Government of Haryana
Food And Drugs Administration Haryana,
Sco-94, Sector-5, Panchkula, Panchkula,
Haryana-134109, India

FORM 25 (See rule 70)

Licence to manufacture for sale or for distribution of drugs other than those specified in Schedules C and C (1) and X

File No: **HR/ML/F24/2022/00025** Licence No: **MLF252022HR000003** Issue Date: **29-NOV-2022**

Site Id: **HR0004379** Old Licence No: **NA**

1. M/s. **SCOUT LIFESCIENCE PRIVATE LIMITED** is hereby licensed to manufacture the following categories of drugs being drugs other than those specified in Schedules C, C(1) and X to the Drugs Rules, 1945, on the premises situated at **Plot No 353, Sector 2, Industrial Growth Centre HSIIDC, Saha ,Ambala ,Ambala ,Haryana ,India ,133104** under the direction and supervision of the following competent technical staff-

A. Competent Technical Staff:

(I). Name(s) of staff responsible for testing

Member ID	Member Name	Assign Role / Designation	Qualification
20225927325	Mr. Ravinder Kumar	Analytical Chemist	B.Sc

(II). Name(s) of staff responsible for manufacturing

Member ID	Member Name	Assign Role / Designation	Qualification
20228163471	Mr. Harbir Singh	Manufacturing Chemist	B.Sc

B. Name of Drugs (each item to be separately specified) See **Annexure 'A'**

2. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence, subject to the conditions applicable to licence for sale

3. The licence unless sooner suspended or cancelled shall remain valid perpetually.However,the compliance with the conditions of licence and the provisions of the Drugs & Cosmetics Act,1940 (23 of 1940) and the Drugs Rules , 1945 shall be assessed not less than once in three years or as needed as per risk based approach.

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs & Cosmetics Act 1940 (23 of 1940).

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Licensing Authority

Conditions of Licence

1. This licence shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs & Cosmetics Act 1940 (23 of 1940).
2. Any change in the Competent Technical Staff named in the licence shall be forthwith reported to the Licensing Authority.
3. If the licensee wants to manufacture for sale additional items of drugs not included above, he should apply to the Licensing Authority for the necessary endorsement as provided in Rule 69(5).This licence will be deemed to extend to the categories so endorsed.
4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

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Annexure 'A'

File No: **HR/ML/F24/2022/00025**
Licence No: **MLF252022HR000003**
Issue Date: **29-NOV-2022**
Site Id: **HR0004379**
Old Licence No: **NA**

List of Approved Drugs

Product No	Generic Name	Dosage Form	Pharmacological	Composition
10120220600083	Pantoprazole Sodium + Domperidone	Capsules	Gastro Resistance	Pantoprazole Sodium , I.P., 40mg; Domperidone, I.P., 30mg
10120220900158	Rabeprazole Sodium	Pellets	Antihistamines	Hydroxyl Propyl Methyl Cellulose E5, I.P., 6.03% w/w; L 30 D(Methacrylic Acid Copolymer Suspension), I.P., 17.53% w/w; Light Magnesium Oxide, I.P., 1.40% w/w; Rabeprazole Sodium , I.P., 20.0% w/w; Iron Oxide Red, U. S.P., 0.38% w/w; Polysorbate 80, I.P., 0.12% w/w; Sodium Hydroxide Pellets, I.P., 1.84% w/w; Hydroxy Propyl Methyl Cellulose E15, I.P., 2.51% w/w; Talcum Powder, I.P., 3.67% w/w; Di- Ethyl Pthalate, I.P., 1.75% w/w; Non Peirl Seed/ Sugar Spheres, I.P., 44.77% w/w
10120220900160	Domperidone	Pellets	Antihistamines	Sodium Methylparaben, I.P., 0.020% w/w; Sugar 20 # 30 Spheres (Pharma Grade), U.S. P., 81.10% w/w; Sucrose, I.P., 7.50% w/w; Sodium Propylparaben, I.P., 0.010% w/w; Domperidone, I.P., 10.0% w/w; Lake Of Sunset Yellow, In House Specification, 0.09% w/w; Lake Of Sunset Yellow, I. P., 1.38% w/w
10120220900147	Omeprazole	Capsules	Antihistamines	Omeprazole , I.P., 40.0mg
10120220900145	Omeprazole	Capsules	Antihistamines	Omeprazole , I.P., 20.0mg

10120220900161	Domperidone	Pellets	Antihistamines	Sodium Methylparaben, I.P., 0.020% w/w; Talcum Powder, I.P., 1.38% w/w; Iso Propyl Alcohol , I.P., 16.5% w/w; Methylene Dicholride, I.P., 7.5% w/w; Domperidone, I.P., 30.0% w/w; Sodium Propylparaben, I. P., 0.010% w/w; Sugar 20#30 Spheres, I.P., 28.0% w/w; Lake Of Sunset Yellow, In House Specification, 0.01% w/w; Sucrose, I.P., 5.5% w/w; Ethyl Cellulose, I.P., 10.98% w/w
10120220900162	Omeprazole	Pellets	Antihistamines	Hydroxy Propyl Methyl Cellulose E5, I.P., 7.50% w/w; Titanium Dioxide, U.S.P., 1.20% w/w; Disodium Hydrogen Phosphate, I.P., 0.94% w/w; Sodium Lauryl Sulphate, I.P., 1.24% w/w; Omeprazole , I.P., 10.0% w/w; Talcum Powder, I. P., 1.53% w/w; Sugar 20#30 Spheresa (Pharma Grade), U.S. P., 44.50% w/w; Mannitol, I.P., 3.98% w/w; Sodium Hydroxide Pellets, I.P., 0.98% w/w; L 30 D (Methacrylic Acid Copolymer Suspension), U.S.P., 27.0% w/w; Polysorbate 80, I.P., 0.15% w/w; Dethyl Phthalte, I. P., 0.98% w/w
10120220900163	Lansoprazole	Pellets	Antihistamines	Lansoprazole, I.P., 8.50% w/w; Talcum Powder , I.P., 1.53% w/w; Sugar, U.S.P., 46.00% w/w; Disodium Hydrogen Phosphate, I.P., 0.94% w/w; Sodium Lauryl Sulphate, I.P., 1.24% w/w; Mannitol, I.P., 3.98% w/w; Titanium Dioxide, I. P., 1.20% w/w; Sodium Hydroxide Pellets, I.P., 0.98% w/w; L 30 D(Methacrylic Acid Copolymer Suspension), U.S.P., 27.00% w/w; Polysorbate 80, I. P., 0.15% w/w; Diethyl Phthalate, I.P., 0.98% w/w

10120220900164	Pantoprazole Sodium	Pellets	Antihistamines	Pantoprazole Sodium , I.P., 22.50% w/w; Brilliant Blue , In House Specification, 0.103% w/w; Hydroxy Propyl Methyll Cellulose E5, I.P., 5.44% w/w; Talcum Powder , I.P., 2.67% w/w; Sugar 20 # 30 Spheres (Pharma Grade), U.S.P., 31.86% w/w; Disodium Hydrogen Phosphate, I.P., 3.59% w/w; Sodium Lauryl Sulphate, I.P., 0.765% w/w; Mannitol, I.P., 2.56% w/w; Titanium Dioxide, I. P., 0.154% w/w; Sodium Hydroxide Pellets, I.P., 0.154% w/w; L 30 D(Methacrylic Acid Copolymer Suspension), U.S.P., 20.0% w/w; L 30 D (Methacrylic Acid Copolymer Suspension), I.P., 0.154% w/w; Diethyl Phthalate, I.P., 2.36% w/w; Calcium Carbonate , I.P., 5.13% w/w; Sodium Carbonate , I.P., 2.56% w/w
10120220900165	Esomeprazole Magnesium Trihydrate	Pellets	Antihistamines	Esomeprazole Magnesium Trihydrate, I.P., 8.50% w/w; Color(Approved), In House Specification, 0.10% w/w; Hydroxy Propyl Methyl Cellulose (5 Cps), I.P., 7.50% w/w; Talcum Powder , I.P., 1.53% w/w; Sugar, U.S.P., 46.0% w/w; Disodium Hydrogen Phosphate, I.P., 0.94% w/w; Sodium Lauryl Sulphate, I.P., 1.24% w/w; Mannitol, I.P., 3.88% w/w; Titanium Dioxide, I.P., 1.20% w/w; Sodium Hydroxide Pellets, I.P., 0.98% w/w; Polysorbate 80, I.P., 0.15% w/w; Diethyl Phthalate, I.P., 0.98% w/w; L 30 D (Methacrylic Acid Copolymer Suspension) (30 % Aqueous Dispersion), U.S.P., 27.0% w/w

10120220900167	Domperidone + Omeprazole	Capsules	Antihistamines	Domperidone, I.P., 10.0mg; Omeprazole , I.P., 20.0mg
10120220900168	Aceclofenac + Rabeprazole Sodium	Capsules	Antihistamines	Rabeprazole Sodium , I.P., 20.0 mg; Aceclofenac, I.P., 200.0mg
10120220900169	Aceclofenac	Pellets	Antihistamines	Aceclofenac, I.P., 70.0% w/w; Talcum Powder, I.P., 1.38% w/w; Sugar, U.S.P., 21.9% w/w; Sucrose, I.P., 5.5% w/w; Sodium Propylparaben , I.P., 0.010% w/w; Sodium Methylparaben, I.P., 0.020% w/w; Ethyl Cellulose, I.P., 1.09% w/w; Color, In House Specification, 0.1% w/w
10120220700004	Domperidone + Rabeprazole Sodium	Capsules	Gastro Resistance	Rabeprazole Sodium , I.P., 20mg; Domperidone, I.P., 30mg
10120220700003	Lansoprazole + Domperidone	Capsules	Gastro Resistance	Lansoprazole, I.P., 30mg; Domperidone, I.P., 10mg

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