



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 : SARAH LALDINTLUANGI, Assistant Director (Food and Drugs)
Sr. CMO Office
Serchhip-796181
- Serial No. and date of Inspector's memorandum : 015/IPA-CPI/24 , 13-DEC-2024
- Number of Sample : NIL
- Date of receipt : 02-JAN-2025
- Names of drugs purporting to be contained in the sample : Pantoprazole For Injection BP (Prazoto-IV)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2024-25/1954	GUW/LS/2024-25/1979	24GE03P	May-2024 Apr-2026	NA	MMG Healthcare, Trilokpur Road, Kala Amb, Distt. sirmour-173030 (H.P.)

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 24-Jan-2025 To 24-Mar-2025

COMPOSITION : Each vial contains:
Pantoprazole Sodium IP (Sterile Lyophilized dry Mixture of Pantoprazole Sodium IP & Mannitol IP) eq. to Pantoprazole 40 mg.

Protocol Applied : B.P.

Sr No.	Test Name	Result	Limits
1	Description	White powder filled in colorless transparent glass vials along with sodium Chloride injection, in blister pack, supplied in paper carton.	NA
2	Identification	Gives positive test for Pantoprazole.	NA
3	Average filled content	0.1202 g	NA
4	Sterility	Passes the test for Sodium Chloride Injection and Pantoprazole Injection.	NA
5	Bacterial Endotoxins	Complies for Sodium Chloride Injection.	NA
6	Particulate Matter	Passes the test.	NA
7	pH	9.8 .	9.0 to 11.5 .

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Pantoprazole Sodium eq. to Pantoprazole	41.25 mg/vial	40 mg/vial	103.125	93 % to 105 %	B.P.

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 conform to claim as per B.P. in respect of test performed.

Date: 28-MAR-2025


GOVERNMENT ANALYST

Rinku Kalita
Government Analyst
R.D.T.L., Guwahati-22

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

