



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 and D)
CMO West Office
Kulikawn, Aizawl- 796005
2. Serial No. and date of Inspector's memorandum : B.11012/5/2024-CMO (W)/DRUGS/62 , 26-MAR-2025
3. Number of Sample : SMP/MZ/TMT/2024-2025/060
4. Date of receipt : 02-APR-2025
5. Names of drugs purporting to be contained in the sample : Omeprazole Gastro-resistant Capsules IP 20 mg
(Omeprazen-20 capsules)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0295	GUW/LS/2025-26/314	MC2411154B	Nov-2024 Oct-2026	NA	MARINE MEDICARE PVT. LTD. Village Kulhariwala & P.O. Mandhala, Tehsil Baddi, Distt. Solan (H.P.), Pincode-174103, INDIA

6. Condition of seals on : Seals were intact & identical to the
[the packet or on portion of sample or container] 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-May-2025 To 26-May-2025

COMPOSITION : Each hard gelatin capsule contains:
Omeprazole IP 20 mg
(As Gastro-resistant pellets)

Protocol Applied : I.P..2022.

Sr No.	Test Name	Result	Limits
1	Description	White pellets filled in transparent colorless and pink colored hard gelatin capsules, in strip pack.	NA
2	Identification	Gives positive test for Omeprazole.	NA
3	Average filled content	0.2762 gm	NA
4	Dissolution Acid Stage	Complies.	NMT 10 % of claim
5	Dissolution Buffer Stage	Complies.	NLT 70 % of claim

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Omeprazole	20.43 mg/Capsule	20 mg/Capsule	102.15	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 conform to claim as per I.P..2022. in respect of test performed.

Date: 30-MAY-2025

GOVERNMENT ANALYST

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

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

