



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 : Mr. R. Vanlalruata, (Assistant Director (F and D))
Office of Chief Medical Officer, Aizwal, Mizoram-796017
2. Serial No. and date of Inspector's memorandum : 20/AZL E/2025/Local , 04-DEC-2025
3. Number of Sample : NIL
4. Date of receipt : 15-DEC-2025
5. Names of drugs purporting to be contained in the sample : Enteric Coated Pantoprazole Sodium 40 mg. &
Domperidone 30 mg. SR Capsules (PANTOPRAZOLE-DSR)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2026-27/0007	GUW/LS/2026-27/10	OC-1483	Jan-2025 Dec-2026	NA	RYX PHARMACEUTICALS. J.R. S. ORYX PHARMACEUTICALS (P) LTD., 217-218, Sector-3, H.S.I.D.C., KARNAL- 132001 (INDIA)

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 19-Jan-2026 To 02-Apr-2026

COMPOSITION : Each hard gelatin capsule contains:
Pantoprazol Sodium I.P. eq. to Pantoprazole 40 mg
(As enteric coated pellets) Domperidone Maleate eq. to Domperidone I.P. 30
mg (As sustained release pellets)

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Multi colored pellets filled hard gelatin capsules, in alu-alu strip pack.	NA
2	Identification	Gives positive test for Pantoprazole Sodium & Domperidone.	NA
3	Filled Content	0.3064 g	NA
4	Dissolution (Acid stage)	Complies for Pantoprazole.	NMT 10 % of claim

5	Dissolution (Buffer Stage)	Complies for Pantoprazole.	NLT 70 % of claim
---	----------------------------	----------------------------	-------------------

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Pantoprazole Sodium equivalent to Pantoprazole	36.9 mg/Capsule	40 mg/Capsule	92.25	90 % to 110 %	I.P. 2022
2	Domperidone	29.75 mg/Capsule	30 mg/Capsule	99.166	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 in respect of test performed.

Date: 07-APR-2026

GOVERNMENT ANALYST

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

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

