

Regional Drugs Testing Laboratory

Directorate General of Health Services, Guwahati (India) - 781022 Fax: 0361-2338555/2330555 Phone No.0361 2338555

Email:rdtlguwahati@cdsco.nic.in

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 (Food and Drugs)

Drugs

CMO West Office

Kulikawn, Aizawl- 796005

2. Serial No. and date of Inspector's memorandum

: B.11012/5/2019-CMO(W)/DRUGS/24, 12-DEC-2024

Number of Sample

: SMP/MZ/TMT/2024-2025/29

4. Date of receipt

: 06-JAN-2025

5. Names of drugs purporting to be contained in the sample : Enteric Coated Rabeprazole Sodium & Domperidone

SR Capsules (BLOCID-DSR)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025- 26/0015	GUW/LS/2025- 26/19	C24J057D	Oct-2024 Sep-2026	NA	Bajaj Formulations, Khasra No. 161, Village- Lakeshwary, Bhagwanpur, Roorkee, Distt. Haridwar- 247661 (U.K.)

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 25-Mar-2025 To 01-Apr-2025

COMPOSITION

Each hard gelatin capsule contains:Rabeprazole Sodium I.P. (As enteric

coated pellets) 20 mg.

Domperidone I.P.(As sustained release pellets) 30 mg.

Protocol Applied: Validated Method

Sr No.	Test Name	Result	Limits
1	Description	Brown and orange colored pellets filled in transparent colorless and red colored hard gelatin capsules, in blister pack.	NA
2	Identification	Gives positive test for Rabeprazole Sodium & Domperidone.	NA
3	Average filled content	0.2789 g	NA

<u>Assay</u>

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
						.*
1	Rabeprazole Sodium	20.99 mg/Capsule	20 mg/Capsul e	104.95	90 % to 110 %	Validated Method

2	Domperidone	28.74 mg/Capsule	30	95.8	90 % to 110 %	Validated Method	1
			mg/Capsul		1 1		
	DE MALE		е	Apply to			

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 Validated Method in respect of test performed.

Date: 02-APR-2025

akaut 2

GOVERNMENT ANALYST

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

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