Regional Drugs Testing Laboratory
Directorate General of Health Services, Guwahati (India)-781022
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Regional Drugs Testing Laboratory Govt. Of India Guwahati-22

FORM 13
(See rule 46)
CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

1. **Name of Inspector from whom received** : Lalruatadika Varte
   Drugs Inspector
   Office of the Senior Chief Medical Officer
   Kolasib, Mizoram- 796082
2. **Serial No. and date of Inspector's memorandum** : KLB/13/2024/DRUGS
   Dated Kolasib, the 16th December, 2024
3. **Number of Sample** : Nil
4. **Date of receipt** :04-FEB-2025
5. **Names of drugs purporting to be contained in the sample:** Pantoprazole Sodium (Enteric Coated & Itopride Hydrochloride (Sustained Release Capsules (40mg/150 mg)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0038	GUW/LS/2025-26/43	GC240447	07/2024 06/2026	NA	M/s Theon Pharmaceuticals Ltd. Vill. Saini Majra, Tehsil Nalagarh, Distt. Solan (H.P) -174 101

6. **Condition of seals on** : Seals were intact & identical to the Specimen impression of the seal received from Drugs Inspector
   [the packet or on portion of sample or container]
7. **Result of test or analysis with protocols or test or analysis applied** :**Please see below**

Date of Testing : From 12-Mar-2025 To 03-Apr-2025

COMPOSITION :
Each hard gelatin capsules contains:
Pantoprazole Sodium IP
eq.to Pantoprazole 40mg
(as enteric coated pellets)
Itopride Hydrochloride IP 150mg
(as sustained release pellets)

Protocol Applied: Manufacturer's Specification

Sr No.	Test Name	Result	Limits
1	Description	Red cap and blue body hard gelatin capsule containing blue and white colour pellets in Alu- Alu strip pack.	NA
2	Identification	Gives positive test for Pantoprazole and Itopride Hydrochloride.	NA
3	Average filled content	0.4728 gm.	NA
4	Uniformity of weight	Passes the test.	NA
5	Dissolution	Passes the test for Pantoprazole.	NA
6	Dissolution (Acid stage)	Passes the test for Pantoprazole (Release of all six units are found below 15%)	NMT 15 % of claim
7	Dissolution (Buffer stage)	Passes the test for Pantoprazole (Release of all six units are found above 70+5%)	NLT 70 % of claim

8	Dissolution	Passes the test for Itopride Hydrochloride.		NA
Level	No. of unit taken	Time	Result (Drug release range between)	Acceptance Criteria
L1	6	1st hour	19.00% to 21.64%	15.0% to 40.0%
		4th hours	56.72% to 62.51%	30.0% to 65.0%
		8th hours	74.00% to 77.23%	60.0% to 85.0%
		12th hours	78.96% to 89.87%	NLT 70 % of claim

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Pantoprazole Sodium eq.to Pantoprazole	42.35 mg/Capsule	40mg/Capsule	105.875	90 % to 110 %	Manufacturer's Specification
2	Itopride Hydrochloride	149.38 mg/Capsule	150 mg/Capsule	99.586	90 % to 110 %	

In the opinion of the under signed the sample referred to above **is of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules thereunder for the reasons given below:-

The sample conforms to Manufacturer's specification with respect to the above tests only.

Date: 08-APR-2025

GOVERNMENT ANALYST
Dilip Kr. Sarkar
Government Analyst
R.D.T.L., Guwahati-22

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