



FORM 13
 (See rule 46)

CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER
 SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

- Name of Inspector from whom received : K.Lalngilneia
Asst. Director (F & D)
CMO Office, Mamit Distric: Mamit
Pin - 796441.
- Serial No. and date of Inspector's memorandum : B.17011/12/09-CMO(M)/DRUGS/35 Date 9th Dec, 24
- Number of Sample :MD08/35
- Date of receipt :20-DEC-2024
- 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/2024-25/1831	GUW/LS/2024-25/1855	CAF-24035	JAN. 2024	DEC. 2025	M/s Prochem Pharmaceuticals (P) Ltd. 140-141, Makkanpur, Bhagwanpur, Roorkee, Distt. Haridwar-247661 (U.K.)

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 04-Mar-2025 To 10-Mar-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	White pellets filled in hard gelatin capsule having pink colour cap and transparent body in strip pack.	NA
2	Identification	Gives positive test for Omeprazole.	NA
3	Filled Content	0.20876 gm.	NA
4	Uniformity of weight	Complies.	NA
5	Dissolution	Complies.	NA
6	Dissolution	Complies for Acid stage (Release of all six units found below 10 %).	NMT 10 % of claim
7	Dissolution	Complies for Buffer stage (Release of all six units found above 'Q' 70+5%).	NLT 70 % of claim

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Omeprazole	20.65 mg/Capsule	20 mg/Capsule	103.25	90 % to 110 %	I.P. 2022

In the opinion of the under signed 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.

Date: 12-MAR-2025



GOVERNMENT ANALYST

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

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

