



Regd. AD | By Hand Delivery

Food & Drugs Administration (Maharashtra State)

Letter No: MH/MZ4/RNW/25A-KD/2185A
Food & Drugs Administration, KONKAN Division
OFFICE OF JOINT COMMISSIONER (K.D.)
4TH FLE.SIC BLD, WAGLE ESTATE
Thane - 400604

License Retention With Products

Validity Period: 13/08/2018 To 12/08/2023

To :

711491- LOK-BETA PHARMACEUTICALS(I) PVT.LTD (Private Limited)
324, CORPORATE CENTRE,, NIRMAL LIFE STYLE L.B.S MARG MULUND
W, MUMBAI - 400080
Taluka: MULUND, District: Mumbai-Zone4

LICENSE No : 25A-KD/2185A
& Dt : 28/06/2018

Sir,

Ref :- Your Inward Application vide Inward ID:- 97042 (RNW) Dated :- 20/06/2018

With reference to your Inward application, we inform you that your said application is considered & following
LICENSE has been **Retained**

Type	Form	LIC No / Validity	First Date / Rev
L-J.DUNCAN HEALTHCARE PVT.LTD.(705500)	25A	KD/2185A 12/08/2023	13/08/2008 13/08/2018
Prod	Name of Drugs		
1. 601465	Abacavir & Lamivudine premix Each 1104 mg premix contains:	- Abacavir Sulphate USP equivalent to Abacavir (600 mg) - Lamivudine USP (300 mg) - Excipients (- QS)	Export (IHS(In House))
2. 540018	Abacavir & Lamivudine Tablets 900 mg Each film coated tablet contains:	- Abacavir Sulphate USP Eq. to Abacavir (600 mg) - Lamivudine USP (300 mg) - Approved colour added (-) - Excipients (- QS)	Export (IHS(In House))
3. 333842	ABACAVIR, LAMIVUDINE AND ZIDOVUDINE TABLETS (300 mg+150mg) +300mg) Each film coated tablet contains:	- Abacavir Sulphate USP equivalent to Abacavir (300 mg) - Lamivudine USP (150 mg) - Zidovudine USP (300 mg) - Excipients (- QS) - Colour: Approved colours added (-)	Export (IHS(In House))
4. 164779	ABACAVIR AND LAMIVUDINE TABLETS 450 MG Each film coated tablet contains:	- Abacavir sulphate USP Eq. to Abacavir (300 mg) - Lamivudine USP (150 mg) - Excipients (- QS) - Colour: Approved colour added (-)	Export (IHS)
5. 164784	DACAVIR 450 / ABACAVIR AND LAMIVUDINE TABLETS 450 MG Each film	- Abacavir sulphate USP Eq. to Abacavir (300 mg) - Lamivudine USP (150 mg) - Excipients (- QS) - Colour: Approved colour added (-)	Export (IHS)
6. 164785	DACAVIR 900 / ABACAVIR AND LAMIVUDINE TABLETS 900 MG Each film coated tablet contains:	- Abacavir sulphate USP Eq. to Abacavir (600 mg) - Lamivudine USP (300 mg) - Excipients (- QS) - Colour: Approved Colours Added (-)	Export (IHS)
7. 165762	ABACAVIR AND LAMIVUDINE TABLETS 900 MG (Qty.2,00,000 tablets for Russia) Each film coated tablet contains:	- Abacavir Sulphate USP Eq. to Abacavir USP (600 mg) - Lamivudine USP (300 mg) - Excipients (- QS) - Colour: Approved colour added (-)	Export (IHS)
8. 401191	ABACAVIR TABLETS USP 300 MG Each film coated tablet contains:	- Abacavir Sulphate USP equivalent to Abacavir (300 mg) - Excipients (- QS) - Colour: Approved colours added (-)	Export
9.	ACECLOFENAC AND PARACETAMOL TABLETS		Domestic (IHS)

Fee Payment(s) : DB-Id: 301934 - 20/06/2018 (Amt: 179250) (RENEWL/RETENSION OF MFG LIC) ,Balance : 0

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Division	MFG ID No	Type: License Renewal	License No	Issue Date
KONKAN (TZ4)	711491	RNW-97042-20/06/2018	25A-KD/2185A	28/06/2018

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71. 645304	EFAREZ / Efavirenz Tablets USP 600 mg Each film coated tablet contains:	- Efavirenz USP (600 mg) - Approved colours added (-) - Excipients (- QS)	Export (USP)
72. 182129	EFFECTIVE MUSCLE RELAXANT, ANTI-INFLAMMATORY, ANALGESIC GEL Composition:	- Diclofenac Diethylamine BP (1.16 % W/W) - equivalent to Diclofenac Sodium BP (1.0 % W/W) - Methyl Salicylate IP (5 % W/W) - Turpentine Oil IP-66 (3 % W/W) - Gel Base (- QS) - Mephonesin IP-85 (5 % W/W) - Menthol IP (2 % W/W)	Domestic
73. 164905	EMTRICITABINE CAPSULES 200 MG Each capsule contains:	- Emtricitabine (In House) (200 mg) - Excipients (- QS) - Approved colour are used in capsule shells (-)	Export (IHS)
74. 401193	ENTECAVIR TABLETS 1.0 MG Each film coated tablet contains:	- Entecavir Monohydrate equivalent to Entecavir (In House) (1.0 mg) - Excipients (- QS) - Colour: Approved colours added (-)	Export
75. 164977	ENTERIC COATED PANTOPRAZOLE SODIUM AND DOMPERIDONE SR CAPSULES Each capsule contains:	- Pantoprazole sodium IP Eq. to pantoprazole (As enteric coated pellets) (40 mg) - Domperidone IP (As sustained release pellets) (30 mg) - Approved colours used in empty gelatin capsules (-)	Domestic (IHS)
76. 635265	Eplerenone Tablets 50 mg Each film coated tablet contains:	- Eplerenone (In House) (50 mg) - Ferric Oxide Red, Ferric Oxide Yellow & Titanium Dioxide (-) - Excipients (- QS)	Export (IHS(In House))
77. 413457	EPLERENONE TABLETS USP 25MG Each film coated tablet contains:	- Eplerenone USP (25 mg) - Excipients (- QS) - Colour: Approved colours added (-)	Export (USP)
78. 166412	ETHAMBUTOL TABLETS BP 400 MG Each uncoated tablet contains:	- Ethambutol Hydrochloride BP (400 mg) - Excipients (- QS)	Export (BP)
79. 166418	ETHIONAMIDE TABLETS USP 250 MG TABLETS Each enteric coated tablet contains:	- Ethionamide USP (250 mg) - Ethionamide USP (250 mg) - Excipients (- QS) - Colour: Approved colour added (-)	Export (USP)
80. 413458	EVEROLIMUS TABLETS 0.25 MG Each tablet contains:	- Everolimus (0.25 mg) - Excipients (- QS) - Colour: Approved colours added (-)	Export
81. 413459	EVEROLIMUS TABLETS 0.5 MG Each tablet contains:	- Everolimus (0.5 mg) - Excipients (- QS) - Colour: Approved colours added (-)	Export
82. 413460	EVEROLIMUS TABLETS 0.75 MG Each tablet contains:	- Everolimus (0.75 mg) - Excipients (- QS) - Colour: Approved colours added (-)	Export
83. 413461	EVEROLIMUS TABLETS 1.0 MG Each tablet contains:	- Everolimus (1.0 mg) - Excipients (- QS) - Colour: Approved colours added (-)	Export
84. 164912	FEBUXOSTAT TABLETS 40 MG Each film coated tablet contains:	- Febuxostat (In House) (40 mg) - Colour: Titanium Dioxide I.P. (-)	Domestic (IHS)
85. 164913	Fexofenadine Hydrochloride and Montelukast Tablets (120mg+10mg) Each film coated tablet contains:	- Fexofenadine Hydrochloride IP (120 mg) - Montelukast Sodium IP equivalent to Montelukast (10 mg) - Colour: Yellow oxide of Iron & Titanium Dioxide I.P. (-) - Excipients (- QS)	Domestic (IHS(In House))
86. 324338	FINASTERIDE TABLETS USP 5 MG Each film coated tablet contains:	- Finasteride USP (5 mg) - Excipients (- QS) - Colour: Approved colours added (-)	Export (USP)
87.	FLUCONAZOLE CAPSULES 150 MG		Export (IHS)

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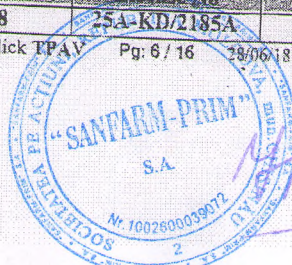
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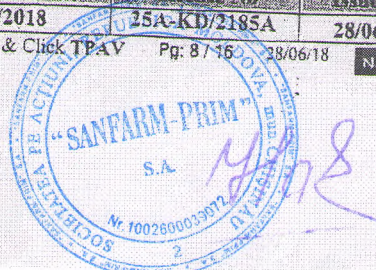
165181	Each film coated tablet contains:	- Ivermectin BP (6 mg) - Excipients (- QS) - Colour: Titanium Dioxide (-)	
106. 681988	Ketoprofen Gel 5% Each gm contains:	- Ketoprofen BP (5 % W/W) - Excipients (- QS)	Export (IHS(In House))
107. 595660	Ketoprofen Gel BP 2.5 % Composition:	- Ketoprofen BP (2.5 % W/W) - Excipients (- QS)	Export (BP)
108. 601466	Lamivudine & Zidovudine premix Each 641 mg premix contains:	- Lamivudine USP (150 mg) - Zidovudine USP (300 mg) - Excipients (- QS)	Export (IHS(In House))
109. 401192	LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS (300 MG + 300 MG) Each film coated tablet contains:	- Lamivudine USP (300 mg) - Tenofovir Disoproxil Fumarate 300 mg Equivalent to Tenofovir Disoproxil (245 mg) - Excipients (- QS) - Colour: Approved Colours added (-)	Export
110. 164719	FARNOVIR / LAMIVUDINE AND ZIDOVUDINE TABLETS 450 MG Each film coated tablet contains:	- Lamivudine USP (150 mg) - Zidovudine USP (300 mg) - Excipients (- QS) - Colours: Approved colours added (-)	Export (IHS)
111. 164808	LAMIVUDINE AND ZIDOVUDINE TABLETS 450 MG Each film coated tablet contains:	- Lamivudine USP (150 mg) - Zidovudine USP (300 mg) - Excipients (- QS) - Colours: Approved colours added (-)	Export (IHS)
112. 164721	FARNOVIR 900 / LAMIVUDINE AND ZIDOVUDINE TABLETS 900 MG Each film coated tablet contains:	- Lamivudine USP (300 mg) - Zidovudine USP (600 mg) - Excipients (- QS) - Colours: Approved colours added (-)	Export (IHS)
113. 164926	LAMIVUDINE AND ZIDOVUDINE TABLETS USP 900 MG Each film coated tablet contains:	- Lamivudine USP (300 mg) - Zidovudine USP (600 mg) - Excipients (- QS) - Colour: Approved colour added (-)	Export (USP)
114. 166694	LAMIVUDINE TABLETS 100 MG Each film coated tablet contains:	- Lamivudine USP (100 mg) - Excipients (- QS) - Colour: Approved colour added (-)	Export (IHS)
115. 167012	LUMIDIN-100 / LAMIVUDINE TABLETS 100 MG Each film coated tablet contains:	- Lamivudine USP (100 mg) - Excipients (- QS) - Colours: Approved colour added (-)	Export (IHS)
116. 165796	LUMIDIN-150 / LAMIVUDINE TABLETS 150 MG Each film coated tablet contains:	- Lamivudine USP (150 mg) - Excipients (- QS) - Colours: Approved colour added (-)	Export (IHS)
117. 166703	LAMIVUDINE TABLETS 150 MG Each film coated tablet contains:	- Lamivudine USP (150 mg) - Excipients (- QS) - Colour: Approved colour added (-)	Export (IHS)
118. 165797	LUMIDIN-300 / LAMIVUDINE TABLETS 300 MG Each film coated tablet contains:	- Lamivudine USP (300 mg) - Excipients (- QS) - Colours: Approved colour added (-)	Export (IHS)
119. 165798	LAMIVUDINE TABLETS 300 MG Each film coated tablet contains:	- Lamivudine USP (300 mg) - Excipients (-) - Colour: Approved colour added (-)	Export (IHS)
120. 401190	LAMIVUDINE, ZIDOVUDINE AND NEVIRAPINE TABLETS (150 MG + 300 MG + 200 MG) Each film coated tablet contains:	- Lamivudine USP (150 mg) - Zidovudine USP (300 mg) - Nevirapine USP (200 mg) - Colour: Approved colours added (-) - Excipients (- QS)	Export

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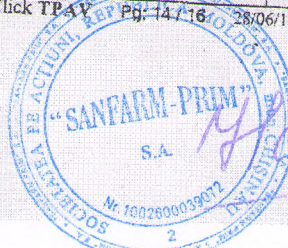


164892	Each film coated tablet contains:	- Tenofovir Disoproxil Fumarate 300 mg Eq. to Tenofovir Disoproxil (In House) (245 mg) - Emtricitabine (In House) (200 mg) - Excipients (- QS) - Colours: Approved colours added (-)	Export (IHS(In House))
204. 671040	Tenofovir Disoproxil Fumarate, Emtricitabine & Efavirenz Premix Each 1550 mg of premix contains:	- Part A) Efavirenz premix: Each 912 mg of premix contains: Efavirenz USP (600 mg) - Part B) Tenofovir Disoproxil Fumarate & Emtricitabine premix: Each 638 mg of premix contains: Tenofovir Disoproxil Fumarate 300 mg Eq. to Tenofovir Disoproxil (In House) (245 mg) - Emtricitabine (In House) (200 mg) - Approved colour added (-) - Excipients (- QS)	Export (IHS)
164898	TENOFOVIR DISOPROXIL FUMARATE, EMTRICITABINE AND EFAVIRENZ TABLETS (300 MG + 200 MG + 600 MG) Each film coated tablet contains:	- Tenofovir Disoproxil Fumarate 300 mg Eq. to Tenofovir Disoproxil (In House) (245 mg) - Emtricitabine (In House) (200 mg) - Efavirenz USP (600 mg) - Colours: Approved colours added (-)	Export (IHS)
500308	LONARENZ / TENOFOVIR DISOPROXIL FUMARATE, EMTRICITABINE AND EFAVIRENZ TABLETS (300 MG + 200 MG + 600 MG) Each film coated tablet contains:	- Emtricitabine (200 mg) - Efavirenz USP (600 mg) - Tenofovir Disoproxil Fumarate 300 mg equivalent to Tenofovir Disoproxil (245 mg) - Excipients (- QS) - Colour: Approved colours added (-)	Export
167291	TENOFOVIR TABLETS 300 MG Each film coated tablet contains:	- Tenofovir Disoproxil Fumarate Eq. to Tenofovir (300 mg) - Excipients (- QS) - Colour: Approved colour added (-)	Export (IHS)
595662	Terbinafine Cream 1% Composition:	- Terbinafine Hydrochloride BP (1 % W/W) - Benzyl Alcohol BP (1 % W/W) - In a cream base (-)	Export (IHS(In House))
681989	Terbinafine Gel 1% Each gm contains:	- Terbinafine Hydrochloride BP (1 % W/W) - Excipients (- QS)	Export (IHS(In House))
596090	Terizidone Capsules 300 mg Each hard gelatin capsule contains:	- Terizidone IH (300 mg) - Approved colours used in capsule shells (-) - Excipients (- QS)	Export (IHS(In House))
601463	Terizidone & Pyridoxine premix Each 300mg premix contains:	- Terizidone (250 mg) - Pyridoxine Hydrochloride USP (10 mg) - Excipients (- QS)	Export (IHS(In House))
601464	Terizidone & Pyridoxine premix Each 350mg premix	- Terizidone (300 mg) - Pyridoxine Hydrochloride USP (10 mg) - Excipients (- QS)	Export (IHS(In House))
596089	Terizidone Capsules 150 mg Each hard gelatin capsule contains:	- Terizidone IH (150 mg) - Approved colors used in capsule shells (-) - Excipients (- QS)	Export (IHS(In House))
16732	TERIZIDONE CAPSULES 250 MG Each hard gelatin capsule contains:	- Terizidone (250 mg) - Excipients (- QS) - Approved colours are used in capsule shells (-)	Export (IHS)
596079	Terizidone premix Each 300mg premix contains:	- Terizidone (300 mg) - Excipients (- QS)	Export (IHS(In House))
598980	Terizidone premix Each 320mg premix contains:	- Terizidone (150 mg) - Excipients (- QS)	Export (IHS(In House))
598981	Terizidone premix Each 300mg premix contains:	- Terizidone (250 mg) - Excipients (- QS)	Export (IHS(In House))
218.	THIOLCHOLCHICOSIDE & ACECLOFENAC TABLETS		Domestic (IHS)

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164742	Each ml contains:	- Lopinavir USP (80 mg) - Ritonavir USP (20 mg) - Excipients (- QS) - Approved colour and flavour added (-)	
137.	TINAROVIR / LOPINAVIR AND RITONAVIR TABLETS 125 MG		Export (MS)
164722	Each film coated tablet contains:	- Lopinavir USP (100 mg) - Ritonavir USP (25 mg) - Excipients (- QS) - Colour: Approved colour added (-)	
138.	LORATIDINE TABLETS 5 MG		Export (MS)
167235	Each tablet contains:	- Loratidine (5 mg) - Excipients (- QS)	
139.	METFORMIN HYDROCHLORIDE TABLETS USP 500 MG		Export
500210	Each Film Coated tablet contains:	- Metformin Hydrochloride USP (500 mg) - Excipients (- QS) - Colour: Approved Colours added (-)	
140.	METFORMIN TABLETS BP 1 GM		Export (BP)
166434	Each film coated tablet contains:	- Metformin Hydrochloride BP (1000 mg) - Excipients (- QS) - Colour: Approved colour added (-)	
141.	METFORMIN TABLETS BP 250 MG		Export (BP)
167209	Each film coated tablet contains:	- Metformin Hydrochloride BP (250 mg) - Excipients (- QS) - Colour: Approved colour added (-)	
142.	METFORMIN TABLETS BP 500 MG		Export (BP)
166419	Each film coated tablet contains:	- Metformin Hydrochloride BP (500 mg) - Excipients (- QS) - Colour: Approved colour added (-)	
143.	METFORMIN TABLETS BP 850 MG		Export (BP)
166426	Each film coated tablet contains:	- Metformin Hydrochloride BP (850 mg) - Excipients (- QS) - Colour: Approved colour added (-)	
144.	Metronidazole Gel USP 1%		Export (USP)
596225	Each gm contains:	- Metronidazole USP (1.0 % W/W) - Excipients (- QS)	
145.	- / Metronidazole Oral Suspension USP 200 mg/5 ml		Export (USP)
531854	Each 5 ml contains:	- Metronidazole Benzoate USP Eq. to Metronidazole (200 mg)	
146.	- / Metronidazole Tablets USP 400 mg		Export (USP)
531849	Each tablet contains:	- Metronidazole USP (400 mg) - Titanium Dioxide & Sunset Yellow (-) - Excipients (- QS)	
147.	Mometasone Furoate Cream USP 0.10 %		Export (USP)
595657	Composition:	- Mometasone Furoate USP (0.10 % W/W) - Excipients (- QS)	
148.	MONTELUKAST SODIUM AND LEVOCETIRIZINE DIHYDROCHLORIDE TABLETS		Domestic
182130	Each uncoated bilayer tablet contains:	- Montelukast Sodium IP equivalent to Montelukast (10 mg) - Levocetirizine Dihydrochloride IP (5 mg) - Excipients (- QS) - Colours: Approved colours used (-)	
149.	MOXIFLOXACIN TABLETS 400 MG		Export (MS)
167197	Each film coated tablet contains:	- Moxifloxacin Hydrochloride BP Eq. to Moxifloxacin (400 mg) - Excipients (- QS) - Colour: Approved colour added (-)	
150.	ROTEMOX / MOXIFLOXACIN TABLETS 400 MG		Export (MS/MS House)
475246	Each film coated tablet contains:	- Moxifloxacin Hydrochloride USP Equivalent to Moxifloxacin (400 mg) - Excipients (- QS) - Colour: Approved colours added (-)	
151.	MYCOPHENOLATE MOFETIL TABLETS USP 500 MG		Export
165730	Each film coated tablet contains:	- Mycophenolate Mofetil USP (500 mg) - Excipients (- mg) - Colours: Approved colours used (-)	
152.	LIRASEPT ORAL POWDER / NELFINAVIR ORAL POWDER		Export (MS)
165756	Each gm contains:	- Nelfinavir Mesylate Eq. to Nelfinavir (50 mg) - Excipients (- QS) - Approved colour and flavour added (-)	
153.	LIRASEPT 250 / NELFINAVIR TABLETS 250 MG		Export (MS)
165753	Each film coated tablet contains:	- Nelfinavir Mesylate Eq. to Nelfinavir (250 mg) - Excipients (- QS) - Colour: Approved colour added (-)	

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165346	Each capsule contains:	- Fluconazole USP USP (150 mg) - Excipients (- QS) - Approved colours are used in capsule shells (-)	Export (IHS)
88.	FLUCONAZOLE CAPSULES 50 MG		
165345	Each capsule contains:	- Fluconazole USP USP (50 mg) - Excipients (- QS) - Approved colours are used in capsule shells (-)	Export (USP)
89.	FOSINOPRIL SODIUM TABLETS USP 10 MG		
166464	Each uncoated tablet contains:	- Fosinopril Sodium USP (10 mg) - Excipients (- QS)	Export
90.	FOSIP 10 / FOSINOPRIL SODIUM TABLETS USP 10 MG		
182126	Each uncoated tablet contains:	- Fosinopril Sodium USP (10 mg) - Excipients (- QS)	Export (USP)
91.	FOSILOK 20 / Fosinopril Sodium Tablets USP 20 mg		
551408	Each uncoated tablet contains:	- Fosinopril Sodium USP (20 mg) - Excipients (- QS)	Export (USP)
92.	FOSINOPRIL SODIUM TABLETS USP 40 MG		
166490	Each uncoated tablet contains:	- Fosinopril Sodium USP (40 mg) - Excipients (- QS)	Export (USP)
93.	GEMFIBROZIL TABLETS USP 600 MG		
166498	Each film coated tablet contains:	- Gemfibrozil USP (600 mg) - Excipients (- QS) - Colour/Approved colour added (-)	Export (USP)
94.	GLIBENCLAMIDE AND METFORMIN HYDROCHLORIDE TABLETS (5 MG/1000MG)		
164806	Each film coated tablet contains:	- Glibenclamide BP (5 mg) - Metformin Hydrochloride (1000 mg) - Excipients (- QS) - Colour/Titanium Dioxide (-)	Export (IHS)
95.	GLIBENCLAMIDE AND METFORMIN HYDROCHLORIDE TABLETS (5 MG/500MG)		
164804	Each film coated tablet contains:	- Glibenclamide BP (5 mg) - Metformin Hydrochloride BP (500 mg) - Excipients (- QS) - Colour/Titanium Dioxide (-)	Export (IHS)
96.	GLIMECRON / GLICLAZIDE TABLETS BP 80 MG		
166534	Each uncoated tablet contains:	- Gliclazide BP (80 mg) - Excipients (- QS)	Export (USP)
97.	GLIMEPIRIDE TABLETS USP 1 MG (Qty.45,000x3x10 tablets for Russia) / (As per NOC granted by DCGL New Delhi vide letter No.7-5/2009-DCG (A88)-33 DATED 04.02.2009)		
166565	Each uncoated tablet contains:	- Glimepiride USP (1 mg) - Excipients (- QS)	Export (USP)
98.	GLIMEPIRIDE TABLETS USP 2 MG (Qty.40,000 x3x10 tablets for Russia) / (As per NOC granted by DCGL New Delhi vide letter No.7-5/2009-DCG (A88)-33 DATED 04.02.2009)		
166570	Each uncoated tablet contains:	- Glimepiride USP (2 mg) - Excipients (- QS)	Export (BP)
99.	Ibuprofen Gel BP 2.5 %		
595655	Composition:	- Ibuprofen BP (2.5 % W/W) - Excipients (- QS)	Export (BP)
100.	Ibuprofen Gel BP 5.0 %		
595656	Composition:	- Ibuprofen BP (5.0 % W/W) - Excipients (- QS)	Export (BP)
101.	IBUPROFEN TABLETS BP 400 MG		
165841	Each film coated tablet contains:	- Ibuprofen BP (400 mg) - Excipients (- QS) - Colour/Approved colour added (-)	Export (USP)
102.	IRBESARTAN TABLETS USP 150 MG		
40171	Each film coated tablet contains:	- Irbesartan USP (150 mg) - Excipients (- QS) - Colour/Approved colours added (-)	Export (IHS)
103.	ITRACONAZOLE CAPSULES 100 MG		
166530	Each capsule contains:	- Itraconazole pellets (100 mg) - Excipients (- QS) - Approved colours are used in capsule shells (-)	Export (IHS)
104.	IVERMECTIN TABLETS 6 MG		
166530	Each film coated tablet contains:	- Ivermectin BP (6 mg) - Excipients (- QS) - Colour/Approved colour added (-)	Domestic (USP)
105.	IVERMECTIN TABLETS USP 6 MG		

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