Regional Drugs Testing Laboratory
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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** : TIMOTHY THANCHUNGNUNGA,
   Assistant Director (F&D),
   CMO West Office,
   Kulikawn, Aizawl- 796005
2. **Serial No. and date of Inspector's memorandum** : B.11012/5/2024-CMO (W)/DRUGS/8
   Dated Aizawl, the 23rd September, 2024
3. **Number of Sample** : SMP/MZ/TMT/2024-2025/013
4. **Date of receipt** : 04-OCT-2024
5. **Names of drugs purporting to be contained in the sample** : Pantoprazole Sodium Enteric Coated & Domperidone Sustained Release Capsules (Gasopep-DSR)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1307	GUW/LS/2024-25/1329	YC-24009C	APR. 2024	MAR. 2026	Yuventis Life Sciences, Plot No. 7 Ext. Phase III, HPSIDC, Baddi, Distt. Solan. (H.P.) 173205

6. **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

7. **Result of test or analysis with protocols or test or analysis applied** : **Please see below**

Date of Testing : From 22-Oct-2024 To 02-Dec-2024

COMPOSITION : Each hard gelatin capsule contains:
Pantoprazole Sodium IP
Eq. to Pantoprazole 40 mg
(As enteric coated pellets)
Domperidone IP 30 mg
(As Sustained 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, orange and white colour pellets in aluminium foil strip.	NA
2	Identification	Gives positive test for Pantoprazole and Domperidone.	NA
3	Filled Content	0.2942 gm.	NA
4	Uniformity of weight	Passes the test.	NA
5	Dissolution	Passes the test 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	1st hour	19.04% to 31.93%	15% to 40%
		4th hour	33.56% to 50.64%	30% to 60%
		8th hour	57.94% to 69.75%	55% to 85%
		12th hour	81.34% to 83.43%	Not less than 70%

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	PantoprazoleSodium Eq. to Pantoprazole	42.21mg/Capsule	40 mg/Capsule	105.525	90 % to 110 %	I.P.
2	Domperidone	29.96mg/Capsule	30 mg/Capsule	99.866	90 % to 110 %	

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 thereunder for the reasons given below:-

The sample conforms to I.P. with respect to the above tests only.

Note: The monograph of "Pantoprazole Sodium Enteric Coated & Domperidone Sustained Release Capsules" is in I.P. hence the label of the sample should be corrected accordingly.

Date: 06-DEC-2024

GOVERNMENT ANALYST

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

.....END OF REPORT.....