



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 : Mrs. C. Ramdinmawii  
Assistant Director (Food & Drugs)  
C.M.O. Office, Champhai-796321, Mizoram.
- Serial No. and date of Inspector's memorandum :012/IPA-CPI/24 Date: 27/11/2024
- Number of Sample :Nil
- Date of receipt :11-DEC-2024
- Names of drugs purporting to be contained in the sample : Co-trimoxazole Tablets I.P. (D.S.=Double Strength)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1425	GUW/LS/2024-25/1450	PT30119	05/2023	04/2025	OMEGA PHARMA Khasra No.-482, Village-Saliyar, Roorkee - 247667. Distt- Haridwar, (Uttarakhand)

- 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

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

Date of Testing : From 13-Dec-2024 To 23-Dec-2024

COMPOSITION : Each uncoated tablet contains:  
 Sulphamethoxazole I.P. 800 mg  
 Trimethoprim I.P. 160 mg

**Protocol Applied: I.P. 2022**

Sr No.	Test Name	Result	Limits
1	Description	Off white colour, elongated, bi-convex, uncoated tablet, having a dosage line on one side, in blister pack.	NA
2	Identification	Gives positive test for Trimethoprim and Sulphamethoxazole.	NA
3	Average weight	1.0144 gm.	NA
4	Uniformity of weight	Complies.	NA
5	Dissolution	Does not comply.	NA
		Does not Comply for Trimethoprim.	NA
Level	No. units tested	Result	Acceptance Criteria
S <sub>1</sub>	6	Release of each individual unit obtained are as follows: Unit 1=19.6%; Unit 2=22.4%; Unit 3=22.3%; Unit 4=18.9%; Unit 5=19.6%; Unit 6=19.0% Drug release of all (6) units are found less than 75% of claim (70+5%).	Each unit is not less than 'Q' 70+ 5% of Claim. Where 'Q' is 70%, (Specified in individual monograph)



S <sub>2</sub>	6	Release of each individual unit obtained are as follows: <b>Unit 1=35.0%; Unit 2=58.2%; Unit 3=17.0%; Unit 4=53.2%; Unit 5=60.4%; Unit 6=34.9%</b> i).Average drug release of 12 units (S <sub>1</sub> +S <sub>2</sub> ) is: <b>31.7%</b> of claim (<70%) ii).Out of 12 units drug release of 10 units are found less than <b>55%</b> of claim (<Q- 15%).	Average of 12 units (S <sub>1</sub> +S <sub>2</sub> ) is ≥ 70% (≥Q) and no unit is < 55% of claim (Q-15%).
S <sub>3</sub>	12	Out of 12 units drug release of <b>10</b> units are found less than <b>55%</b> (S <sub>1</sub> + S <sub>2</sub> ) as well as all <b>09</b> units are found less than 45% of claim (<Q-25%)	Average of 24 units (S <sub>1</sub> +S <sub>2</sub> +S <sub>3</sub> ) ≥ 70% (≥Q), Not more than 2 units are <Q-15% (i.e. 55%) and no unit is <Q-25% (i.e. 45%)
		<b>Does not comply for Sulphamethoxazole.</b>	NA
S <sub>1</sub>	6	Release of each individual unit obtained are as follows: <b>Unit 1=6.5%; Unit 2=6.5%; Unit 3=6.4%; Unit 4=5.9%; Unit 5=6.5%; Unit 6=5.9%</b> Drug release of all (6) units are found less than 75% of claim (70+5%).	Average of 12 units (S <sub>1</sub> +S <sub>2</sub> ) is ≥ 70% (≥Q) and no unit is < 55% of claim (Q-15%).
S <sub>2</sub>	6	Release of each individual unit obtained are as follows: <b>Unit 1=11.2%; Unit 2=19.7%; Unit 3=6.0%; Unit 4=13.5%; Unit 5=20.9%; Unit 6=11.2%</b> i). Average drug release of 12 units (S <sub>1</sub> +S <sub>2</sub> ) is: 10.1% of claim (<70%). ii).Drug release of all 12 units are found less than <b>55%</b> of claim (<Q- 15%).	Average of 12 units (S <sub>1</sub> +S <sub>2</sub> ) is ≥ 70% (≥Q) and no unit is < 55% of claim (Q-15%).
S <sub>3</sub>	12	All 12 units (S <sub>1</sub> + S <sub>2</sub> ) drug release are found less than 55% of claim (<Q-15%) as well as all 12 units are found less than 45% of claim (<Q-25%)	Average of 24 units (S <sub>1</sub> +S <sub>2</sub> +S <sub>3</sub> ) ≥ 70% (≥Q), Not more than 2 units are <Q-15% (i.e. 55%) and no unit is <Q-25% (i.e. 45%)

### Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Sulphamethoxazole	790.22 mg/Tablet	800 mg/Tablet	98.777	92.5 % to 107.5%	I.P. 2022
2	Trimethoprim	159.07 mg/Tablet	160 mg/Tablet	99.418	92.5 % to 107.5%	I.P. 2022

In the opinion of the under signed the sample referred to above is **not of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules there under for the reasons given below:-

**The sample does not conform to I.P. with respect to the tests for "Dissolution" (Trimethoprim and Sulphamethoxazole).**

Date: 26-DEC-2024

GOVERNMENT ANALYST

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

Report in red coloured paper indicates the sample is Not of Standard Quality

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