

PROVISIONAL HUMAN HERBAL REGISTER - NOVEMBER 2022

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/10011	GRIFFON BIOMETRIX PVT.LTD	METRO PHARMACEUTICALS LIMITED	GRIFFON BALM	ZOETIS MANUFACTURING AND RESEARCH SPAIN, S.L-CTRA. DE CAMPRODIN, S/N, FINCA LA RIBA, VALL DE BIANYA, 17813, GIRONA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X10.0 G BOTTLE	28/02/2022
2	NDA/MAL/HHP/10012	REVITAL HEALTHCARE (EPZ) LTD	REVITAL HEALTH CARE LTD	PILEENO OINTMENT	PAUL BROOKS HOMOEOPATHY LABS-A-69, PHASE 1,SITE SUPER HIGHWAY INDUSTRIAL AREA, SCHEME 33,KARACHI-PAKISTAN	PAKISTAN	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE	28/02/2022
3	NDA/MAL/HHP/10013	REVITAL HEALTHCARE (EPZ) LTD	REVITAL HEALTH CARE LTD	SLIM TRIM CAPSULES.	PAUL BROOKS HOMOEOPATHY LABS-A-69, PHASE 1,SITE SUPER HIGHWAY INDUSTRIAL AREA, SCHEME 33,KARACHI-PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X30.0 CAPSULE BLISTER	28/02/2022
4	NDA/MAL/HHP/10014	REVITAL HEALTHCARE (EPZ) LTD	REVITAL HEALTH CARE LTD	NEUROCARE	PAUL BROOKS HOMOEOPATHY LABS-A-69, PHASE 1,SITE SUPER HIGHWAY INDUSTRIAL AREA, SCHEME 33,KARACHI-PAKISTAN	PAKISTAN	TOPICAL EXTERNAL OINTMENTS	1.0X50.0 G TUBE	28/02/2022

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5	NDA/MAL/HHP/10015	REVITAL HEALTHCARE (EPZ) LTD	REVITAL HEALTH CARE LTD	DOMO CREAM.	PAUL BROOKS HOMOEOPATHY LABS-A-69, PHASE 1, SITE SUPER HIGHWAY INDUSTRIAL AREA, SCHEME 33, KARACHI-PAKISTAN	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	28/02/2022
6	NDA/MAL/HHP/10016	REVITAL HEALTHCARE (EPZ) LTD	REVITAL HEALTH CARE LTD	TOTO CARE.	PAUL BROOKS HOMOEOPATHY LABS-A-69, PHASE 1, SITE SUPER HIGHWAY INDUSTRIAL AREA, SCHEME 33, KARACHI-PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY LIQUIDS	1.0X150.0 ML BOTTLE	28/02/2022
7	NDA/MAL/HHP/10017	REVITAL HEALTHCARE (EPZ) LTD	REVITAL HEALTH CARE LTD	MARKONIL CREAM.	PAUL BROOKS HOMOEOPATHY LABS-A-69, PHASE 1, SITE SUPER HIGHWAY INDUSTRIAL AREA, SCHEME 33, KARACHI-PAKISTAN	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X100.0 G TUBE	28/02/2022
8	NDA/MAL/HHP/10019	CHARAK PHARMA PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	LIVOMYN TABLETS	CHARAK PHARMA PVT. LTD., PLOT NO. 371, SAYLI RAKHOLI ROAD, SILVASSA-396 230, D.T. OF DADRA & NAGAR HAVELI. INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X20.0 TABLET BLISTER	07/03/2022
9	NDA/MAL/HHP/10020	KALBE INTERNATIONAL PTE LTD	ABACUS PHARMA (AFRICA) LIMITED	WOOD'S PEPPERMINT LOZENGES (ORIGINAL FLAVOUR)	PT. KALBE FARMA TBK- JL. M.H. THAMRIN BLOK A3-1, KAWASAN INDUSTRI DELTA SILIKON, LIPPO CIKARANG, BEKASI-	SINGAPORE	ORAL SOLID ORDINARY LOZENGES	1.0X15.0X6.0 LOZENGE SACHET	10/03/2022

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10	NDA/MAL/HHP/10021	KALBE INTERNATIONAL PTE LTD	ABACUS PHARMA (AFRICA) LIMITED	WOOD'S PEPPERMINT LOZENGES(CHERRY FLAVOUR)	PT.KALBE FARMA TBK- JL.M.H.THAMRIN BLOK A3-1, KAWASAN INDUSTRI DELTA SILIKON,LIPPO CIKARANG,BEKASI-	SINGAPORE	ORAL SOLID ORDINARY LOZENGES	1.0X15.0X6.0 LOZENGE SACHET	10/03/2022
11	NDA/MAL/HHP/10022	KALBE INTERNATIONAL PTE LTD	ABACUS PHARMA (AFRICA) LIMITED	WOOD'S PEPPERMINT LOZENGES (ORANGE FLAVOUR)	PT.KALBE FARMA TBK- JL.M.H.THAMRIN BLOK A3-1, KAWASAN INDUSTRI DELTA SILIKON,LIPPO CIKARANG,BEKASI-	SINGAPORE	ORAL SOLID ORDINARY LOZENGES	1.0X15.0X6.0 LOZENGE SACHET	10/03/2022
12	NDA/MAL/HHP/10023	KREMOINT PHARMA PVT.LTD	PLANET PHARMACEUTICALS UGANDA LTD	KOFFENGES COUGH SYRUP	KREMOINT PHARMA PRIVATE LIMITED-A-10/M.I.D.C. TALOJA - 410208, TAL-PANVEL, DIST: RAIGAD, MAHARASHTRA - INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	05/04/2022
13	NDA/MAL/HHP/10024	GAYATRI AYUPHARMA PRIVATE LIMITED	VIDA AFRICA LTD	LOZETS MENTHOMAX PLUS	PRINCE SUPPLICO-PLOT NO. 90-A, G.I.D.C, CHITRA, BHAVNAGAR	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X50.0X2.0 LOZENGE BLISTER,1.0X10.0X2.0 LOZENGE BLISTER	05/04/2022
14	NDA/MAL/HHP/10025	GAYATRI AYUPHARMA PRIVATE LIMITED	VIDA AFRICA LTD	HERO PAIN BALM	GAYATRI AYUPHARMA PRIVATE LIMITED-234/2/2, PATEL ESTATE, NIKOL ROAD, AHMEDABAD: 382 350, GUJARAT (INDIA)	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X10.0 ML JAR	05/04/2022

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15	NDA/MAL/HHP/10026	NEOMI PHARMACEUTICALS PVT LTD	ROYAL PHARMA 2011 LIMITED	NEOSILS HERBAL COUGH LOZENGES	LEAMARK HEALTHCARE PVT LTD- SARKHEJ BAVLA HIGHWAY,MATODA 382213 AHMEDABAD GUJARAT	INDIA	ORAL SOLID ORDINARY LOZENGES	25.0X2.0 LOZENGE STRIP	11/04/2022
16	NDA/MAL/HHP/10027	BHARGAVA PHYTO LAB PVT. LTD	REDDYS PHARMA LIMITED	ACTIVATED CHARCOAL TABLETS	BHARGAVA PHYTO LAB PVT.LTD-E-1216 PHASE-1, EXTN. GHATAL,BHIWADI INDUSTRIAL AREA, BHIWADI(RAJ.) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X90.0 TABLET BOTTLE	21/04/2022
17	NDA/MAL/HHP/10406	GAYATRI AYUPHARMA PRIVATE LIMITED	VIDA AFRICA LTD	LOTUS FEMIWASH	GAYATRI AYUPHARMA PRIVATE LIMITED-234/2/2, PATEL ESTATE, NIKOL ROAD, AHMEDABAD: 382 350, GUJARAT (INDIA)	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X25.0 ML BOTTLE	04/10/2022
18	NDA/MAL/HHP/10409	CHETAN & DIPTI (C&D) PHARMA PVT LTD	KAMCARE PHARMA LIMITED	HERBOXIL LOZENGES	LEAMARK HEALTHCARE PVT LTD- SARKHEJ BAVLA HIGHWAY,MATODA 382213 AHMEDABAD GUJARAT	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X50.0X2.0 LOZENGE STRIP	12/10/2022
19	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	01/07/2001

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20	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	01/07/2000
21	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	01/07/2008
22	NDA/MAL/HHP/5518	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	PENODEX OINTMENT	MEHTA UNANI PHARMACY & CO LTD-INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G CONTAINER	01/07/2007
23	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	01/07/2004
24	NDA/MAL/HHP/5528	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	AQUAREST	288,SIDCO ESTATE-AMBATTUR, CHENNAI 600 098, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY POWDERS	1.0X10.0X765.0 MG SACHET	01/07/2009

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25	NDA/MAL/HHP/5532	MACK BROWN PHARMACEUTICALS PVT LIMITED	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	01/07/2009
26	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,1.0X1.2 ML VIAL,1.0X4.0 ML VIAL,1.0X9.0 ML VIAL,1.0X30.0 ML	01/07/2004
27	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	01/07/2015
28	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	01/07/2001
29	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	01/07/2015

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30	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,1.0X100.0 ML BOTTLE	01/07/2014
31	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	01/07/2001
32	NDA/MAL/HHP/5561	MACK BROWN PHARMACEUTICALS PVT LIMITED	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	01/07/2009
33	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	01/07/2013
34	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	01/07/2011

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35	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	01/07/2009
36	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	01/07/2007
37	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	01/07/2016
38	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	1.0X2.0X6.0 LOZENGE BLISTER	01/07/2014
39	NDA/MAL/HHP/5623	UNIQUE PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	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	01/07/2005

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40	NDA/MAL/HHP/5629	UNIQUE PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	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	01/07/2005
41	NDA/MAL/HHP/5630	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	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	01/07/2000
42	NDA/MAL/HHP/5631	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	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	01/07/2014
43	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,1.0X2.0X6.0 LOZENGE BLISTER	01/07/2016
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	01/07/2015

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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	01/07/2012
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	01/07/2015
47	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	01/07/2015
48	NDA/MAL/HHP/7942	MEGA LIFESCIENCES 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	01/07/2016
49	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	01/07/2015

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50	NDA/MAL/HHP/7947	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICALS LTD)	PLANET PHARMACEUTICALS UGANDA LTD	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	01/07/2014
51	NDA/MAL/HHP/7949	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICALS LTD)	PLANET PHARMACEUTICALS UGANDA LTD	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	01/07/2016
52	NDA/MAL/HHP/7950	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICALS LTD)	PLANET PHARMACEUTICALS UGANDA LTD	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	01/07/2014
53	NDA/MAL/HHP/7954	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICALS LTD)	PLANET PHARMACEUTICALS UGANDA LTD	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	01/07/2014
54	NDA/MAL/HHP/7956	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICALS LTD)	PLANET PHARMACEUTICALS UGANDA LTD	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	01/07/2015

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55	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	01/07/2017
56	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	01/07/2017
57	NDA/MAL/HHP/8379	CHARAK PHARMA PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	M2 TONE TABLET	CHARAK PHARMA PVT LTD- INDUSTRIAL STATE, SHAUTI MILL LANE, MUMBAI-400011	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE	20/09/2017
58	NDA/MAL/HHP/8505	CHARAK PHARMA PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	LIVOMYN SYRUP	CHARAK PHARMA PVT LTD- INDUSTRIAL STATE, SHAUTI MILL LANE, MUMBAI-400011 CHARAK PHARMA PVT. LTD,-PLOT NO. 371, SAYLI RAKHOLI ROAD, SILVASSA-396 230, D.T. OF DADRA & NAGAR HAVELI. INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X200.0 ML BOTTLE	02/02/2018
59	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	02/02/2018

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60	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 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	02/02/2018
61	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	29/11/2017
62	NDA/MAL/HHP/8510	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	FRICKS COUGH SYRUP	BLISS GVS PHARMA LIMITED- NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	06/03/2018
63	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	24/10/2017
64	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	13/07/2017

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65	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	10/11/2017
66	NDA/MAL/HHP/9091	UNOSOURCE PHARMA LTD	MEDVIN PHARMA LIMITED	KOFCLEAN SYRUP (HERBAL COUGH SYRUP)	MAXCURE NUTRAVEDICS LTD - PLOT NO.13 SEC-6A IIE,SIDCUL,RANIPUR,HARIDWAR-249 403, UTTARAKHAND	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	28/01/2019
67	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	22/03/2019
68	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	22/03/2019
69	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	29/01/2020

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70	NDA/MAL/HHP/9254	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	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	18/07/2020
71	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	31/08/2020
72	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	31/08/2020
73	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	27/08/2021
74	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	27/08/2021

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75	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	27/08/2021
76	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	27/08/2021
77	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	27/08/2021
78	NDA/MAL/HHP/9711	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	GINSOMIN	MEGA LIFESCIENCES PUBLIC CO. LTD-PLANT 1; 384 MOO 4, SOI 6, BANGPOO INDUSTRIAL ESTATE, PATTANA 3 ROAD, PHRAEKSA, MUEANG, SAMUTPRAKARN 10280 THAILAND	THAILAND	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	07/10/2021
79	NDA/MAL/HHP/9923	GAYATRI AYUPHARMA PRIVATE LIMITED	VIDA AFRICA LTD	CHARCO-PLUS	GAYATRI AYUPHARMA PRIVATE LIMITED-234/2/2, PATEL ESTATE, NIKOL ROAD, AHMEDABAD: 382 350, GUJARAT (INDIA)	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	21/12/2021

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80	NDA/MAL/HHP/9928	AUSHADHI WELLNESS PVT LTD	MATRIX (U) LTD	TEENCLEEN	AUSHADHI WELLNESS PVT. LTD.,RAJKOT,GUJARAT INDIA- SURVEY NO. 654,PLOT NO. 1,VILLAGE: RAVKI, TALUKA,LODHKA, DISTRICT:RAJKOT- 360035	INDIA	TOPICAL EXTERNAL COMBINATION PACK CREAMS	1.0X20.0 G TUBE,1.0X50.0 G TUBE	21/02/2022
81	NDA/MAL/HHP/9929	AUSHADHI WELLNESS PVT LTD	MATRIX (U) LTD	HONYKOF	AUSHADHI WELLNESS PVT. LTD.,RAJKOT,GUJARAT INDIA- SURVEY NO. 654,PLOT NO. 1,VILLAGE: RAVKI, TALUKA,LODHKA, DISTRICT:RAJKOT- 360035	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE	21/02/2022
82	NDA/MAL/HHP/9930	AUSHADHI WELLNESS PVT LTD	MATRIX (U) LTD	RAPIDCOOL	AUSHADHI WELLNESS PVT. LTD.,RAJKOT,GUJARAT INDIA- SURVEY NO. 654,PLOT NO. 1,VILLAGE: RAVKI, TALUKA,LODHKA, DISTRICT:RAJKOT- 360035	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X25.0 G TUBE,1.0X50.0 G TUBE	21/02/2022