



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 : B.LALZAMLIANA, Drugs Inspector (F and D)
CMO West Office
Kulikawn, Aizawl- 796005
2. Serial No. and date of Inspector's memorandum : B.11012/5/2024-CMO (W)/DRUGS/58 , 26-MAR-2025
3. Number of Sample : SMP/MZ/TMT/2024-2025/056
4. Date of receipt : 02-APR-2025
5. Names of drugs purporting to be contained in the sample : Pantoprazole for Injection B.P. (PROTONFIX-40 Injection)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0657	GUW/LS/2025-26/661	MD24B07	Feb-2024 Jan-2026	NA	MARTIN & BROWN BIO-SCIENCES PVT. LTD., K.No. 918/419, Malkumajra, Nalagarh Road, Baddi, Dist. Solan (H.P.)-173205

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 27-May-2025 To 27-Aug-2025

COMPOSITION : Each vial contains:
Pantoprazole Sodium Sesquihydrate B.P. (Sterile/Lyophilized) eq. to
Pantoprazole (Anhydrous) 40 mg

Protocol Applied : B.P. 2025

Sr No.	Test Name	Result	Limits
1	Description	White powder filled in amber colored sealed glass vials, along with Sodium Chloride for injection in sealed plastic vials.	NA
2	Identification	Gives positive test for Pantoprazole Sodium.	NA
3	Filled Content	0.1141 g	NA
4	Particulate contamination	Passes the test.	NA
5	Sterility	Passes for Pantoprazole for Injection and Sodium Chloride for Injection.	NA
6	BET	Complies for Sodium Chloride for Injection.	NA

7	pH	9.62	9.0 to 11.5
8	Clarity and colour of solution	Passes the test.	NA

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Pantoprazole Sodium (as Sesquihydrate) equivalent to Pantoprazole	40.91 mg/vial	40 mg/vial	102.275	93 % to 105 %	B.P. 2025

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. 2025 in respect of test performed.

Date: 04-SEP-2025

GOVERNMENT ANALYST

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

END OF REPORT

