



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 : B.LALZAMLIANA, Drugs Inspector (F and D)
CMO West Office
Kulikawn, Aizawl- 796005
- Serial No. and date of Inspector's memorandum : B.11012/5/2024-CMO(W)/DRUGS/65 , 22-APR-2025
- Number of Sample : 010/IPA-AZL W/II-25
- Date of receipt : 05-MAY-2025
- Names of drugs purporting to be contained in the sample : Co-trimoxazole Tablets I.P. (S.S. Single Strength)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-GUW/LS/2025-26/0412	26/414	PT40104	Sep-2024 Aug-2026	NA	OMEGA PHARMA,, Khasra No.482, Village Saliyar, Roorkee-247667, Distt. Haridwar (Uttarakhand).

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 23-May-2025 To 11-Jun-2025

COMPOSITION : Each uncoated tablet contains:
Sulphamethoxazole I.P. 400 mg
Trimethoprim I.P. 80 mg

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	White, round shaped, biconvex, uncoated tablets, in blister pack.	NA
2	Identification	Gives positive test for Trimethoprim and Sulphamethoxazole.	NA
3	Average weight	0.5045 g	NA
4	Uniformity of weight	Complies.	±5% of average weight
5	Dissolution	Complies.	NLT 70% of claim
6	Dissolution of Trimethoprim	Complies.	NLT 70 % of claim
7	Dissolution of Sulphamethoxazole	Complies.	NLT 70 % of claim

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Trimethoprim	78.64 mg/Tablet	80 mg/Tablet	98.3	92.5 % to 107.5 %	I.P. 2022
2	Sulphamethoxazole	387.56 mg/Tablet	400 mg/Tablet	96.89	92.5 % to 107.5 %	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: 26-JUN-2025

GOVERNMENT ANALYST

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

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

