



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 : 374/24 Date: 04/10/2024
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 & Domperidone Prolonged-Release Capsules IP (Pantra D SR)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1550	GUW/LS/2024-25/1574	WPD23026	SEP. 2023	AUG. 2025	Windlas Biotech Limited (Plant-2) Khasra No. 141 to 143 & 145, Mohabewala Indl. Area, Dehradun- 248110 (U.K.) R.O.:40/1, Mohabewala Indl. Area, Dehradun.

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 11-Jan-2025 To 20-Jan-2025

COMPOSITION : Each hard gelatin capsule contains:
 Pantoprazole Sodium IP
 Equivalent to Pantoprazole 40 mg
 (as blue colour gastro-resistant pellets)
 Domperidone IP, 30 mg
 (as orange colour prolonged-release pellets)

Protocol Applied: I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Pink cap and transparent body hard gelatin capsule containing blue and orange colour pellets in alu – alu strip.	NA
2	Identification	Gives positive test for Pantoprazole and Domperidone.	NA
3	Filled Content	0.2733 gm	NA
4	Uniformity of weight	Complies.	NA
5	Dissolution	Complies for Pantoprazole (Acid stage and Buffer stage).	NA

6	Dissolution for Pantoprazole (Acid Stage)	Complies (Release of all six units are found below 10 %).	NMT 10 % of claim
7	Dissolution for Pantoprazole (Buffer Stage)	Complies (Release of all six units are found above 'Q' 70 + 5%).	NLT 70 % of claim

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Pantoprazole Sodium eq.to Pantoprazole	40.74 mg/Capsule	40 mg/Capsule	101.85	90 % to 110 %	I.P. 2022
2	Domperidone	31.07 mg/Capsule	30 mg/Capsule	103.566	90 % to 110 %	I.P. 2022

In the opinion of the under signed the sample referred to above is of standard quality as defined in the Drugs and Cosmetics Act, 1940, and Rules thereunder for the reasons given below:-

The sample conforms to claim with respect to the above tests only.

Note: Dissolution for "Domperidone" could not be performed for want of Manufacturer's Method of Analysis with Specification (dissolution profile).

Date: 22-JAN-2025

GOVERNMENT ANALYST

Dilip Kr. Sarkar
Government Analyst
R.D.T.L., Guwahati-22

