



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 : B.LALZAMLIANA, Drugs Inspector (F and D)
CMO West Office
Kulikawn, Aizawl- 796005
2. Serial No. and date of Inspector's memorandum : B.11012/5/2024-CMO(W)/DRUGS/61, 26-MAR-2025
3. Number of Sample : SMP/MZ/TMT/2024-2025/059
4. Date of receipt : 02-APR-2025
5. Names of drugs purporting to be contained in the sample : Pantoprazole Gastro-resistant And Domperidone
Prolonged-release Capsules IP (Panboost-DSR)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-GUW/LS/2025-26/0598	26/603	UC-25142A	Feb-2025 Jan-2027	NA	Ultra Drugs Pvt. Ltd., (Unit - II) HS No. 211, K. No. 77/1, 78/1 Vill. Katha, Baddi, Distt. Solan (H.P.) - 173205

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 29-May-2025 To 04-Jul-2025

COMPOSITION : Each hard gelatin capsule contains:
Pantoprazole Sodium IP Eq. to Pantoprazole 40mg
(As gastro-resistant pellets)
Domperidone IP 30 mg
(As prolonged release pellets)

Protocol Applied : I.P. 2022 and Manufacturer's Specification

Sr No.	Test Name	Result	Limits
1	Description	Blue and orange colored spherical pellets filled in transparent colorless and red colored hard gelatin capsules, in blister pack.	NA
2	Identification	Gives positive test for Pantoprazole Sodium and Domperidone.	NA
3	Filled Content	0.2839 g	NA
4	Dissolution for Pantoprazole	Complies.	NA
5	Dissolution For Pantoprazole (Acid Stage)	Complies.	NMT 10 % of claim
6	Dissolution For Pantoprazole (Buffer Stage)	Complies.	NLT 70 % of claim

7	Dissolution for Domperidone	Complies.(As per Manufacturer's specification)	NA
8	Dissolution For Domperidone (1st Hour)	Complies.	15% to 40 % of claim
9	Dissolution For Domperidone (4th Hour)	Complies.	30% to 70 % 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	38.87 mg/Capsule	40 mg/Capsule	97.175	90 % to 110 %	I.P. 2022
2	Domperidone	31.11 mg/Capsule	30 mg/Capsule	103.7	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 and Manufacturer's specification in respect of test performed.

Date: 22-AUG-2025

GOVERNMENT ANALYST

Rinku Kalita
Government Analyst
R.D.T.L., Guwahati-77

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