



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)
State FDA
Champhai-796321 Mizoram
2. Serial No. and date of Inspector's memorandum : 031/IPA-CPI/24 , 17-JAN-2025
3. Number of Sample : NIL
4. Date of receipt : 03-FEB-2025
5. Names of drugs purporting to be contained in the sample : Pantoprazole Gastro-Resistant & Domperidone Sustained Release Capsules IP (Panitra-DSR)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-GUW/LS/2025-26/0502	26/509	ZC24032B	May-2024 Apr-2026	NA	M/s Zenon Lifesciences Pvt. Ltd., Survey-no. 343/P, Bavla-Sanand Highway, Modasar, Ahmedabad, Gujarat, INDIA 382220.

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 18-Mar-2025 To 27-Jun-2025

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

Protocol Applied : Manufacturer Specification

Sr No.	Test Name	Result	Limits
1	Description	Orange and blue colored pellets filled in transparent colorless and red colored hard gelatin capsules, in alu-alu strip.	NA
2	Identification	Gives positive test for Pantoprazole Sodium & Domperidone.	NA
3	Average filled content	0.2748 g	NA
4	Uniformity of weight	Complies.	±7.5% of average weight
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
8	Dissolution For Domperidone (1st Hour)	Complies.	15% to 40 % of claim
9	Dissolution For Domperidone (4th Hour)	Complies.	30% to 60 % of claim
10	Dissolution For Domperidone (8th Hour)	Complies.	55% to 85 % of claim
11	Dissolution For Domperidone (12th Hour)	Complies.	NLT 70 % of claim

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Pantoprazole Sodium eq. to Pantoprazole	38.4 mg/Capsule	40 mg/Capsule	96	90 % to 110 %	Manufacturer Specification
2	Domperidone	29.6 mg/Capsule	30 mg/Capsule	98.666	90 % to 110 %	Manufacturer Specification

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 Manufacturer Specification in respect of test performed.

Date: 21-JUL-2025

GOVERNMENT ANALYST

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

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