



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 : B.LALZAMLIANA, Drug Inspector (F and D)
CMO West Office
Kulikawn, Aizawl- 796005
- Serial No. and date of Inspector's memorandum : B.11012/5/2024-CMO (W)/DRUGS/48 , 25-FEB-2025
- Number of Sample : SMP/MZ/TMT/2024-2025/043
- Date of receipt : 06-MAR-2025
- Names of drugs purporting to be contained in the sample : Pantoprazole for Injection (Pantolet 40)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-GUW/LS/2025-26/0369	26/404	W807	Feb-2024 Jan-2026	NA	Macin Remedies India Ltd.,, B-21, Ind. Focal Point, Moga (PB) 142001.

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 24-Mar-2025 To 09-Jun-2025

COMPOSITION : Each vial contains:
Pantoprazole Sodium IP Eq. to pantoprazole anhydrous 40 mg

Protocol Applied : Manufacturer's Specification

Sr No.	Test Name	Result	Limits
1	Description	White powder filled in amber colored sealed glass vials, supplied in paper carton.	NA
2	Identification	Gives positive test for Pantoprazole Sodium.	NA
3	Average filled content	0.1294 g	NA
4	Sterility	Passes the test.	NA
5	Bacterial endotoxins	Complies.	NA
6	Particulate matter	Passes the test.	NA
7	pH	9.74 .	9.0 to 11.5 .

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Pantoprazole	40.47 mg/vial	40 mg/vial	101.175	90 % to 110 %	Manufacturer's Specification

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 Manufacturer's Specification in respect of test performed.

Date: 24-JUN-2025

GOVERNMENT ANALYST

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

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

