



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 Mizoram
2. Serial No. and date of Inspector's memorandum : 024/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 (Omifrench 20)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1611	GUW/LS/2024-25/1623	CAF-24035	Jan-2024	Dec-2025	Prochem Pharmaceuticals (P) Ltd., 140-141, Makkanpur, Bhagwanpur, Roorkee, Dist. Haridwar (U.K.) 247661

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 21-Jan-2025 To 29-Jan-2025

COMPOSITION : Each hard gelatin capsule contains:
Omeprazole IP 20 mg.
(As enteric coated pellets)

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Bi-colour (white and pink), hard capsule containing off-white pellets in aluminium strip.	NA
2	Identification	Gives positive test for Omeprazole.	NA
3	Average filled content	0.2125 g	NA
4	Dissolution	Passes the test for both Acid and Buffer Stage.	Acid Stage: NMT 10 % Buffer Stage: NLT 70 %

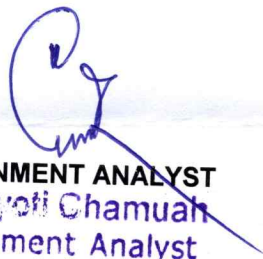
Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Omeprazole	19.96 mg/Capsule	20.0 mg/Capsule	99.8	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: 29-JAN-2025


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

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

