

Regional Drugs Testing Laboratory

Directorate General of Health Services. Guwahati (India) -781022

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FORM 13 (See rule 46)

CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER ASC SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

1. Name of Inspector from whom received

Mrs. C. Ramdinmawii, Assistant Director (Food and

Drugs)

C.M.O. Office.

Champhai-796321 Mizoram

2. Serial No. and date of Inspector's memorandum

: 019/IPA-CPI/24, 16-DEC-2024

3. Number of Sample

: NIL

4. Date of receipt

: 31-DEC-2024

5. Names of drugs purporting to be contained in the sample: Pantoprazole Gastro-resistant Tablets IP 40 mg

(Pantozec-40)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1565	GUW/LS/2024- 25/1629	2310034	Oct-2023	Sep-2025	M/s Sanctus Global Formulations Limited, K.No. 587/588, Village Kunjhal,
	- Z				Jharmajri; Baddi, DistSolan (H.P.)-174103

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 15-Jan-2025 To 16-Jan-2025

COMPOSITION

Each gastro-resistant tablet contains:

Pantoprazole Sodium IP (as Sesquihydrate) equivalent to Pantoprazole 40 mg

Protocol Applied: I.P. 2022

Sr No.	Test Name	Result	Limits	
1 Description		Light brown colored, round, slightly biconvex tablets, in blister pack.	NA	
2	Identification	Gives positive test for Pantoprazole sodium.	NA	
3	Average weight	0.1102 gm	NA	
4	Dissolution	Complies.	NA	
5	Dissolution For Pantoprazole (Acid Stage)	Complies.	NMT 10 % of claim	
6 Dissolution For Pantoprazole (Buffer Stage)		Complies.	NLT 75 % of claim	

<u>Assay</u>

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method/
1	Pantoprazole Sodium eq. to Pantoprazole	39.45 mg/Tablet	40 mg/Tablet	98.625	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 there under for the reasons given below:-

The sample conform to claim as per I.P. 2022 in respect of test performed.

Date: 29-JAN-2025

GOVERNMENT ANALYST

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

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