



FORM 13
(See rule 46)

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

- Name of Inspector from whom received : R. Vanlalsiama
Asst Director (F&D),
Sr. CMO Office, Lunglei.
- Serial No. and date of Inspector's memorandum : 8, 19-FEB-2025
- Number of Sample : MS-40
- Date of receipt : 06-MAR-2025
- Names of drugs purporting to be contained in the sample : Pantoprazole Gastro Resistant Tablets IP 40 mg
(Pdazole -40 Tablets)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-GUW/LS/2025-26/0649	26/655	ZBT-7770	Aug-2024 Jul-2026	NA	Zoic Biotech Pvt. Ltd., Plot No. C-15, Focal Point, Ind. Area, Chanalon, Mohali (Punjab) 140103

- 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

- Result of test or analysis with protocols or test or analysis applied : Please see below
Date of Testing : From 30-Apr-2025 To 26-Aug-2025

COMPOSITION : Each Enteric coated Tablet contains:
Pantoprazole Sodium Sesquihydrate IP Eq. to Pantoprazole 40 mg
Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Yellow colored, round, bi-convex, coated tablets, in alu-alu strip.	NA
2	Identification	Gives positive test for Pantoprazole Sodium Sesquihydrate.	NA
3	Average weight	0.2531 g	NA
4	Dissolution (Acid Stage)	Complies.	NMT 10 % of claim
5	Dissolution (Buffer Stage)	Does not comply.	NLT 75%of claim
6	Level B1 (6 units)	Release of Pantoprazole of each individual unit is found as follows: Unit 1=57.0%; Unit 2=81.4%; Unit 3=88.1%; Unit 4=50.3%; Unit 5=80.2%; Unit 6=83.5%. Release of Pantoprazole of 02 units are found less than 80% of claim i.e. (Q+5%) where Q is 75% of claim.	Each unit is not less than Q+5% i.e. 80% of claim where Q is 75%.

7	Level B2 (6 units)	Release of Pantoprazole of each individual unit is found as follows: Unit 1=3%; Unit 2=16%; Unit 3=5%; Unit 4=6%; Unit 5=5%; Unit 6=6% . Average release of Pantoprazole of 12 units (B1+B2) is 40% of claim which is less than Q i.e. 75% of claim. Release of 08 units are found less than 60% of claim i.e.Q-15%.	Average of 12 units (B1+B2) $\geq$ 75% of claim and no unit is less than 60% of claim (Q-15%)
8	Level B3	Average release of Pantoprazole of 12 units (B1+B2) is found 40% which is less than Q i.e. 75% and out of 12 units 8 units are found less than 60% i.e. Q-15% as well as 06 units are found less than 50% of claim i.e. Q-25% .	Average of 24 units (B1+B2+B3) $\geq$ 75% of claim, not more than 2 units are less than 60% of claim i.e. (Q-15%) and no unit is less than 50% of claim (Q-25%)

Assay

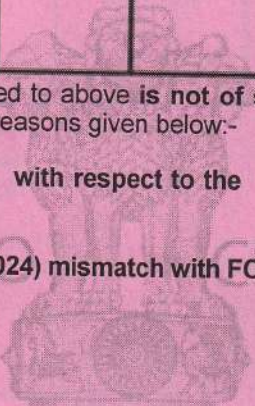
Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Pantoprazole Sodium (as Sesquihydrate) equivalent to Pantoprazole	38 mg/Tablet	40 mg/Tablet	95	90 % to 110 %	I.P. 2022

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

The sample does not conform as per I.P. 2022 with respect to the test for "Dissolution in Buffer Stage" for Pantoprazole.

Note: Manufacturing date of sample (MFG. AUG.2024) mismatch with FORM-18 (Mfg dt.09/24) sent by Inspector.

Date: 03-SEP-2025


 सत्यमेव जयते
 MINISTRY OF HEALTH, GOVERNMENT OF INDIA
 GOVERNMENT ANALYST
 Rinku Kalita
 Government Analyst
 R.D.T.L., Guwahati-22

Report in the red colored paper indicates the sample is not of standard quality.

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