5/2020
124	NDA/MAL/HHP/9483	LIBRA DRUGS INDIA	VEERAM HEALTHCARE (U) LIMITED	GLYTUSS NATURAL COUGH SUPPRESSANT WITH HONEY	LIBRA DRUGS INDIA-145/146/92 B, MANGALWAR PETH,PARGE CHOWK, PUNE - 411011,MAHARASTRA, INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X150.0 ML BOTTLE,1.0X200.0 ML BOTTLE,1.0X300.0 ML BOTTLE	12/11/2020
125	NDA/MAL/HHP/9484	RUSAN PHARMA LTD	NORVIK ENTERPRISES LIMITED	ISPAHUSK ORANGE	RUSAN PHARMA LTD'-PLOT NO. 59 - 65, SECTOR II, KANDLA SPECIAL - ECONOMIC ZONE, GANDHIDHAM	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X30.0X3.5 G SACHET	1/27/2021

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126	NDA/MAL/HHP/9485	AL-HIKMA FZCO VISION TOWER	GOODMAN INTERNATIONAL LTD	LOZATY - PEPPERMINT	MEKSMAR NATURAL AND HEALTHY PRODUCTS PRODUCTION AND MARKETING LTD.CO-1333. STREET NO: 27 06370 IVEDIK O.S,B / ANKARA- TURKEY	TURKEY	ORAL SOLID ORDINARY LOZENGES	1.0X24.0 LOZENGE BLISTER	1/27/2021
127	NDA/MAL/HHP/9486	AL-HIKMA FZCO VISION TOWER	GOODMAN INTERNATIONAL LTD	LOZATY- GINGER	MEKSMAR NATURAL AND HEALTHY PRODUCTS PRODUCTION AND MARKETING LTD.CO-1333. STREET NO: 27 06370 IVEDIK O.S,B / ANKARA- TURKEY	TURKEY	ORAL SOLID ORDINARY LOZENGES	1.0X24.0 LOZENGE CARTON	1/27/2021
128	NDA/MAL/HHP/9487	AL-HIKMA FZCO VISION TOWER	GOODMAN INTERNATIONAL LTD	LOZATY - ORANGE	MEKSMAR NATURAL AND HEALTHY PRODUCTS PRODUCTION AND MARKETING LTD.CO-1333. STREET NO: 27 06370 IVEDIK O.S,B / ANKARA- TURKEY	TURKEY	ORAL SOLID ORDINARY LOZENGES	1.0X24.0 LOZENGE CARTON	1/27/2021
129	NDA/MAL/HHP/9488	AL-HIKMA FZCO VISION TOWER	GOODMAN INTERNATIONAL LTD	LOZATY- HONEY AND LEMON	MEKSMAR NATURAL AND HEALTHY PRODUCTS PRODUCTION AND MARKETING LTD.CO-1333. STREET NO: 27 06370 IVEDIK O.S,B / ANKARA- TURKEY	TURKEY	ORAL SOLID ORDINARY LOZENGES	1.0X24.0 LOZENGE CARTON	1/27/2021
130	NDA/MAL/HHP/9489	KALBE INTERNATIONAL PTE LTD	ABACUS PHARMA (AFRICA) LIMITED	WOOD'S HERBAL COUGH SYRUP	PT.KALBE FARMA TBK-JL.M.H.THAMRIN BLOK A3-1, KAWASAN INDUSTRI DELTA SILIKON,LIPPO CIKARANG,BEKASI-	INDONESIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	2/9/2021
131	NDA/MAL/HHP/9558	HEALTHCARE LTD.	HEALTHCARE LTD.	DR.ZEE HERBAL VAPOREX	ZEE LABORATORIES LTD-BEHIND 47, INDUSTRIAL AREA, PAONTA SAHIB-173025 DISTT. SIRMOUR HIMACHAL PRADESH	INDIA	NASAL TOPICAL OINTMENTS	1.0X25.0 G JAR	3/1/2021

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132	NDA/MAL/HHP/9559	SYDLER REMEDIES PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	EAZOL MOUTH ULCER GEL	SYDLER REMEDIES-PRIM-190, MIDC, WALUJ, AURANGABAD-431136, MAHARASHTRA, INDIA	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X10.0 G TUBE	3/1/2021
133	NDA/MAL/HHP/9568	BHARGAVA PHYTO LAB PVT LTD	SHREEJI CARE LIMITED	JAGUAR POWER	BHARGAVA PHYTO LAB PVT.LTD-E-1216 PHASE-1, EXTN. GHATAL,BHIWADI INDUSTRIAL AREA, BHIWADI(RAJ.) INDIA	INDIA	ORAL LIQUID ORDINARY OTHER LIQUIDS	1.0X10.0 G BOTTLE	3/5/2021
134	NDA/MAL/HHP/9569	CHEMICURE LABORATORIES PVT. LTD.	GOOD DAY PHARMACY LIMITED	VYPOGERM	CHEMICURE LABORATORIES PVT. LTD-325, CHARAK MARG, UDAIPUR -313001	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TIN,1.0X12.0X18.0 G TIN	3/18/2021
135	NDA/MAL/HHP/9570	GAYATRI AYUPHARMA PRIVATE LIMITED	SONA PHARMACEUTICALS LIMITED	BIO-SLIM ACTIVE	GAYATRI AYUPHARMA PRIVATE LIMITED-234/2/2, PATEL ESTATE, NIKOL ROAD, AHMEDABAD: 382 350, GUJARAT (INDIA)	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X6.0X10.0 CAPSULE BLISTER	3/22/2021
136	NDA/MAL/HHP/9571	BHARGAVA PHYTO LAB PVT LTD	SONA PHARMACEUTICALS LIMITED	HERO LIQUID BALM	BHARGAVA PHYTO LAB PVT.LTD-E-1216 PHASE-1, EXTN. GHATAL,BHIWADI INDUSTRIAL AREA, BHIWADI(RAJ.) INDIA	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X10.0 ML BOTTLE	4/15/2021
137	NDA/MAL/HHP/9680	SOUTH INDIA RESEARCH INSTITUTE PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	TTK GRIPE WATER	SOUTH INDIA RESEARCH INSTITUTE PVT.LTD-SIRINAGAR, VIJAYAWADA – 520 007. INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X130.0 ML BOTTLE	6/17/2021

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138	NDA/MAL/HHP/9693	SYDLER REMEDIES PVT LTD M-190	ABACUS PHARMA (AFRICA) LIMITED	EAZOL COUGH SYRUP	SYDLER REMEDIES-PRIM-190, MIDC, WALUJ, AURANGABAD-431136, MAHARASHTRA, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/19/2021
139	NDA/MAL/HHP/9694	GRIFFON BIOMETRIX PVT.LTD	ABACUS PHARMA (AFRICA) LIMITED	THROWCUF SYRUP	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- - 382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/22/2021
140	NDA/MAL/HHP/9700	GRIFFON BIOMETRIX PVT.LTD	METRO PHARMACEUTICALS LIMITED	TOTO GRIPE WATER	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- - 382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X120.0 ML BOTTLE	8/27/2021
141	NDA/MAL/HHP/9701	GRIFFON BIOMETRIX PVT.LTD	ABACUS PHARMA (AFRICA) LIMITED	THROWCUF PLUS SYRUP	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- - 382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE	8/27/2021
142	NDA/MAL/HHP/9702	GRIFFON BIOMETRIX PVT.LTD	METRO PHARMACEUTICALS LIMITED	GRIFFON STRONG BALM	RAJESH PHARMACEUTICALS-7, DESHVALI,CHANDLODIYA ROAD,AHMEDABAD, GUJARAT 382 481	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X9.0 ML BOTTLE	8/27/2021
143	NDA/MAL/HHP/9703	GRIFFON BIOMETRIX PVT.LTD	ABACUS PHARMA (AFRICA) LIMITED	CURODEX OINTMENT	RAJESH PHARMACEUTICALS-7, DESHVALI,CHANDLODIYA ROAD,AHMEDABAD, GUJARAT 382 481	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G BOTTLE	8/27/2021

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144	NDA/MAL/HHP/9704	GRIFFON BIOMETRIX PVT.LTD	ABACUS PHARMA (AFRICA) LIMITED	MENTHOXYL INHALER	RAJESH PHARMACEUTICALS-7, DESHVALI,CHANDLODIYA ROAD,AHMEDABAD, GUJARAT 382 481	INDIA	NASAL TOPICAL LIQUID INHALATIONS	1.0X0.5 ML INHALER	8/27/2021

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