Regional Drugs Testing Laboratory
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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** : B LALZAMLIANA,
Drugs Inspector (Food and Drgs)
CMO West Office
Kulikawn, Aizawl- 796005

2. **Serial No. and date of Inspector's memorandum** : B.11012/5/2019-CMO (W)/DRUGS/99 ,
Dated Aizawl, the 27-MAY-2024

3. **Number of Sample** : SMP/MZ/TMT/2024-25/002

4. ***Date of receipt*** : *11-JUN-2024*

5. **Names of drugs purporting to be contained in the sample** : PANTOPRAZOLE (EC) & LEVOSULPIRIDE (SR) CAPSULES (LTP-LS Capsules)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1544	GUW/LS/2024-25/1570	LTLSC501	Mar-2024	Feb-2026	M/S Tulbros Formulations., Plot No. 91, Sector IIDC, IIE Pantnagar, SIDCUL, Dist. U.S. Nagar- 263153 (Uttrakhand).

6. **Condition of seals on** [the packet or on portion of sample or container] : Seals were intact & identical to the Specimen impression of the seal received from Drugs Inspector

7. **Result of test or analysis with protocols or test or analysis applied** :**Please see below**

Date of Testing : From 17-Jan-2025To 20-Jan-2025

COMPOSITION : Each hard gelatin capsule contains:
Pantoprazole Sodium Sesquihydrate IP
eq. to Pantoprazole 40mg (As enteric Coated Pellets)
Levosulpiride 75 mg
(As Sustained Release Pellets)

Protocol Applied : Manufacturer's Specification

Sr No.	Test Name	Result	Limits
1	Description	Bi-colour (white and pink), hard capsule containing white and blue pellets in aluminium strip.	NA
2	Identification	Gives positive test for Pantoprazole and Levosulpiride.	NA
3	Average filled content	0.2869 g	NA
4	Uniformity of filled content	Passes the test. (Method I.P.)	NA
5	Dissolution	Passes the test for both Pantoprazole and Levosulpiride.	NA

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Pantoprazole Sodium Sesquihydrate eq. to Pantoprazole	42.02 mg/Capsule	40 mg/Capsule	105.05	90 % to 110 %	Manufacturer's Specification
2	Levosulpiride	71.94 mg/Capsule	75 mg/Capsule	95.92	90 % to 110 %	Manufacturer's Specification

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

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

Date: 21-JAN-2025

GOVERNMENT ANALYST
Amar Jyoti Chamuah
Government Analyst
R.D.T.L., Guwahati-22

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