



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 : SARAH LALDINTLUANGI  
ASSISTANT DIRECTOR (FOOD & DRUGS)  
Sr. CMO OFFICE, SERCHHIP-796181, SERCHHIP
2. Serial No. and date of Inspector's memorandum : 003/2024 Date 3.10.2024
3. Number of Sample : Nil
4. Date of receipt : 28-OCT-2024
5. Names of drugs purporting to be contained in the sample : Pantoprazole Gastro-resistant Tablets I.P. (40 mg)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1250	GUW/LS/2024-25/1284	PPB-521	04/23	03/25	Healer's Lab Unit II Plot No.33, H.P.S.I.D.C., Extn., Baddi, Distt-Solan (H.P.)

6. Condition of seals on : Seals were intact & identical to the  
[the packet or on portion of sample or container] 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 18-Nov-2024 To 22-Nov-2024

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

Protocol Applied: I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Yellowish colour, round, bi-convex, enteric coated tablet, packed in aluminium blister pack.	NA
2	Identification	Gives positive test for Pantoprazole.	NA
3	Average weight	0.1436 gm.	NA
4	Dissolution	Complies.	NA
5	Dissolution	Complies for Acid stage (Release of all six units were found below 10 %).	NMT 10 % of claim
6	Dissolution	Complies for Buffer stage (Release of all six units were found above 'Q' 75+5%).	NLT 75 % of claim

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Pantoprazole Sodium Sesquihydrate Equivalent to Pantoprazole	40.72 mg/Tablet	40 mg/Tablet	101.8	90 % to 110 %	I.P. 2022

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 thereunder for the reasons given below:-

The sample conforms to I.P. with respect to the above tests only.

Date: 27-NOV-2024



GOVERNMENT ANALYST

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

.....END OF REPORT.....

