



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 : Lalruatdika Varte, Drugs Inspector
Drugs Inspector
Office of the Chief Medical Officer, Kolasib, Mizoram-796082
- Serial No. and date of Inspector's memorandum : KLB/07/2024/DRUGS , 21-NOV-2024
- Number of Sample : NIL
- Date of receipt : 09-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/2024-25/1664	GUW/LS/2024-25/1696	CAF-23417	Aug-2023	Jul-2025	M/s Prochem Pharmaceuticals Pvt. Ltd., 140-141, Makkanpur, Bhagwanpur, Roorkee, Distt. Haridwar, (Uttarakhand), 247661

6. Condition of seals on : Seals were intact & identical to the specimen impression of the seal received from Drugs Inspector
[the packet or on portion of sample or container]

7. Result of test or analysis with protocols or test or analysis applied : Please see below

Date of Testing : From 17-Jan-2025 To 10-Feb-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 transparent pink and colorless hard gelatin capsules, in strip pack.	NA
2	Identification	Gives positive test form Omeprazole.	NA
3	Filled Content	0.2104 g	NA
4	Dissolution	Complies.	NA
5	Dissolution (Acid Stage)	Complies.	NMT 10 % of claim
6	Dissolution (Buffer Stage)	Complies.	NLT 70 % of claim

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Omeprazole	19.3 mg/Capsule	20 mg/Capsule	96.5	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: 11-FEB-2025

Rinku Kalita
GOVERNMENT ANALYST

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

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

