

## Regional Drugs Testing Laboratory

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

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## 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

: Mrs. C. Ramdinmawii,

Assistant Director (Food & Drugs) C.M.O. Office, Champhai- 796321 Incia

Mizoram

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

: 022/IPA-CPI/24, Date: 16-DEC-2024

3. Number of Sample

: --

4. Date of receipt

: 31-DEC-2024

5. Names of drugs purporting to be contained in the sample : Omeprazole Capsules IP 20 mg (OMEZ)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	
LSD/GUW/2024- 25/1574	GUW/LS/2024- 25/1593	E2401805	Jul-2024	Jun-2027	DR.REDDYS LABORATORIES LTD., Village Mauja Thana, Nalagarh Road, Baddi, Distt. Solan (HP) 173 205

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 20-Jan-2025 To 23-Jan-2025

COMPOSITION

Each capsule contains: Omeprazole IP 20 mg

(As enteric-coated pellets)

Protocol Applied: I.P. 2022

यस्यवेत जयते

Sr No.	Test Name	Result	Limits
1	Description	Bi-colour (white and pink) hard capsule containing white spherical pellets in aluminium strip.	NA
2	Identification	Gives positive test for Omeprazole.	NA
3	Average Filled Content	0.1933 g	NA
4	Dissolution	Passes the test for both Acid and Buffer Stage.	Acid Stage: NMT 10 % Buffer Stage: NL 70 %

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Omeprazole	20.19 mg/Capsule	20.02 mg/Capsule	100.95	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: 23-JAN-2025

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

