

DEPARTMENT OF HEALTH

NO. R. 3396

12 May 2023

NOTIFICATION OF REGISTRATION OF MEDICINES IN TERMS OF SECTION 17 OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965) AS AMENDED						
Registration Number	Registration Date	Product Name	Dosage Form	Applicant Name	Ingredients	Conditions of Registration
56/26/0353	2023/01/24	DETENER	Infusion	Encure Pharmaceutical South Africa (Pty) Ltd	EACH 10.0 ml SOLUTION CONTAINS BUSULFAN 60 mg	Annexure A
55/2.5/0480	2023/01/24	CARBAMAZEPINE 200 AUSTELL	Tablet	Austell Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS CARBAMAZEPINE 200 mg	Annexure A
57/2.8/0731	2023/01/24	CODPARAFEN	Capsule	Adcock Ingram Limited	EACH CAPSULE CONTAINS CODEINE PHOSPHATE 10 mg, IBUPROFEN 200 mg & PARACETAMOL 250 mg	Annexure A
56/1.2/0801	2023/01/24	CONUFEN 18	Tablet	Sandoz South Africa (Pty) Ltd	EACH TABLET CONTAINS METHYLPHENIDATE HYDROCHLORIDE 18 mg	Annexure A
56/1.2/0802	2023/01/24	CONUFEN 27	Tablet	Sandoz South Africa (Pty) Ltd	EACH TABLET CONTAINS METHYLPHENIDATE HYDROCHLORIDE 27 mg	Annexure A
56/1.2/0803	2023/01/24	CONUFEN 36	Tablet	Sandoz South Africa (Pty) Ltd	EACH TABLET CONTAINS METHYLPHENIDATE HYDROCHLORIDE 36 mg	Annexure A
56/1.2/0804	2023/01/24	CONUFEN 54	Tablet	Sandoz South Africa (Pty) Ltd	EACH TABLET CONTAINS METHYLPHENIDATE HYDROCHLORIDE 54 mg	Annexure A
54/21.2/0563.561	2023/01/24	DAPAGLIFLOZIN 10 mg GLENMARK	Tablet	Glenmark Pharmaceuticals South Africa (Pty) Ltd	EACH TABLET CONTAINS DAPAGLIFLOZIN 10 mg	Annexure A
54/21.2/0562.560	2023/01/24	DAPAGLIFLOZIN 5 mg GLENMARK	Tablet	Glenmark Pharmaceuticals South Africa (Pty) Ltd	EACH TABLET CONTAINS DAPAGLIFLOZIN 5 mg	Annexure A
54/21.2/0561	2023/01/24	DAPTICA 10 mg	Tablet	Glenmark Pharmaceuticals South Africa (Pty) Ltd	EACH TABLET CONTAINS DAPAGLIFLOZIN 10 mg	Annexure A
54/21.2/0560	2023/01/24	DAPTICA 5 mg	Tablet	Glenmark Pharmaceuticals South Africa (Pty) Ltd	EACH TABLET CONTAINS DAPAGLIFLOZIN 5 mg	Annexure A
54/7.5/0330.326	2023/01/24	DYNATOR PLUS 10/10 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS & EZETIMIBE 10 mg & ATORVASTATIN CALCIUM TRIHYDRATE EQUIVALENT TO ATORVASTATIN 10 mg	Annexure A

54/7.5/0331.327	2023/01/24	DYNATOR PLUS 10/20 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS & EZETIMIBE 10 mg & ATORVASTATIN CALCIUM TRIHYDRATE EQUIVALENT TO ATORVASTATIN 20 mg	Annexure A
54/7.5/0332.328	2023/01/24	DYNATOR PLUS 10/40 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS & EZETIMIBE 10 mg & ATORVASTATIN CALCIUM TRIHYDRATE EQUIVALENT TO ATORVASTATIN 40 mg	Annexure A
54/7.5/0333.329	2023/01/24	DYNATOR PLUS 10/80 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS & EZETIMIBE 10 mg & ATORVASTATIN CALCIUM TRIHYDRATE EQUIVALENT TO ATORVASTATIN 80 mg	Annexure A
54/7.5/0326	2023/01/24	DYTOREZ 10/10	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS & EZETIMIBE 10 mg & ATORVASTATIN CALCIUM TRIHYDRATE EQUIVALENT TO ATORVASTATIN 10 mg	Annexure A
54/7.5/0327	2023/01/24	DYTOREZ 10/20	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS & EZETIMIBE 10 mg & ATORVASTATIN CALCIUM TRIHYDRATE EQUIVALENT TO ATORVASTATIN 20 mg	Annexure A
54/7.5/0328	2023/01/24	DYTOREZ 10/40	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS & EZETIMIBE 10 mg & ATORVASTATIN CALCIUM TRIHYDRATE EQUIVALENT TO ATORVASTATIN 40 mg	Annexure A
54/7.5/0329	2023/01/24	DYTOREZ 10/80	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS & EZETIMIBE 10 mg & ATORVASTATIN CALCIUM TRIHYDRATE EQUIVALENT TO ATORVASTATIN 80 mg	Annexure A
55/26/0125	2023/01/24	ENZUTIX	Capsule	Eurolab (Pty) Ltd	EACH CAPSULE CONTAINS ENZALUTAMIDE 40 mg	Annexure A
53/34/0486	2023/01/24	FINGOSOL 0,5	Capsule	Cipla Medpro (Pty) Ltd	EACH CAPSULE CONTAINS FINGOLIMOD HCl EQUIVALENT TO FINGOLIMOD 0,5 mg	Annexure A
22/24.5/03	2023/01/24	LIBRELA 10 mg/ml	Injection	Zoetis South Africa (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS BEDINVETMAB 10 mg	Annexure A
22/24.5/04	2023/01/24	LIBRELA 15 mg/ml	Injection	Zoetis South Africa (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS BEDINVETMAB 15 mg	Annexure A
22/24.5/05	2023/01/24	LIBRELA 20 mg/ml	Injection	Zoetis South Africa (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS BEDINVETMAB 20 mg	Annexure A
22/24.5/06	2023/01/24	LIBRELA 30 mg/ml	Injection	Zoetis South Africa (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS BEDINVETMAB 30 mg	Annexure A
22/24.5/02	2023/01/24	LIBRELA 5 mg/ml	Injection	Zoetis South Africa (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS BEDINVETMAB 5 mg	Annexure A
56/26/0354.353	2023/01/24	MELIORA	Infusion	Encure Pharmaceutical South Africa (Pty) Ltd	EACH 10,0 ml SOLUTION CONTAINS BUSULFAN 60 mg	Annexure A

54/11.4.1/0741.739	2023/01/24	PANTOPRAZOLE OTC MYLAN	Tablet	Viatrix South Africa (Pty) Ltd	EACH TABLET CONTAINS PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 20 mg	Annexure A
54/11.4.1/0740.739	2023/01/24	PANZOLYM OTC	Tablet	Viatrix Healthcare (Pty) Ltd	EACH TABLET CONTAINS PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 20 mg	Annexure A
57/20.2.8/0360	2023/01/24	PAXLOVID	Tablet	Pfizer Laboratories (Pty) Ltd	EACH TABLET CONTAINS NIRMATRELVIR 150 mg & RITONAVIR 100 mg	Annexure A
54/11.4.1/0739	2023/01/24	PRAZGEN OTC	Tablet	Viatrix Healthcare (Pty) Ltd	EACH TABLET CONTAINS PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 20 mg	Annexure A
53/21.10/0735	2023/01/24	PRINOLID 11,25	Injection	Eurolab (Pty) Ltd	EACH VIAL CONTAINS LEUPROLIDE ACETATE 11,25 mg	Annexure A
53/21.10/0733	2023/01/24	PRINOLID 3,75	Injection	Eurolab (Pty) Ltd	EACH VIAL CONTAINS LEUPROLIDE ACETATE 3,75 mg	Annexure A
53/21.10/0734	2023/01/24	PRINOLID 7,5	Injection	Eurolab (Pty) Ltd	EACH VIAL CONTAINS LEUPROLIDE ACETATE 7,5 mg	Annexure A
55/34/0542	2023/01/24	SENUOM 2 ml	Injection	Cipla Medpro (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS SUGAMMADEX SODIUM 100 mg	Annexure A
55/34/0543	2023/01/24	SENUOM 5 ml	Injection	Cipla Medpro (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS SUGAMMADEX SODIUM 100 mg	Annexure A
55/26/0640	2023/01/24	SPALBEND 100	Infusion	Ruby Pharmaceuticals (Pty) Ltd	EACH VIAL CONTAINS BENDAMUSTINE HYDROCHLORIDE 100 mg	Annexure A
55/26/0639	2023/01/24	SPALBEND 25	Infusion	Ruby Pharmaceuticals (Pty) Ltd	EACH VIAL CONTAINS BENDAMUSTINE HYDROCHLORIDE 25 mg	Annexure A
55/26/0433	2023/01/24	SPALGEM 1 000 mg	Injection	Ruby Pharmaceuticals (Pty) Ltd	EACH VIAL CONTAINS GEMCITABINE HCl EQUIVALENT TO GEMCITABINE 200 mg	Annexure A
55/26/0432	2023/01/24	SPALGEM 200 mg	Injection	Ruby Pharmaceuticals (Pty) Ltd	EACH VIAL CONTAINS GEMCITABINE HCl EQUIVALENT TO GEMCITABINE 1 000 mg	Annexure A
55/26/0661	2023/01/24	TYREC 100	Tablet	KAHMA BIOTECH (Pty) Ltd	EACH TABLET CONTAINS ERLOTINIB HCl EQUIVALENT TO ERLOTINIB 100 mg	Annexure A
55/26/0662	2023/01/24	TYREC 150	Tablet	KAHMA BIOTECH (Pty) Ltd	EACH TABLET CONTAINS ERLOTINIB HCl EQUIVALENT TO ERLOTINIB 150 mg	Annexure A
55/26/0660	2023/01/24	TYREC 25	Tablet	KAHMA BIOTECH (Pty) Ltd	EACH TABLET CONTAINS ERLOTINIB HCl EQUIVALENT TO ERLOTINIB 25 mg	Annexure A

55/5.4.1/0807	2023/01/24	XADAGO 100 mg	Tablet	Adcock Ingram Limited	EACH TABLET CONTAINS SAFINAMIDE METHANESULFONATE EQUIVALENT TO SAFINAMIDE 100 mg	Annexure A
55/5.4.1/0806	2023/01/24	XADAGO 50 mg	Tablet	Adcock Ingram Limited	EACH TABLET CONTAINS SAFINAMIDE METHANESULFONATE EQUIVALENT TO SAFINAMIDE 50 mg	Annexure A
55/7.1/0015	2023/01/24	ZANTIPRES 30 mg	Tablet	LeBasi Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS ZOFENOPRIL CALCIUM 30 mg	Annexure A
55/7.1/0014	2023/01/24	ZANTIPRES 7,5 mg	Tablet	LeBasi Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS ZOFENOPRIL CALCIUM 7,5 mg	Annexure A
55/7.1/0017.015	2023/01/24	ZOFARIL 30 mg	Tablet	LeBasi Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS ZOFENOPRIL CALCIUM 30 mg	Annexure A
55/7.1/0016.014	2023/01/24	ZOFARIL 7,5 mg	Tablet	LeBasi Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS ZOFENOPRIL CALCIUM 7,5 mg	Annexure A
55/13.8.2/0751	2023/01/31	AMORTIVO 5 %	Lacquer	Activo Health (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS AMOROLFINE HCl EQUIVALENT TO AMOROLFINE 50 mg	Annexure A
54/7.1.5/0033	2023/01/31	AMOTAD 20	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS TADALAFIL 20 mg	Annexure A
54/7.1.5/0032	2023/01/31	AMOTAD 5	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS TADALAFIL 5 mg	Annexure A
55/26/0541	2023/01/31	NERLYNX	Tablet	Pierre Fabre South Africa (Pty) Ltd	EACH TABLET CONTAINS NERATINIB MALEATE EQUIVALENT TO NERATINIB 40 mg	Annexure A
57/20.2.8/0334	2023/01/31	REKAMBYS 600 mg	Injection	Janssen Pharmaceutica (Pty) Ltd	EACH VIAL CONTAINS RILPIVIRINE 600 mg	Annexure A
57/20.2.8/0335	2023/01/31	REKAMBYS 900 mg	Injection	Janssen Pharmaceutica (Pty) Ltd	EACH VIAL CONTAINS RILPIVIRINE 900 mg	Annexure A
54/8.1/0886	2023/02/07	CYKLOCLOT 100 mg/ml	Injection	KAHMA BIOTECH (Pty) Ltd	EACH 5,0 ml AMPOULE CONTAINS TRANEXAMIC ACID 500 mg	Annexure A
55/26/0833	2023/02/07	ENZALUTAMIDE 40 mg CIPLA	Capsule	Cipla Medpro (Pty) Ltd	EACH CAPSULE CONTAINS ENZALUTAMIDE 40 mg	Annexure A
56/26/0823	2023/02/07	EQUIBEN 100	Infusion	Equity Pharmaceutical (Pty) Ltd	EACH VIAL CONTAINS BENDAMUSTINE HYDROCHLORIDE 100 mg	Annexure A
56/26/0822	2023/02/07	EQUIBEN 25	Infusion	Equity Pharmaceutical (Pty) Ltd	EACH VIAL CONTAINS BENDAMUSTINE HYDROCHLORIDE 25 mg	Annexure A
55/5.7.2/0452	2023/02/07	FOSAPREPITANT CIPLA	Infusion	Cipla Medpro (Pty) Ltd	EACH VIAL CONTAINS FOSAPREPITANT DIMEGLUMINE EQUIVALENT TO FOSAPREPITANT 150 mg	Annexure A
54/34/0877	2023/02/07	IMATINIB 100 ZYDUS	Tablet	Zydus Healthcare (Pty) Ltd	EACH TABLET CONTAINS IMATINIB MESILATE EQUIVALENT TO IMATINIB 100 mg	Annexure A
54/34/0878	2023/02/07	IMATINIB 400 ZYDUS	Tablet	Zydus Healthcare (Pty) Ltd	EACH TABLET CONTAINS IMATINIB MESILATE EQUIVALENT TO IMATINIB 400 mg	Annexure A

55/2.9/0841	2023/02/07	SESODEX	Infusion	Austell Pharmaceuticals (Pty) Ltd	EACH VIAL CONTAINS DEXMEDETOMIDINE HCl EQUIVALENT TO DEXMEDETOMIDINE 200 µg	Annexure A
53/7.1.3/0251	2023/02/07	TESAMOLOT 40/10	Tablet	Dr Reddy's Laboratories (Pty) Ltd	EACH TABLET CONTAINS TELMISARTAN 40 mg & AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10 mg	Annexure A
53/7.1.3/0253	2023/02/07	TESAMOLOT 80/10	Tablet	Dr Reddy's Laboratories (Pty) Ltd	EACH TABLET CONTAINS TELMISARTAN 80 mg & AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10 mg	Annexure A
53/7.1.3/0252	2023/02/07	TESAMOLOT 80/5	Tablet	Dr Reddy's Laboratories (Pty) Ltd	EACH TABLET CONTAINS TELMISARTAN 80 mg & AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5 mg	Annexure A
53/7.1.3/0250	2023/02/07	TESAMOLOT 40/5	Tablet	Dr Reddy's Laboratories (Pty) Ltd	EACH TABLET CONTAINS TELMISARTAN 40 mg & AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5 mg	Annexure A
56/26/0642	2023/02/07	ZOLASOL	Infusion	Ando Pharma (Pty) Ltd	EACH VIAL CONTAINS TOPOTECAN HYDROCHLORIDE 4 mg	Annexure A
55/5.7.1/0310.309	2023/02/14	ALERNOVA 0.5 mg/ml	Solution	Trinity Pharma (Pty) Ltd	EACH 1.0 ml SOLUTION CONTAINS LEVOCETIRIZINE DIHYDROCHLORIDE 0.5 mg	Annexure A
54/13.9.1/0567.564	2023/02/14	APREMILAST 10 mg GLENMARK	Tablet	Glenmark Pharmaceuticals South Africa (Pty) Ltd	EACH TABLET CONTAINS APREMILAST 10 mg	Annexure A
54/13.9.1/0568.565	2023/02/14	APREMILAST 20 mg GLENMARK	Tablet	Glenmark Pharmaceuticals South Africa (Pty) Ltd	EACH TABLET CONTAINS APREMILAST 20 mg	Annexure A
54/13.9.1/0569.566	2023/02/14	APREMILAST 30 mg GLENMARK	Tablet	Glenmark Pharmaceuticals South Africa (Pty) Ltd	EACH TABLET CONTAINS APREMILAST 300 mg	Annexure A
54/13.9.1/0564	2023/02/14	APTIKA 10 mg	Tablet	Glenmark Pharmaceuticals South Africa (Pty) Ltd	EACH TABLET CONTAINS APREMILAST 10 mg	Annexure A
54/13.9.1/0565	2023/02/14	APTIKA 20 mg	Tablet	Glenmark Pharmaceuticals South Africa (Pty) Ltd	EACH TABLET CONTAINS APREMILAST 20 mg	Annexure A
54/13.9.1/0566	2023/02/14	APTIKA 30 mg	Tablet	Glenmark Pharmaceuticals South Africa (Pty) Ltd	EACH TABLET CONTAINS APREMILAST 300 mg	Annexure A
53/20.1/0604	2023/02/14	DABUCOR 350	Injection	Accord Healthcare (Pty) Ltd	EACH VIAL CONTAINS DAPTOMYCIN 350 mg	Annexure A
53/20.1/0605	2023/02/14	DABUCOR 500	Injection	Accord Healthcare (Pty) Ltd	EACH VIAL CONTAINS DAPTOMYCIN 500 mg	Annexure A
55/5.4/0036	2023/02/14	FENRI	Solution for Inhalation	Viatrix Healthcare (Pty) Ltd	EACH 3.0 ml SOLUTION CONTAINS REVEFENACIN 175 µg	Annexure A
55/20.1.7/0783.782	2023/02/14	IMMANAZ	Infusion	Ruby Pharmaceuticals (Pty) Ltd	EACH VIAL CONTAINS VORICONAZOLE 200 mg	Annexure A

55/20.1.7/0782	2023/02/14	IMMAVOR	Infusion	Ruby Pharmaceuticals (Pty) Ltd	EACH VIAL CONTAINS VORICONAZOLE 200 mg	Annexure A
55/5.7.1/0309	2023/02/14	LEVOWAY 0.5 mg/ml	Solution	Trinity Pharma (Pty) Ltd	EACH 1.0 ml SOLUTION CONTAINS LEVOCETIRIZINE DIHYDROCHLORIDE 0.5 mg	Annexure A
54/18.3/0663	2023/02/14	QUATRO-SODA CRANBERRY	Granules	Pharmacare Limited	EACH 4.0 g GRANULES CONTAIN SODIUM BICARBONATE 1 716 mg; TARTARIC ACID 858 mg; CITRIC ACID 702 mg & SODIUM CITRATE 613 mg	Annexure A
55/5.4/0037.036	2023/02/14	REFENA	Solution for Inhalation	Viatriis Healthcare (Pty) Ltd	EACH 3.0 ml SOLUTION CONTAINS REVEFENACIN 175 ug	Annexure A
55/21.5.4/0278	2023/02/14	SPIRODISC 50/100	Powder for Inhalation	Austell Pharmaceuticals (Pty) Ltd	EACH DOSE CONTAINS SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 50 ug & FLUTICASON PROPRIONATE 100 ug	Annexure A
55/21.5.4/0279	2023/02/14	SPIRODISC 50/250	Powder for Inhalation	Austell Pharmaceuticals (Pty) Ltd	EACH DOSE CONTAINS SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 50 ug & FLUTICASON PROPRIONATE 250 ug	Annexure A
55/21.5.4/0280	2023/02/14	SPIRODISC 50/500	Powder for Inhalation	Austell Pharmaceuticals (Pty) Ltd	EACH DOSE CONTAINS SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 50 ug & FLUTICASON PROPRIONATE 500 ug	Annexure A
53/34/0059.057	2023/02/14	TAMSULOSIN ALKEM	Capsule	ALKEM LABORATORIES (PTY) LTD	EACH CAPSULE CONTAINS TAMSULOSIN HYDROCHLORIDE 0.4 mg	Annexure A
53/34/0057	2023/02/14	URIWEL	Capsule	ALKEM LABORATORIES (PTY) LTD	EACH CAPSULE CONTAINS TAMSULOSIN HYDROCHLORIDE 0.4 mg	Annexure A
53/34/0058.057	2023/02/14	UROTAL	Capsule	ALKEM LABORATORIES (PTY) LTD	EACH CAPSULE CONTAINS TAMSULOSIN HYDROCHLORIDE 0.4 mg	Annexure A
55/5.4/0038.036	2023/02/14	YUPREV	Solution for Inhalation	Viatriis Healthcare (Pty) Ltd	EACH 3.0 ml SOLUTION CONTAINS REVEFENACIN 175 ug	Annexure A
55/7.1.3/0018	2023/02/14	ZANTIPRES CO 30 mg/12.5 mg	Tablet	LeBasi Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS ZOFENOPRIL CALCIUM 30 mg & HYDROCHLOROTHIAZIDE 12.5 mg	Annexure A
55/7.1.3/0019.018	2023/02/14	ZOFARIL CO 30 mg/12.5 mg	Tablet	LeBasi Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS ZOFENOPRIL CALCIUM 30 mg & HYDROCHLOROTHIAZIDE 12.5 mg	Annexure A
53/2.6.5/0756	2023/02/21	APIZE 10 mg	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS ARIPIRAZOLE 10 mg	Annexure A
53/2.6.5/0757	2023/02/21	APIZE 15 mg	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS ARIPIRAZOLE 15 mg	Annexure A
53/2.6.5/0758	2023/02/21	APIZE 30 mg	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS ARIPIRAZOLE 30 mg	Annexure A
53/2.6.5/0755	2023/02/21	APIZE 5 mg	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS ARIPIRAZOLE 5 mg	Annexure A

53/2.6.5/0760.756	2023/02/21	ARIPHRENZ 10 mg	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS ARIPRAZOLE 10 mg	Annexure A
53/2.6.5/0761.757	2023/02/21	ARIPHRENZ 15 mg	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS ARIPRAZOLE 15 mg	Annexure A
53/2.6.5/0762.758	2023/02/21	ARIPHRENZ 30 mg	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS ARIPRAZOLE 30 mg	Annexure A
53/2.6.5/0759.755	2023/02/21	ARIPHRENZ 5 mg	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS ARIPRAZOLE 5 mg	Annexure A
53/2.6.5/0764.756	2023/02/21	ARIPRAZOLE 10 mg ALKEM	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS ARIPRAZOLE 10 mg	Annexure A
53/2.6.5/0765.757	2023/02/21	ARIPRAZOLE 15 mg ALKEM	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS ARIPRAZOLE 15 mg	Annexure A
53/2.6.5/0766.758	2023/02/21	ARIPRAZOLE 30 mg ALKEM	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS ARIPRAZOLE 30 mg	Annexure A
53/2.6.5/0763.755	2023/02/21	ARIPRAZOLE 5 mg ALKEM	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS ARIPRAZOLE 5 mg	Annexure A
57/17.1/0701	2023/02/21	BENCLOPRO 15	Capsule	Adcock Ingram Limited	EACH CAPSULE CONTAINS CYCLOBENZAPRINE HYDROCHLORIDE 15 mg	Annexure A
57/17.1/0702	2023/02/21	BENCLOPRO 30	Capsule	Adcock Ingram Limited	EACH CAPSULE CONTAINS CYCLOBENZAPRINE HYDROCHLORIDE 30 mg	Annexure A
56/26/0216	2023/02/21	BENDAMUSTINE 180 mg/4 ml DRL	Infusion	Dr Reddy's Laboratories (Pty) Ltd	EACH 4.0 ml SOLUTION CONTAINS BENDAMUSTINE HYDROCHLORIDE 180 mg	Annexure A
55/26/0656	2023/02/21	IBOZARD 100 mg	Infusion	Aurogen South Africa (Pty) Ltd	EACH VIAL CONTAINS BENDAMUSTINE HYDROCHLORIDE 100 mg	Annexure A
55/26/0655	2023/02/21	IBOZARD 25 mg	Infusion	Aurogen South Africa (Pty) Ltd	EACH VIAL CONTAINS BENDAMUSTINE HYDROCHLORIDE 25 mg	Annexure A
53/5.10/0647	2023/02/21	KEMOPREV/IV	Infusion	Austell Pharmaceuticals (Pty) Ltd	EACH VIAL CONTAINS PALONOSETRON HCl EQUIVALENT TO PALONOSETRON 250 µg	Annexure A
53/11.5/0675	2023/02/21	PHOLIPEG HS	Oral Solution	Strides Pharma (SA) (Pty) Ltd	EACH SACHET CONTAINS MACROGOL 3350 6.5625 g ; POTASSIUM CHLORIDE 0.0233 g ; SODIUM BICARBONATE 0.08925 g & SODIUM CHLORIDE 0.17535 g	Annexure A
53/11.5/0676.675	2023/02/21	PHYGLETON HS	Oral Solution	Strides Pharma (SA) (Pty) Ltd	EACH SACHET CONTAINS MACROGOL 3350 6.5625 g ; POTASSIUM CHLORIDE 0.0233 g ; SODIUM BICARBONATE 0.08925 g & SODIUM CHLORIDE 0.17535 g	Annexure A
54/2.9/0696	2023/02/21	SEDMEX 100 µg/ml	Injection	KAHMA BIOTECH (Pty) Ltd	EACH 1.0 ml SOLUTION CONTAINS DEXMEDETOMIDINE HCl EQUIVALENT TO DEXMEDETOMIDINE 100 µg	Annexure A

53/20.1.1/0075	2023/02/21	TIGECYCLINE 50 mg PFIZER	Infusion	Pfizer Laboratories (Pty) Ltd	EACH VIAL CONTAINS TIGECYCLINE 50 mg	Annexure A
55/26/0658.656	2023/02/21	ZIGOZARD 100 mg	Infusion	Aurogen South Africa (Pty) Ltd	EACH VIAL CONTAINS BENDAMUSTINE HYDROCHLORIDE 100 mg	Annexure A
55/26/0657.655	2023/02/21	ZIGOZARD 25 mg	Infusion	Aurogen South Africa (Pty) Ltd	EACH VIAL CONTAINS BENDAMUSTINE HYDROCHLORIDE 25 mg	Annexure A
54/21.12/0163.162	2023/02/28	ARMITRAZ	Tablet	Aurogen South Africa (Pty) Ltd	EACH TABLET CONTAINS ANASTROZOLE 1 mg	Annexure A
54/21.12/0162	2023/02/28	CABREXID	Tablet	Aurogen South Africa (Pty) Ltd	EACH TABLET CONTAINS ANASTROZOLE 1 mg	Annexure A
56/20.2.8/0117	2023/02/28	CABRIMIV	Tablet	Viatrix Healthcare (Pty) Ltd	EACH TABLET CONTAINS ABACAVIR SULPHATE EQUIVALENT TO ABACAVIR 600 mg & LAMIVUDINE 300 mg	Annexure A
55/3.3/0336	2023/02/28	COLCHICINE 0,5 mg TRINITY	Tablet	Trinity Pharma (Pty) Ltd	EACH TABLET CONTAINS COLCHICINE 0,5 mg	Annexure A
54/20.2.8/0188	2023/02/28	DOLVIDIN	Tablet	Novagen Pharma (Pty) Ltd	EACH TABLET CONTAINS ABACAVIR SULPHATE EQUIVALENT TO ABACAVIR 600 mg; DOLUTEGRAVIR SODIUM EQUIVALENT TO DOLUTEGRAVIR 50 mg & LAMIVUDINE 300 mg	Annexure A
55/21.2/0678	2023/02/28	GLUSITA PLUS 50/1 000 mg	Tablet	Sandoz South Africa (Pty) Ltd	EACH TABLET CONTAINS SITAGLIPTIN PHOSPHATE MONOHYDRATE EQUIVALENT TO SITAGLIPTIN 50 mg & METFORMIN HYDROCHLORIDE 1 000 mg	Annexure A
55/21.2/0676	2023/02/28	GLUSITA PLUS 50/500 mg	Tablet	Sandoz South Africa (Pty) Ltd	EACH TABLET CONTAINS SITAGLIPTIN PHOSPHATE MONOHYDRATE EQUIVALENT TO SITAGLIPTIN 50 mg & METFORMIN HYDROCHLORIDE 500 mg	Annexure A
55/21.2/0677	2023/02/28	GLUSITA PLUS 50/850 mg	Tablet	Sandoz South Africa (Pty) Ltd	EACH TABLET CONTAINS SITAGLIPTIN PHOSPHATE MONOHYDRATE EQUIVALENT TO SITAGLIPTIN 50 mg & METFORMIN HYDROCHLORIDE 850 mg	Annexure A
56/26/0165.162	2023/02/28	IPALIB 100 mg	Capsule	Cipla Medpro (Pty) Ltd	EACH CAPSULE CONTAINS PALBOCICLIB 100 mg	Annexure A
56/26/0166.163	2023/02/28	IPALIB 125 mg	Capsule	Cipla Medpro (Pty) Ltd	EACH CAPSULE CONTAINS PALBOCICLIB 125 mg	Annexure A
56/26/0164.161	2023/02/28	IPALIB 75 mg	Capsule	Cipla Medpro (Pty) Ltd	EACH CAPSULE CONTAINS PALBOCICLIB 75 mg	Annexure A
55/21.2/0681.678	2023/02/28	JOSISITIN PLUS 50/1 000 mg	Tablet	Sandoz South Africa (Pty) Ltd	EACH TABLET CONTAINS SITAGLIPTIN PHOSPHATE MONOHYDRATE EQUIVALENT TO SITAGLIPTIN 50 mg &	Annexure A

						METFORMIN HYDROCHLORIDE 1 000 mg			Annexure A
55/21.2/0679.676	2023/02/28		JOSISITIN PLUS 50/500 mg	Tablet		Sandoz South Africa (Pty) Ltd	Tablet	EACH TABLET CONTAINS SITAGLIPTIN PHOSPHATE MONOHYDRATE EQUIVALENT TO SITAGLIPTIN 50 mg & METFORMIN HYDROCHLORIDE 500 mg	Annexure A
55/21.2/0680.677	2023/02/28		JOSISITIN PLUS 50/850 mg	Tablet		Sandoz South Africa (Pty) Ltd	Tablet	EACH TABLET CONTAINS SITAGLIPTIN PHOSPHATE MONOHYDRATE EQUIVALENT TO SITAGLIPTIN 50 mg & METFORMIN HYDROCHLORIDE 850 mg	Annexure A
56/26/0162	2023/02/28		PALBOCICLIB 100 mg CIPLA	Capsule		Cipla Medpro (Pty) Ltd	Capsule	EACH CAPSULE CONTAINS PALBOCICLIB 100 mg	Annexure A
56/26/0163	2023/02/28		PALBOCICLIB 125 mg CIPLA	Capsule		Cipla Medpro (Pty) Ltd	Capsule	EACH CAPSULE CONTAINS PALBOCICLIB 125 mg	Annexure A
56/26/0161	2023/02/28		PALBOCICLIB 75 mg CIPLA	Capsule		Cipla Medpro (Pty) Ltd	Capsule	EACH CAPSULE CONTAINS PALBOCICLIB 75 mg	Annexure A
56/3.1/0924	2023/02/28		QULOXIB 100	Capsule		Sandoz South Africa (Pty) Ltd	Capsule	EACH CAPSULE CONTAINS CELECOXIB 100 mg	Annexure A
56/3.1/0925	2023/02/28		QULOXIB 200	Capsule		Sandoz South Africa (Pty) Ltd	Capsule	EACH CAPSULE CONTAINS CELECOXIB 200 mg	Annexure A
57/20.2.8/0166	2023/03/28		RELIVZATE	Tablet		Austell Pharmaceuticals (Pty) Ltd	Tablet	EACH TABLET CONTAINS LAMIVUDINE 300 mg & TENOFOVIR DISOPROXIL FUMARATE EQUIVALENT TO TENOFOVIR DISOPROXIL 245 mg	Annexure A
55/3.3/0337.336	2023/02/28		URICID 0,5 mg	Tablet		Trinity Pharma (Pty) Ltd	Tablet	EACH TABLET CONTAINS COLCHICINE 0,5 mg	Annexure A
55/30.3/0752	2023/03/07		CINRYZE	Injection		Takeda (Pty) Ltd	Injection	EACH VIAL CONTAINS C1 INHIBITOR 500 IU	Annexure A
55/5.7.2/0659	2023/03/07		EASAN	Infusion		KAHMA BIOTECH (Pty) Ltd	Infusion	EACH VIAL CONTAINS FOSAPREPITANT DIMEGLUMINE EQUIVALENT TO FOSAPREPITANT 150 mg	Annexure A
56/26/0229	2023/03/07		MVASI 100 mg/4 ml	Infusion		Amgen South Africa (Pty) Ltd	Infusion	EACH 4,0 ml SOLUTION CONTAINS BEVACIZUMAB 100 mg	Annexure A
56/26/0230	2023/03/07		MVASI 400 mg/16 ml	Infusion		Amgen South Africa (Pty) Ltd	Infusion	EACH 16,0 ml SOLUTION CONTAINS BEVACIZUMAB 400 mg	Annexure A
55/8.5/0736	2023/03/07		ZIEXTENZO	Injection		Sandoz South Africa (Pty) Ltd	Injection	EACH 0,6 ml SOLUTION CONTAINS PEGFILGRASTIM 6 mg	Annexure A
54/13.8.2/0172	2023/03/14		AMOFUN 5 %	Solution		Austell Pharmaceuticals (Pty) Ltd	Solution	EACH 1,0 ml SOLUTION CONTAINS AMOROLFINE HCl EQUIVALENT TO AMOROLFINE 50 mg	Annexure A

54/13.8.2/0173.172	2023/03/14	FUNGORYL 5 %	Solution	Austell Pharmaceuticals (Pty) Ltd	EACH 1.0 ml SOLUTION CONTAINS AMOROLFINE HCl EQUIVALENT TO AMOROLFINE 50 mg	Annexure A
55/20.1/0096	2023/03/14	DAPICUB	Infusion	KAHMA BIOTECH (Pty) Ltd	EACH VIAL CONTAINS DAPTOMYCIN 500 mg	Annexure A
55/2.9/0235	2023/03/14	RUTREX	Oral Solution	LeBasi Pharmaceuticals (Pty) Ltd	EACH 1.0 ml SOLUTION CONTAINS METHADONE HYDROCHLORIDE 10 mg	Annexure A
56/26/0920	2023/03/14	NUTAND	Capsule	Cipla Medpro (Pty) Ltd	EACH CAPSULE CONTAINS ENZALUTAMIDE 40 mg	Annexure A
56/26/0921.920	2023/03/14	XZALU	Capsule	Cipla Medpro (Pty) Ltd	EACH CAPSULE CONTAINS ENZALUTAMIDE 40 mg	Annexure A
54/20.1/0841	2023/03/24	DAPTOMYCIN EQUITY	Infusion	Equity Pharmaceutical (Pty) Ltd	EACH VIAL CONTAINS DAPTOMYCIN 500 mg	Annexure A
55/1.2/0743	2023/03/24	ATOXTRIN 10 mg	Capsule	Trinity Pharma (Pty) Ltd	EACH CAPSULE CONTAINS ATOMOXETINE HCl EQUIVALENT TO ATOMOXETINE 10 mg	Annexure A
55/1.2/0744	2023/03/24	ATOXTRIN 18 mg	Capsule	Trinity Pharma (Pty) Ltd	EACH CAPSULE CONTAINS ATOMOXETINE HCl EQUIVALENT TO ATOMOXETINE 18 mg	Annexure A
55/1.2/0745	2023/03/24	ATOXTRIN 25 mg	Capsule	Trinity Pharma (Pty) Ltd	EACH CAPSULE CONTAINS ATOMOXETINE HCl EQUIVALENT TO ATOMOXETINE 25 mg	Annexure A
55/1.2/0746	2023/03/24	ATOXTRIN 40 mg	Capsule	Trinity Pharma (Pty) Ltd	EACH CAPSULE CONTAINS ATOMOXETINE HCl EQUIVALENT TO ATOMOXETINE 40 mg	Annexure A
55/1.2/0747	2023/03/24	ATOXTRIN 60 mg	Capsule	Trinity Pharma (Pty) Ltd	EACH CAPSULE CONTAINS ATOMOXETINE HCl EQUIVALENT TO ATOMOXETINE 60 mg	Annexure A
55/1.2/0748	2023/03/24	ATOXTRIN 80 mg	Capsule	Trinity Pharma (Pty) Ltd	EACH CAPSULE CONTAINS ATOMOXETINE HCl EQUIVALENT TO ATOMOXETINE 80 mg	Annexure A
55/26/0797	2023/03/24	TAZATRED 20	Tablet	Dr Reddy's Laboratories (Pty) Ltd	EACH TABLET CONTAINS DASATINIB 20 mg	Annexure A
55/26/0798	2023/03/24	TAZATRED 50	Tablet	Dr Reddy's Laboratories (Pty) Ltd	EACH TABLET CONTAINS DASATINIB 50 mg	Annexure A
55/26/0799	2023/03/24	TAZATRED 70	Tablet	Dr Reddy's Laboratories (Pty) Ltd	EACH TABLET CONTAINS DASATINIB 70 mg	Annexure A
55/26/0800	2023/03/24	TAZATRED 100	Tablet	Dr Reddy's Laboratories (Pty) Ltd	EACH TABLET CONTAINS DASATINIB 100 mg	Annexure A
57/20.2.3/0176	2023/03/24	FRIPNIT	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS RIFAPENTINE 300 mg	Annexure A
53/20.1.2/0151	2023/03/28	AMOXICILLIN 125 S PORTFOLIO	Suspension	Portfolio Laboratories (Pty) Ltd	EACH 5.0 ml SUSPENSION CONTAINS AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 125 mg	Annexure A

53/20.1.2/0152	2023/03/28	AMOXICILLIN 250 SF PORTFOLIO	Suspension	Portfolio Laboratories (Pty) Ltd	EACH 5.0 ml SUSPENSION CONTAINS AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 250 mg	Annexure A
54/20.2.8/0343	2023/03/28	RARUDINE	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS DOLUTEGRAVIR SODIUM EQUIVALENT TO DOLUTEGRAVIR 50 mg, LAMIVUDINE 300 mg & TENOFOVIR DISOPROXIL FUMARATE 300 mg	Annexure A
55/15.4/0700	2023/03/28	ADORTIM	Solution	Trinity Pharma (Pty) Ltd	EACH 1.0 ml SOLUTION CONTAINS DORZOLAMIDE HCl EQUIVALENT TO DORZOLAMIDE 20 mg & TIMOLOL MALEATE EQUIVALENT TO TIMOLOL 5 mg	Annexure A
55/15.4/0701.700	2023/03/28	OPTITRIN	Solution	Trinity Pharma (Pty) Ltd	EACH 1.0 ml SOLUTION CONTAINS DORZOLAMIDE HCl EQUIVALENT TO DORZOLAMIDE 20 mg & TIMOLOL MALEATE EQUIVALENT TO TIMOLOL 5 mg	Annexure A
55/15.4/0702.700	2023/03/28	GLAUSPEC	Solution	Trinity Pharma (Pty) Ltd	EACH 1.0 ml SOLUTION CONTAINS DORZOLAMIDE HCl EQUIVALENT TO DORZOLAMIDE 20 mg & TIMOLOL MALEATE EQUIVALENT TO TIMOLOL 5 mg	Annexure A

Annexure A

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of current Good Manufacturing Practices as determined by SAHPRA.
2. The manufacture of this medicine is subject to regular investigation and inspections by the inspectors appointed in terms of Section 26 of the Act, to assess compliance with current Good Manufacturing Practices.
3. The information in the professional information shall be updated on a regular basis to conform to the professional information recently approved by SAHPRA.
4. The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965).
5. The registration of this medicine shall be subject to review at intervals as determined by SAHPRA regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues SAHPRA may deem fit.
6. The first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration, and the validation report must be submitted within a month after completion of the validation.
7. The product may be advertised to the professions only.
54. The Score document must be maintained and must be consistent with the current approved information.