



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 : P Laltlanzova, Asst Drugs Inspector (F and D)
CMO Office,
Lawngtlai District- 796891, Mizoram
2. Serial No. and date of Inspector's memorandum : 022/IPA-LTI/II-25, 15-APR-2025
3. Number of Sample : NIL
4. Date of receipt : 06-MAY-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/2025-26/0572	GUW/LS/2025-26/576	CAF-24136	Mar-2024 Feb-2026	NA	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 08-Jul-2025 To 11-Jul-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 colorless and pink colored hard gelatin capsules, in strip package.	NA
2	Identification	Gives positive test for Omeprazole.	NA
3	Filled Content	0.2269 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	21.58 mg/Capsule	20 mg/Capsule	107.9	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: 13-AUG-2025

GOVERNMENT ANALYST

Rinku Kalita
Government Analyst

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

