



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 : Mrs. C. Ramdinmawii, Assistant Director (Food and Drugs)  
C.M.O. Office,  
Champhai-796321 Mizoram
2. Serial No. and date of Inspector's memorandum : 002/IPA-CPI/24 , 27-NOV-2024
3. Number of Sample : NIL
4. Date of receipt : 11-DEC-2024
5. Names of drugs purporting to be contained in the sample : Pantoprazole Gastro-resistant & Domperidone Prolonged Release Capsules IP (DrPlan-DSR)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1647	GUW/LS/2024-25/1672	CG24-0351A	Jun-2024	May-2026	Athens Life Sciences ..., Mauza Rampur Jattan, Nahan Road. Kala Amb, Distt. Sirmour, HP-173030

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 05-Feb-2025

COMPOSITION : Each hard gelatin capsule contains:  
Pantoprazole Sodium IP eq. to Pantoprazole 40 mg  
(as enteric coated pellets)  
Domperidone IP 30 mg  
(as Prolonged-release pellets)

**Protocol Applied : I.P. 2022**

Sr No.	Test Name	Result	Limits
1	Description	Multicolored( blue and orange) pellets filled in transparent colorless and pink colored hard gelatin capsules, in alu-alu strip.	NA
2	Identification	Gives positive test for Pantoprazole Sodium & Domperidone.	NA
3	Average weight	0.2660 g	NA
4	Dissolution	Complies for Pantoprazole.	NA
5	Dissolution (Acid Stage)	Complies.	NMT 10 % of claim
6	Dissolution (Buffer Stage)	Complies.	NLT 70 % of claim

## Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Pantoprazole Sodium equivalent to Pantoprazole	40.19 mg/Capsule	40 mg/Capsule	100.475	90 % to 110 %	I.P. 2022
2	Domperidone	29.8 mg/Capsule	30 mg/Capsule	99.333	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. Note : "Dissolution" of Domperidone could not perform due to want of "Dissolution Profile" for Domperidone.

Date: 07-FEB-2025

*Rinku Kalita*  
GOVERNMENT ANALYST

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

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

