



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&D)
CMO West Office
Kulikawn, Aizawl- 796005
2. Serial No. and date of Inspector's memorandum : B.11012/5/2019-CMO (W)/DRUGS/100 , Dated Aizawl, the 27th MAY, 2024
3. Number of Sample : SMP/MZ/TMT/2024-25/003
4. Date of receipt : 11-JUN-2024
5. Names of drugs purporting to be contained in the sample : PANTOPRAZOLE (EC) & DOMPERIDONE (SR) CAPSULES (LTP-DSR CAPSULES)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1219	GUW/LS/2024-25/1243	LTDSRC503	Mar-2024	Feb-2026	M/S Tulbros Formulations., Plot No. 91, Sector IIDC, IIE Pantnagar, SIDCUL, Dist. U.S. Nagar- 263153 (Uttarakhand).

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 13-Nov-2024 To 18-Nov-2024

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

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Bi-colour (light yellow and light brown), hard capsule containing blue, orange and white pellets in aluminium strip.	NA
2	Identification	Gives positive test for Pantoprazole and Domperidone.	NA
3	Average filled content	0.2934 g	NA
4	Uniformity of filled content	Complies.	NA
5	Dissolution	Pantoprazole: Passes the test for both Acid and Buffer Stage.	Acid Stage: NMT 10% Buffer Stage: NLT 70%
		Domperidone: Passes the test.	1 st hour: 15% to 40% 4 th hour: 30% to 60% 8 th hour: 55% to 85% 12 th hour: NLT 70%

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Pantoprazole Sodium Sesquihydrate eq.to Pantoprazole	37.22 mg/Capsule	40 mg/Capsule	93.05	90 % to 110 %	I.P. 2022
2	Domperidone	27.41 mg/Capsule	30 mg/Capsule	91.366	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 conforms to I.P. with respect to the above tests only.

Date: 19-NOV-2024


GOVERNMENT ANALYST
 Amar Jyoti Chamuah
 Government Analyst
 R.D.T.L., Guwahati-22

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

