



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 and Drugs)
Sr. CMO Office
Serchhip-796181
2. Serial No. and date of Inspector's memorandum : 008/2024 , 07-OCT-2024
3. Number of Sample : NIL
4. Date of receipt : 23-OCT-2024
5. Names of drugs purporting to be contained in the sample : Pantoprazole Gastro-resistant and Domperidone Prolonged-release Capsules I.P. (40 mg/30 mg)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1451	GUW/LS/2024-25/1477	PC30036	Oct-2023	Sep-2025	M/s. GNOSIS Pharmaceuticals Pvt. Ltd., Nahan Road, Village-Moginand, Kala-Amb, Dist.-Sirmour, H.P. - 173 030

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 17-Dec-2024 To 30-Dec-2024

COMPOSITION : Each hard gelatin capsule is purported to contains:
Pantoprazole Sodium IP
Eq. to Pantoprazole 40 mg
(As enteric coated pellets)
Domperidone IP 30 mg
(As sustained release pellets)

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Multicolored pellets, filled in transparent red and colorless hard gelatin capsules, in alu-alu strip.	NA
2	Identification	Gives positive test for Pantoprazole sodium and Domperidone.	NA
3	Filled Content	0.3129 gm	NA
4	Uniformity of weight	Complies.	NA
5	Dissolution	Complies.	NA

6	Dissolution For Pantoprazole (Acid Stage)	Complies.	NMT 10 % of claim
7	Dissolution For Pantoprazole (Buffer Stage)	Complies.	NLT 70 % of claim

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Pantoprazole Sodium eq. to Pantoprazole	41.88 mg/Capsule	40 mg/Capsule	104.7	90 % to 110 %	I.P. 2022
2	Domperidone	30.16 mg/Capsule	30 mg/Capsule	100.533	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 conforms to claim as per I.P. 2022 in respect of test performed.

Date: 30-DEC-2024

GOVERNMENT ANALYST

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

 END OF REPORT

