



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 : Mrs. Zarzokimi Assistant Drugs Inspector (Food and Drugs), C.M.O. Office
Champhai-796321 Mizoram
2. Serial No. and date of Inspector's memorandum : 387/26, 27-FEB-2026
3. Number of Sample : Not mentioned.
4. Date of receipt : 20-MAR-2026
5. Names of drugs purporting to be contained in the sample : Pantoprazole Gastro-resistant Tablets IP (DRPLAN-40)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2026-27/0080	GUW/LS/2026-27/157	TG25-03290	Feb-2025 Jan-2027	NA	Athens Life Sciences, Mauza Rampur Jattan, Nahan Road, Kala Amb, Distt. Sirmour, H.P. -173030

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 19-May-2026 To 10-Jun-2026

COMPOSITION : Each enteric coated tablets contains: Pantoprazole Sodium IP Eq. to Pantoprazole 40 mg.

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Yellow colored, round, biconvex, coated tablets, in blister packing, some tablets are found in broken condition and having uneven surface.	NA
2	Identification	Gives positive test for Pantoprazole Sodium.	NA
3	Average weight	0.1189 g	NA
4	Dissolution	Does not comply in Acid Stage.	
5	Dissolution For Pantoprazole (Acid Stage)	Does not comply in Acid Stage. Average release of Pantoprazole of 12 units in Acid Stage are found 38.29% of claim.	NMT 10 % of claim

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Pantoprazole Sodium eq. to Pantoprazole	37.9 mg/Tablet	40 mg/Tablet	94.75	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 comply as per I.P. 2022 with respect to the test for "Dissolution in Acid Stage" for Pantoprazole. The sample is also not of standard quality for the reason stated under "Description".

Date: 22-JUN-2026

Rinku Kalita
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 -----

