



DRUG EVALUATION AND REGISTRATION DEPARTMENT (DERD)

LIST OF PRODUCTS CONSIDERED FOR MARKETING AUTHORIZATION

No.	PRODUCTS DESCRIPTION	LOCAL AGENT	MANUFACTURER	STATUS OF DOSSIER REPORTS/PRODUCT LABELS (MISSING DATA)	STATUS OF Q.C REPORTS	STATUS OF GMP REPORTS	REMARKS/COMMENTS
1.	Lexspirin (Neomycin Sulfate-3,400units/g, Polymyxin-B Sulfate-5,000units/g and Bacitracin Zinc-400units/g) Ointment-20gm	Balani & Sons, 25/40 Krootown Road, Freetown	Golpadas Visram & Co. Ltd. Plot No. A590:591, T.T.C Industrial Area, M.I.D.C, Mahape, Navi Mumbai, India	GMP & CPP, Expired AMV Protocol & report for both raw API & Finished product	Pending		Deferred
2.	Neo-Hycolex (Neomycin 0.5%, Hydrocortisone 1.5%) eye, nose & ear drops-5ml	Balani & Sons, 25/40 Krootown Road, Freetown	Adore Pharmaceuticals Pvt. Ltd. 5,6 Khokhani Indl. Complex No. 2 Near Sai Temple, Sativali, Vasai (East), Thane 401208, Maharashtra State, India	GMP & CPP, Expired AMV Protocol & report for both raw API & Finished product	Pending		Deferred
3.	Mycorex (Clotrimazole-1%w/w, Betamethasone	Balani & Sons, 25/40 Krootown Road, Freetown	Golpadas Visram & Co. Ltd. Plot No. A590:591, T.T.C	GMP & CPP, Expired AMV Protocol & report	Pending		Deferred



	Dipropionate-0.05%w/w, Neomycin Sulfate-0.5%w/w) Cream-30gm		Industrial Area, M.I.D.C, Mahape, Navi Mumbai, India	for both raw API & Finished product			
4.	Ciprolex-TZ (Ciprofloxacin 500mg, Tinidazole 600mg)	Balani & Sons, 25/40 Krootown Road, Freetown	Dupen Laboratories Pvt. Ltd. C1-49-36 Degam Road, Industrial Township, Vapi (Gujarat)-396 195, India	GMP & CPP, Expired AMV Protocol & report for both raw API & Finished product	Pending		Deferred
5.	COFTA (Ammonium Chloride 30mg, Ipecacuanha 50mg, Liquorice extract 50mg) Syrup	Evans Baroque Import/Wholesale, 15 Lamina Sankoh Street, Freetown	Evans Baroque Pvt. Ltd. Sokhada-388 620 Ta. Khambhat Dist. Anand, Gujarat, India	Satisfactory	Pass		Approved
6.	KAS Amoxi 500 (Amoxicillin) Capsules -500mg	Kumba and Son's Trading (SL) Ltd. 48 Krootown Road, Freetown	Centurion Healthcare Ltd. India	GMP Protocol for long term stability	Pass		Approved
7.	KAS Clox 500 (Ampicillin and Cloxacillin) 500mg Capsules	Kumba and Son's Trading (SL) Ltd. 48 Krootown Road, Freetown	Centurion Healthcare Ltd. India	Comparative dissolution data Protocol for long term stability	Pass		Deferred



				AMV, Protocol & report of impurities			
8.	KAS Amoxy (Amoxicillin) Oral Suspension 125mg/5ml	Kumba and Son's Trading (SL) Ltd. 48 Krootown Road, Freetown	Centurion Healthcare Ltd. India	GMP Certificate, Protocol for long term stability	Pending		Deferred
9.	KAS Cipro IV (Ciprofloxacin) 100ml	Kumba and Son's Trading (SL) Ltd. 48 Krootown Road, Freetown	Abaris Healthcare Pvt. Ltd. Kodi Dist: Mehsana 382740, India	CPP and WHO/EU GMP certificates, Protocol and report for long term and accelerated stability	Pass		Deferred
10	KAS Para 125 (Paracetamol) Oral Suspension- 125mg/5ml	Kumba and Son's Trading (SL) Ltd. 48 Krootown Road, Freetown	Centurion Healthcare Ltd. India	Analytical procedures and validation of analytical procedures for assay and impurities Protocol and report for analytical method validation for test of impurities and related	Pass		Deferred



				substances in the drug products Protocols and reports for long and accelerated stability			
11	KAS Omeprazole 20mg (Omeprozole) Capsules-20mg	Kumba and Son's Trading (SL) Ltd. 48 Krootown Road, Freetown	Centurion Healthcare Ltd. India	GMP Certificates, Protocol for long term stability	Pending		Deferred
12	Ronacal (Calcium with vitamin D) 100ml Suspension	Quality Healthcare Company (SL) Ltd. 10 Krootown Road, Freetown	Ronak Exim Pvt Ltd Gendigate, Baroda-1 India	CPP WHO/EU Format GMP Certificate should be on the official letterhead Protocol for both long term and accelerated stability studies	Pending		Deferred
13	Herofen (Diclofenac Potassium) tabs 50mg	Gemstar Pharmaceuticals, 16 Free Street, Freetown	Syncom Formulation (India) Ltd. At 256-257 Sector-1, Pithampur (Dhar)	WHO/EU, Format GMP, Protocol for long-term and	Pending		Deferred



			454775, India	accelerated stability			
14	Malergem (Arthemether 80mg, Lumefantrine 480mg) tabs	Gemstar Pharmaceuticals, 16 Free Street, Freetown	Syncom Formulation (India) Ltd. At 256- 257 Sector-1, Pithampur (Dhar) 454775, India	WHO/EU,Format GMP Protocol and report for AMV Protocol for long term and accelerated stability studies	Pending		Deferred
15	Globmoxx (Amoxicillin) Capsules 250mg 10 x 10	Excelmed S.L 49 Victoria Street, Freetown	Globela Pharma Pvt. Ltd 357, 358 G.I.D.C, Sachin, Surat-394 230 Gujarat, India	CPP,WHO/EU, GMP certificates, Protocols and reports for long term and accelerated stability, Comparative dissolution data	Pending		Deferred
16	Globmoxx (Amoxicillin) Capsule 500mg 10 x	Excelmed S.L 49 Victoria Street,	Globela Pharma Pvt. Ltd 357, 358 G.I.D.C,	CPP,WHO/EU, GMP certificates, Protocols	Pending		Deferred



	10	Freetown	Sachin, Surat-394 230 Gujarat, India	and reports for long term and accelerated stability, Comparative dissolution data			
17	Gloroxim (Cefuroxime Axetil) Tablet 250mg 1 x10	Excelmed S.L 49 Victoria Street, Freetown	Globela Pharma Pvt. Ltd 357, 358 G.I.D.C, Sachin, Surat-394 230 Gujarat, India	CPP,WHO/EU, GMP certificates, Protocols and reports for long term and accelerated stability, Comparative dissolution data	Pending		Deferred
18	Gloroxim (Cefuroxime Axetil) Tablet 500mg	Excelmed S.L 49 Victoria Street, Freetown	Globela Pharma Pvt. Ltd 357, 358 G.I.D.C, Sachin, Surat-394 230 Gujarat, India	CPP,WHO/EU, GMP certificates, Protocols and reports for long term and accelerated stability, Comparative dissolution data	Pending		Deferred
19	Gloxim (Cefixime) Tablet 400mg	Excelmed S.L 49 Victoria Street, Freetown	Globela Pharma Pvt. Ltd 357, 358 G.I.D.C, Sachin, Surat-394 230 Gujarat, India	CPP,WHO/EU, GMP certificates, Protocols and reports for long term and accelerated stability, Comparative dissolution data	Pending		Deferred



20	Medibest Vital C Effervescent Tablet 1000mg 1 x 20	Excelmed S.L 49 Victoria Street, Freetown	Globela Pharma Pvt. Ltd 357, 358 G.I.D.C, Sachin, Surat-394 230 Gujarat, India	CPP,WHO/EU, GMP certificates, Protocols and reports for long term and accelerated stability	Pass		Deferred
21	Medibest Vital C Effervescent Tablet 1000mg 3 x 20	Excelmed S.L 49 Victoria Street, Freetown	Globela Pharma Pvt. Ltd 357, 358 G.I.D.C, Sachin, Surat-394 230 Gujarat, India	CPP,WHO/EU, GMP certificates, Protocols and reports for long term and accelerated stability	Pass		Deferred
22	Medibest Vital C Zinc (Vitamin C + Zinc) Effervescent Tablet 1000mg +10mg	Excelmed S.L 49 Victoria Street, Freetown	Globela Pharma Pvt. Ltd 357, 358 G.I.D.C, Sachin, Surat-394 230 Gujarat, India	CPP,WHO/EU, GMP certificates, Protocols and reports for long term and accelerated stability	Pending		Deferred
23	Globmoxx (Amoxicillin) Suspension 250mg/5ml	Excelmed S.L 49 Victoria Street, Freetown	Globela Pharma Pvt. Ltd 357, 358 G.I.D.C, Sachin, Surat-394 230 Gujarat, India	CPP,WHO/EU, GMP certificates, Protocols and reports for long term and accelerated stability	Pending		Deferred



24	Globmoxx (Amoxicillin) Suspension 125mg/5ml	Excelmed S.L 49 Victoria Street, Freetown	Globela Pharma Pvt. Ltd 357, 358 G.I.D.C, Sachin, Surat-394 230 Gujarat, India	CPP,WHO/EU, GMP certificates, Protocols and reports for long term and accelerated stability	Pending		Deferred
25	Albaglob- 400 (Albendazole) Tablet- 400mg	Excelmed S.L 49 Victoria Street, Freetown	Globela Pharma Pvt. Ltd 357, 358 G.I.D.C, Sachin, Surat-394 230 Gujarat, India	CPP,WHO/EU, GMP certificates, Protocols and reports for long term and accelerated stability, Comparative dissolution data	Pending		Deferred
26	Ceftriaxone Injection- 1g	Healthwell Pharma (SL) Ltd. 3 Charlotte Street, Freetown	Noronic Pharmaceuticals Pvt. Ltd. Block No. 763/2/A, Indrad- 382715, Ta-Kadi, Dist. Mehsana, Gujarat, India	CPP	Pending		Deferred
27	Fluconazole 200mg Caps	Healthwell Pharma (SL) Ltd. 3 Charlotte Street, Freetown	Noronic Pharmaceuticals Pvt. Ltd. Block No. 763/2/A, Indrad-	CPP, TSE/BSE free certificates of Gelatin capsules, TSE/BSE	Pending		Deferred



			382715, Ta-Kadi, Dist. Mehsana, Gujarat, India	free certificates for Mg Stearate etc,			
28	Amoxicillin 500mg Caps	Healthwell Pharma (SL) Ltd. 3 Charlotte Street, Freetown	Noronic Pharmaceuticals Pvt. Ltd. Block No. 763/2/A, Indrad- 382715, Ta-Kadi, Dist. Mehsana, Gujarat, India	CPP, TSE/BSE free certificates of Gelatin capsules, TSE/BSE free certificates for Mg stearate etc	Pending		Deferred
29	Amoxicillin 250mg Caps	Healthwell Pharma (SL) Ltd. 3 Charlotte Street, Freetown	Noronic Pharmaceuticals Pvt. Ltd. Block No. 763/2/A, Indrad- 382715, Ta-Kadi, Dist. Mehsana, Gujarat, India	CPP, TSE/BSE free certificates of Gelatin capsules, TSE/BSE free certificates for Mg stearate etc,	Pending		Deferred
30	Ampicillin 250mg +Cloxacillin 250mg	Healthwell Pharma (SL) Ltd. 3 Charlotte Street, Freetown	Noronic Pharmaceuticals Pvt. Ltd. Block No. 763/2/A, Indrad- 382715, Ta-Kadi, Dist. Mehsana,	CPP	Pending		Deferred



			Gujarat, India				
31	Artesunate 60mg Injection	Healthwell Pharma (SL) Ltd. 3 Charlotte Street, Freetown	Noronic Pharmaceuticals Pvt. Ltd. Block No. 763/2/A, Indrad-382715, Ta-Kadi, Dist. Mehsana, Gujarat, India	CPP	Pending		Deferred
32	Cyproheptadine + Multivitamins Syrup 200ml	Healthwell Pharma (SL) Ltd. 3 Charlotte Street, Freetown	Noronic Pharmaceuticals Pvt. Ltd. Block No. 763/2/A, Indrad-382715, Ta-Kadi, Dist. Mehsana, Gujarat, India	CPP	Pass		Deferred
33	Amoxicillin 500mg + Clavulanic Acid 125mg Tabs	Healthwell Pharma (SL) Ltd. 3 Charlotte Street, Freetown	Noronic Pharmaceuticals Pvt. Ltd. Block No. 763/2/A, Indrad-382715, Ta-Kadi, Dist. Mehsana, Gujarat, India	CPP	Pending		Deferred
34	Fini-Gas Susp (Aluminium Hydroxide, Magnesium Hydroxide, Simethicone & Oxethazaine)	Lucky Development Corp. Ltd. 29 Wilberforce Street, Freetown	Aura Lifecare Pvt. Ltd. S.No. 254/14/1, Jarod-Savli Road, P.O Karachiya Tal: Savli Dist. Vadodara-391520, Gujarat,	Protocol for AMV for impurities and subsequent substances	Pending		Deferred for Q.C



	Suspension-200ml		India				
35	Fini-Gas Susp (Aluminium Hydroxide, Magnesium Hydroxide, Simethicone & Oxethazaine) Suspension-15ml	Lucky Development Corp. Ltd. 29 Wilberforce Street, Freetown	Aura Lifecare Pvt. Ltd. S.No. 254/14/1, Jarod-Savli Road, P.O Karachiya Tal: Savli Dist. Vadodara- 391520, Gujarat, India	Protocol for AMV for impurities and subsequent substances	Pending		Deferred for Q.C
36	Zincora (Zinc Sulfate) USP Tablet 20mg	Lucky Development Corp. Ltd. 29 Wilberforce Street, Freetown	Aura Lifecare Pvt. Ltd. S.No. 254/14/1, Jarod-Savli Road, P.O Karachiya Tal: Savli Dist. Vadodara- 391520, Gujarat, India	Protocol for AMV for impurities and subsequent substances	Pending		
37	Neoaura (Neomycin Sulfate) Cream- 5mg	Lucky Development Corp. Ltd. 29 Wilberforce Street, Freetown	Aura Lifecare Pvt. Ltd. S.No. 254/14/1, Jarod-Savli Road, P.O Karachiya Tal: Savli Dist. Vadodara- 391520, Gujarat, India	Protocol for AMV for impurities and subsequent substances	Pending		Deferred for Q.C
38	Fini-Piles (Calcium Dobesilate-0.5%w/w, Lidocaine-3.0%w/w, Hydrocortisone Acetate-0.25%w/w, Zinc Oxide-5.0%w/w	Lucky Development Corp. Ltd. 29 Wilberforce Street, Freetown	Aura Lifecare Pvt. Ltd. S.No. 254/14/1, Jarod-Savli Road, P.O Karachiya Tal: Savli Dist. Vadodara- 391520, Gujarat,	Protocol for AMV for impurities and subsequent substances	Pending		Deferred for Q.C



	and Allantoin- 0.5%w/w) Cream 30mg		India				
39	Clindofil-300 (Clindamycin) 300mg caps	Lucky Development Corp. Ltd. 29 Wilberforce Street, Freetown	Aura Lifecare Pvt. Ltd. S.No. 254/14/1, Jarod-Savli Road, P.O Karachiya Tal: Savli Dist. Vadodara- 391520, Gujarat, India	Protocol for AMV for impurities and subsequent substances	Pending		Deferred for Q.C
40	Ketoaura (Ketoconazole) CreamBP 2% w/w	Lucky Development Corp. Ltd. 29 Wilberforce Street, Freetown	Aura Lifecare Pvt. Ltd. S.No. 254/14/1, Jarod-Savli Road, P.O Karachiya Tal: Savli Dist. Vadodara- 391520, Gujarat, India	Protocol for AMV for impurities and subsequent substances	Pending		Deferred for Q.C
41	Whitfield Ointment 20g	Lucky Development Corp. Ltd. 29 Wilberforce Street, Freetown	Aura Lifecare Pvt. Ltd. S.No. 254/14/1, Jarod-Savli Road, P.O Karachiya Tal: Savli Dist. Vadodara- 391520, Gujarat, India	Protocol for AMV for impurities and subsequent substances	Pending		Deferred for Q.C
42	Fini-Mal 80/480 (Artemether 80mg/ Lumefantrine 480mg) Tabs	Lucky Development Corp. Ltd. 29 Wilberforce	Aura Lifecare Pvt. Ltd. S.No. 254/14/1, Jarod-Savli Road, P.O Karachiya Tal:	Protocol for AMV for impurities and subsequent substances	Pending		Deferred for Q.C



		Street, Freetown	Savli Dist. Vadodara-391520, Gujarat, India				
43	Fini-Mal 40/240 (Artemether 40mg/ Lumefantrine 240mg) Tabs	Lucky Development Corp. Ltd. 29 Wilberforce Street, Freetown	Aura Lifecare Pvt. Ltd. S.No. 254/14/1, Jarod-Savli Road, P.O Karachiya Tal: Savli Dist. Vadodara-391520, Gujarat, India	Protocol for AMV for impurities and subsequent substances	Pending		Deferred for Q.C
44	Fini-Mal DT 20/120 (Artemether 20mg/ Lumefantrine 120mg) Tabs	Lucky Development Corp. Ltd. 29 Wilberforce Street, Freetown	Aura Lifecare Pvt. Ltd. S.No. 254/14/1, Jarod-Savli Road, P.O Karachiya Tal: Savli Dist. Vadodara-391520, Gujarat, India	Protocol for AMV for impurities and subsequent substances	Pending		Deferred for Q.C
45	Fini-pain (Paracetamol BP-325mg, Diclofenac Sodium BP-50mg, Magnesium Trisilicate BP-100mg, Chlorphenamine Maleate BP-4mg tablet	Lucky Development Corp. Ltd. 29 Wilberforce Street, Freetown	Aura Lifecare Pvt. Ltd. S.No. 254/14/1, Jarod-Savli Road, P.O Karachiya Tal: Savli Dist. Vadodara-391520, Gujarat, India	Protocol for AMV for impurities and subsequent substances	Pass		Approved pending protocol for AMV submission
46	Relax-pain (Diclofenac Potassium BP-50mg, Paracetamol BP-325mg,	Lucky Development Corp. Ltd. 29 Wilberforce	Aura Lifecare Pvt. Ltd. S.No. 254/14/1, Jarod-Savli Road, P.O Karachiya Tal:	Protocol for AMV for impurities and subsequent substances	Pending		Deferred for Q.C



	Chlorzoxazone USP-250mg) Tablet	Street, Freetown	Savli Dist. Vadodara-391520, Gujarat, India				
47	Fini-pain gel (Diclofenac Diethylamine BP- 1.16%w/w)	Lucky Development Corp. Ltd. 29 Wilberforce Street, Freetown	Aura Lifecare Pvt. Ltd. S.No. 254/14/1, Jarod-Savli Road, P.O Karachiya Tal: Savli Dist. Vadodara-391520, Gujarat, India	Protocol for AMV for impurities and subsequent substances	Pending		Deferred for Q.C
48	Fini-Bung (Clotrimazole USP- 1.0%w/w, Betamethasone Dipropionate USP- 0.05%w/w, Neomycin Sulfate BP- 0.5%w/w) Cream	Lucky Development Corp. Ltd. 29 Wilberforce Street, Freetown	Aura Lifecare Pvt. Ltd. S.No. 254/14/1, Jarod-Savli Road, P.O Karachiya Tal: Savli Dist. Vadodara-391520, Gujarat, India	Protocol for AMV for impurities and subsequent substances	Pass		Approved pending protocol for AMV submission
49	Vagiciaire (Clotrimazole) Vaginal Cream USP 2% w/w	Lucky Development Corp. Ltd. 29 Wilberforce Street, Freetown	Aura Lifecare Pvt. Ltd. S.No. 254/14/1, Jarod-Savli Road, P.O Karachiya Tal: Savli Dist. Vadodara-391520, Gujarat, India	Protocol for AMV for impurities and subsequent substances	Pass		Approved pending protocol for AMV submission
50	Fetotec (Misoprostol) Tablets 200mg	Lucky Development Corp. Ltd. 29	Aura Lifecare Pvt. Ltd. S.No. 254/14/1, Jarod-Savli Road,	Protocol for AMV for impurities and subsequent	Pending		Deferred for Q.C



		Wilberforce Street, Freetown	P.O Karachiya Tal: Savli Dist. Vadodara-391520, Gujarat, India	substances			
51	Micoaura (Miconazole) Cream 2%w/w	Lucky Development Corp. Ltd. 29 Wilberforce Street, Freetown	Aura Lifecare Pvt. Ltd. S.No. 254/14/1, Jarod-Savli Road, P.O Karachiya Tal: Savli Dist. Vadodara-391520, Gujarat, India	Protocol for AMV for impurities and subsequent substances	Pass		Approved pending protocol for AMV submission
52	Weldine (Cyproheptadine) Tablet 4mg	Lucky Development Corp. Ltd. 29 Wilberforce Street, Freetown	Aura Lifecare Pvt. Ltd. S.No. 254/14/1, Jarod-Savli Road, P.O Karachiya Tal: Savli Dist. Vadodara-391520, Gujarat, India	Protocol for AMV for impurities and subsequent substances	Pending		Deferred for Q.C
53	Philco- Para 1g (Paracetamol) Solution for injection-1g/100ml	Bereko Pharma 49 Circular Road, Freetown	Cisein Pharmaceutical Co. Ltd., Chuan Road Jijing High & New Technology Industries Development Zone Shandong PR China	CPP	Pending		Deferred for Q.C
54	Philco-artem 80 (Artemether-80mg)	Bereko Pharma 49 Circular Road,	Jiangsu Ruinin Qianjin	CPP	Pending		Deferred



	Solution for injection	Freetown	Pharmaceutical Co. Ltd., Chuanbou Village Dingshu Town Yixing City, Wuxi City, Jiangsu Province, China.	Validation of analytical procedures for impurities and residual solvents			
55	Philco-Vit B Complex (Vitamin B ₁ , Vitamin B ₂ , Vitamin B ₆ , Nicotinamide, Calcium Pantothenate) Solution for injection	Bereko Pharma 49 Circular Road, Freetown	Jiangsu Ruinin Qianjin Pharmaceutical Co. Ltd., Chuanbou Village Dingshu Town Yixing City, Wuxi City, Jiangsu Province, China	CPP Validation of analytical procedures for impurities and residual solvents	Pending		Deferred
56	Philco-Cloxa OS 125 (Cloxacillin Sodium)-125mg	Bereko Pharma 49 Circular Road, Freetown	Gracure Pharmaceuticals Ltd E105 RIICO Industrial Area Phase III Bhiwadi Awar (Rajshanan), India	Manufacturing license expired, CPP	Pending		Deferred
57	Philco-Artelu 105mg (Artemether 15mg, Lumefantrine 90mg) Power for Oral Suspension	Bereko Pharma 49 Circular Road, Freetown	Gracure Pharmaceuticals Ltd E105 RIICO Industrial Area Phase III Bhiwadi Awar (Rajshanan), India	Manufacturing license expired, CPP	Pending		Deferred



58	Philco-Doxy 100 (Doxycycline Hyclate) Tablet-100mg	Bereko Pharma 49 Circular Road, Freetown	Jiangxi Xier Kangtai Pharmaceutical Co. Ltd., North Park, High Tech Industrial Park Pingxiang City Jiangxi Province, China.	Validation of analytical procedures for assay, impurities and residual solvents Data on forced degradation test AMV protocol and report Certificates of inactive ingredients TSE/BSE free certificate for gelatin and Mg Stearate BMR for finished product Certificate of analysis for the APIs and finished product	Pending		Deferred
59	Philco- Metro 250	Bereko Pharma	Medopharm Pvt. Ltd.	CPP, WHO/EU, GMP	Pending		Deferred



	(Metronidazole-250mg) Tablet	49 Circular Road, Freetown	Medopharm House 25 Puliur II Main Road Trustpuram, CHENNAI-600 024 Tamil Nadu, India	certificates			
60	Philco Ery 500 (Erythromycin Stearate) 500mg	Bereko Pharma 49 Circular Road, Freetown	Medopharm Pvt. Ltd. Medopharm House 25 Puliur II Main Road Trustpuram, CHENNAI-600 024 Tamil Nadu, India	CPP, WHO/EU, GMP certificates	Pending		Deferred
61	Philco-Cotrim 480 (Sulfamethoxazole 400mg, Trimethoprim 80mg) Tablet	Bereko Pharma 49 Circular Road, Freetown	Medopharm Pvt. Ltd. Medopharm House 25 Puliur II Main Road Trustpuram, CHENNAI-600 024 Tamil Nadu, India	CPP, WHO/EU, GMP certificates	Pending		Deferred
62	Philco – Cipro 500 (Ciprofloxacin Hydrochloride) 500mg Tablet	Bereko Pharma 49 Circular Road, Freetown	Medopharm Pvt. Ltd. Medopharm House 25 Puliur II Main Road Trustpuram, CHENNAI-600 024 Tamil Nadu, India	CPP, WHO/EU, GMP certificates	Pending		Deferred
63	Philco-Ampi 500 (Ampicillin Trihydrate) Capsules-500mg	Bereko Pharma 49 Circular Road, Freetown	Medopharm Pvt. Ltd. Medopharm House 25 Puliur II Main Road Trustpuram, CHENNAI-600 024	CPP WHO/EU, GMP certificates	Pending		Deferred



			Tamil Nadu, India				
64	GARDASIL (Human Papillomavirus Vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed) Suspension for Injection-1 dose (0.5ml)	-	MSD (Pty) Ltd. 117-16th Road, Private Bag 3, Halfway House, 1685 South Africa				WHO/PQ
65	Avastin (Bevacizumab) 100mg inj	Sam Jalloh Pharmaceuticals, 16 Lumley Street, Freetown	F. HOFFMANN-LA ROCHE AG, SWITZERLAND WURMISWEG, KAISERAUGST 4303				SRA/APPROVED
66	Avastin (Bevacizumab) 400mg inj	Sam Jalloh Pharmaceuticals, 16 Lumley Street, Freetown	F. HOFFMANN-LA ROCHE AG, SWITZERLAND WURMISWEG, KAISERAUGST 4303				SRA/APPROVED
67	Herceptin (Trastuzumab) 600mg inj	Sam Jalloh Pharmaceuticals, 16 Lumley Street, Freetown	F. HOFFMANN-LA ROCHE AG, SWITZERLAND WURMISWEG,				SRA/APPROVED



			KAISERAUGST 4303				
68	Mabthera (Rituximab) 500mg inj	Sam Jalloh Pharmaceuticals, 16 Lumley Street, Freetown	F. HOFFMANN-LA ROCHE AG, SWITZERLAND WURMISWEG, KAISERAUGST 4303				SRA/APPROVED
69	Madopar (Levodopa & Benserazide) 200mg/50mg Tabs	Sam Jalloh Pharmaceuticals, 16 Lumley Street, Freetown	F. HOFFMANN-LA ROCHE AG, SWITZERLAND WURMISWEG, KAISERAUGST 4303				SRA/APPROVED
70	Perjeta (Pertuzumab) 420mg inj	Sam Jalloh Pharmaceuticals, 16 Lumley Street, Freetown	F. HOFFMANN-LA ROCHE AG, SWITZERLAND WURMISWEG, KAISERAUGST 4303				SRA/APPROVED
71	Recormon (Epoetin beta) 4000IU PF Syringe	Sam Jalloh Pharmaceuticals, 16 Lumley Street, Freetown	F. HOFFMANN-LA ROCHE AG, SWITZERLAND WURMISWEG,				SRA/APPROVED



			KAISERAUGST 4303				
72	Zabdeno Suspension for Injection (One dose (0.5ml) contains: Adenovirus type 26 encoding the Zaire ebolavirus (EBOV) Mayinga variant glycoprotein (GP)*- not less than 8.75 log₁₀ infectious units	-	Janssen-Cilag International NV Business Address: Turnhoutseweg 30 B-2340 Beerse Belgium Phone: +32 479979753 E-mail:... SDHAES@its.inj.com				WHO/PQ
73	MVA-BN-Filo Suspension for Injection (One dose (0.5 mL) contains: Modified Vaccinia Ankara Bavarian Nordic Virus* encoding the: Zaire ebolavirus Mayinga variant glycoprotein (GP) Sudan ebolavirus Gulu variant GP Tai Forest	-	Janssen-Cilag International NV Business Address: Turnhoutseweg 30 B-2340 Beerse Belgium Phone: +32 479979753 E-mail:... SDHAES@its.inj.com				WHO/PQ



	ebolavirus nucleoprotein Marburg marburgvirus Musoke variant GP- not less than 0.7×10⁸ Infectious units						
74							

For more Information, contact Pharmacy Board of Sierra Leone through the regular channels;

- Pharmacy Board of Sierra Leone Phone Numbers: 073994830 or 099117117
- Send an email to info@pharmacyboard.gov.sl, registrar@pharmacyboard.gov.sl;

PHARMACY BOARD OF SIERRA LEONE: Your Medicines Regulatory Experts.