Regional Drugs Testing Laboratory
Directorate General of Health Services, Guwahati (India)-781022
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Regional Drugs Testing Laboratory Govt. Of India Guwahati 22

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** : Lalruatadika Varte
   Drugs Inspector
   Office of the Senior Chief Medical Officer
   Kolasib, Mizoram- 796082
2. **Serial No. and date of Inspector's memorandum** :KLB/07/2025/IPA/DRUGS
   Dated Kolasib, the 20th January,2025
3. **Number of Sample** :Nil
4. **Date of receipt** :05-FEB-2025
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. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0036	GUW/LS/2025-26/33	CAF-24035	JAN. 2024 DEC. 2025	NA	Prochem Pharmaceuticals (P). Ltd. 140-141, Makkanpur, Bhagwanpur, Roorkee, Dist. Haridwar- 247661 (U.K.)

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 04-Mar-2025 To 02-Apr-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	0.20897 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	21.15 mg/Capsule	20 mg/Capsule	105.75	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 there under for the reasons given below:-

The sample conforms to I.P. with respect to the above tests only.

Date: 07-APR-2025

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

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