



FORM 13
(See rule 46)

CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER
SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

- Name of Inspector from whom received : B.LALZAMLIANA,
Drugs Inspector (F & D)
CMO West Office
Kulikawn, Aizawl- 796005
- Serial No. and date of Inspector's memorandum : B.11012/5/2019-CMO(W)/DRUGS/23
Dated Aizawl, the 12th Dec, 2024
- Number of Sample : SMP/MZ/TMT/2024-2025/28
- Date of receipt :06-JAN-2025
- Names of drugs purporting to be contained in the sample: Pantoprazole Gastro-Resistant and Domperidone
Prolonged-Release Capsules IP (Pumptop-DSR Capsules)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0037	GUW/LS/2025-26/44	VC40122	07/2024 06/2026	NA	Vibcare Healthcare Private Limited, Khasra No 6/2/2, Kot Road, Dabkori, Panchkula, Haryana, India-134103

- Condition of seals on :
[the packet or on portion of sample or container] : Seals were intact & identical to the
Specimen impression of the seal
received from Drugs Inspector

- Result of test or analysis with protocols or test or analysis applied :Please see below

Date of Testing : From 18-Mar-2025 To 01-Apr-2025

COMPOSITION :

Each hard gelatin capsule contains:
Pantoprazole Sodium IP
eq. to Pantoprazole 40mg.
(as gastro resistant pellets)
Domperidone IP 30mg.
(as prolonged release pellets)

Protocol Applied : I.P.2022

Sr No.	Test Name	Result	Limits
1	Description	Orange cap and transparent body hard gelatin capsule containing blue and orange colour pellets in Alu- Alu strip pack.	NA
2	Identification	Gives positive test for Pantoprazole and Domperidone.	NA
3	Filled Content	0.2768 gm.	NA
4	Uniformity of weight	Complies.	NA
5	Dissolution	Complies for Pantoprazole.	NA
6	Dissolution (Acid stage)	Passes the test for Pantoprazole (Release of all six units are found below 10%)	NMT 10 % of claim
7	Dissolution (Buffer stage)	Passes the test for Pantoprazole (Release of all six units are found above 70+5%)	NLT 70 % of claim

8	Dissolution	Passes the test for Domperidone.			NA
Level	No. of unit taken	Time	Result (Drug release range between)	Acceptance Criteria (As per Manufacturer's Specification)	
L ₁	6	1 st hour	21.33% to 24.26%	15% to 40%	
		4 th hour	34.4% to 39.63%	30% to 60%	
		12 th hour	92.0% to 106%	Not less than 70%	

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Pantoprazole Sodium equivalent to Pantoprazole	37.16 mg/Capsule	40 mg/Capsule	92.9	90 % to 110 %	Manufacturer's Specification
2	Domperidone	31.76 mg/Capsule	30 mg/Capsule	105.866	90 % to 110 %	

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 I.P. with respect to the above tests only.

Date: 07-APR-2025

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

END OF REPORT

सत्यमेव जयते