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** : TIMOTHY THANCHUNGNUNGA,
Assistant Director (F & D),
CMO West Office,
Kulikawn, Aizawl-796005

2. **Serial No. and date of Inspector's memorandum** : B.11012/5/2024-CMO (W)/DRUGS/41
Dated Aizawl, the 21st January, 2025

3. **Number of Sample** : SMP/MZ/TMT/2024-2025/036

4. **Date of receipt** : 03-FEB-2025

5. **Names of drugs purporting to be contained in the sample:** Pantoprazole Gastro-Resistant Tablets IP 40 mg (Pantojack-40)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1839	GUW/LS/2024-25/1864	T-1261	APR. 2024	MAR. 2026	Jackson Laboratories Pvt. Ltd. 22-24, Majitha Road, Bye Pass, Amritsar-143 001(India)

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 06-Mar-2025 To 10-Mar-2025

COMPOSITION : Each enteric coated tablet contains:
Pantoprazole Sodium
Sesquihydrate IP
eqv. to Pantoprazole 40 mg

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Yellow colour, round, enteric coated tablet, showing, cross sectional (capping defect) fragment detaches supplied in blister pack.	NA
2	Identification	Gives positive test for Pantoprazole.	NA
3	Average weight	0.1735 gm.	NA
4	Dissolution for Acid stage	**Does not comply.** (All the six units were found to be dissolved in Acid medium and no residue remained in the vessel). Hence, further test could not be carried out.	NMT 10% of claim

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method

1	Pantoprazole Sodium Sesquihydrate eqv.to Pantoprazole	42.69 mg/Tablet	40 mg/Tablet	106.725	90 % to 110 %	I.P. 2022

In the opinion of the under signed the sample referred to above **is not of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules thereunder for the reasons given below:-

The sample does not conform to I.P. with respect to the tests for 'Dissolution' (Acid stage) and is also not of standard quality for the reason stated under 'Description'

Date: 17-MAR-2025

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

Report in red coloured paper indicates the sample is Not of Standard Quality

---------- END OF REPORT ----------

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA