



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/13, 18-OCT-2024
3. Number of Sample : SMP/MZ/TMT/2024-2025/018
4. Date of receipt : 28-OCT-2024
5. Names of drugs purporting to be contained in the sample : Pantoprazole Enteric Coated and Domperidone
Sustained Release Capsules I.P. (Pantopmos-DSR
Capsules)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-GUW/LS/2025-26/0027	26/28	RPC1885	Jul-2024 Jun-2026	NA	RATNARAJ HEALTHCARE PVT. LTD., Sub Plot No. 9/C, Pancharatna Ind. Estate Part-2, Changodar, Ahmedabad-382213

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 13-Mar-2025 To 28-Mar-2025

COMPOSITION : Each hard gelatin capsule contains:
Pantoprazole Sodium IP 40 mg
Eq. to pantoprazole
(As enteric coated pellets)
Domperidone IP 30 mg (As SR Pellets)

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

Sr No.	Test Name	Result	Limits
1	Description	Blue and orange colored pellets filled in transparent green and colorless hard gelatin capsules, in alu-alu strip.	NA
2	Identification	Gives positive test for Pantoprazole Sodium and Domperidone.	NA
3	Filled Content	0.2866 g	NA
4	Dissolution	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 (1st Hour)	Complies.	15% to 40 % of claim
8	Dissolution For Domperidone (4th Hour)	Complies.	30% to 60 % of claim
9	Dissolution For Domperidone (8th Hour)	Complies.	55% to 85 % of claim
10	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	37.08 mg/Capsule	40 mg/Capsule	92.7	90 % to 110 %	I.P. 2022
2	Domperidone	32.57 mg/Capsule	30 mg/Capsule	108.566	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: 04-APR-2025

GOVERNMENT ANALYST

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

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