Regional Drugs Testing Laboratory
Directorate General of Health Services, Guwahati (India) - 781022
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Regional Drugs Testing Laboratory Govt. of India * Guwahati-22 *

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** : K.Lalngilneia,Asst.Director (FD)
Asst. Director (F&D), CMO Office,
Mamit Distric: Mamit, Mizoram- 796441.

2. **Serial No. and date of Inspector's memorandum** : B.17011/12/09-CMO(M)/DRUGS/17 , 10-SEP-2024

3. **Number of Sample** : MD08/17

4. **Date of receipt** : 19-SEP-2024

5. **Names of drugs purporting to be contained in the sample** : Pantoprazole Gastro-Resistant & Domperidone Prolonged-Release Capsules I.P. (Panor DSR)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1893	GUW/LS/2024-25/1926	C-231014	Oct-2023	Sep-2025	Unispeed Pharmaceuticals Pvt. Ltd., 445/2, Behind Wrigleys, Vill. Katha, Baddi, Distt-Solan (H.P.) 173 205

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 23-Oct-2024 To 19-Mar-2025

COMPOSITION : Each hard gelatin capsule contains:Pantoprazole Sodium I.P. eq. to Pantoprazole 40 mg.Domperidone I.P. 30mg

Protocol Applied : Manufacturer's Specification

Sr No.	Test Name	Result	Limits
1	Description	Multicoloured pellets filled in transparent colorless and red coloured hard gelatin capsules, in alu-alu strip.	NA
2	Identification	Gives positive test for Pantoprazole sodium and Domperidone.	NA
3	Filled Content	0.3063 gm	NA
4	Uniformity of weight	Complies.	NA
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 75 % of claim

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Pantoprazole Sodium eq. to Pantoprazole	40.9 mg/Capsule	40 mg/Capsule	102.25	90 % to 110 %	Manufacturer's Specification
2	Domperidone	30.1 mg/Capsule	30 mg/Capsule	100.333	90 % to 110 %	Manufacturer's 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's Specification in respect of test performed.

Date: 21-MAR-2025

GOVERNMENT ANALYST

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

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