

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 : R. Vanlalsiama, Asst. Director (F & D), Sr. CMO Office, Lunglei.
- Serial No. and date of Inspector's memorandum : 8 Date 10.12.24
- Number of Sample : MS-1
- Date of receipt : 23-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/2024-25/1628	GUW/LS/2024-25/1653	PT30119	05/2023	04/2025	OMEGA PHARMA Khasra No.-482, Village-Saliyar, Roorkee-247667, Distt. – Haridwar, (Uttarakhand)

7. 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

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

Date of Testing : From 16-Jan-2025 To 29-Jan-2025

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	0.9977 gm.	NA
4	Uniformity of weight	Complies.	NA
5	Dissolution	Does not comply.	NA
		Does not Comply for Sulphamethoxazole.	NA
Level	No. units tested	Result	Acceptance Criteria
S ₁	6	Release of each individual unit obtained are as follows: Unit 1=9.27%; Unit 2=9.69%; Unit 3=14.06%; Unit 4=9.36%; Unit 5=7.87%; Unit 6=7.91% 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 ₂	6	Release of each individual unit obtained are as follows: Unit 1=9.83%; Unit 2=9.34%; Unit 3=9.34%; Unit 4=7.89%; Unit 5=14.11%; Unit 6=7.97% i). Average drug release of 12 units (S ₁ +S ₂) is: 9.72% of claim (<70%). ii). Drug release of all 12 units are found less than 55% of claim (<Q- 15%).	Average of 12 units (S ₁ +S ₂) is ≥ 70% (≥Q) and no unit is < 55% of claim (Q-15%).
S ₃	12	Release of each individual unit obtained are as follows: Unit 1=9.34%; Unit 2=9.49%; Unit 3=14.26%; Unit 4=9.42%; Unit 5=7.92%; Unit 6=7.94%; Unit 7=9.39%; Unit 8=9.88%; Unit 9=14.41%; Unit 10=9.44%; Unit 11=7.96%; Unit 12=8.04% i). Average drug release of 24 units (S ₁ +S ₂ +S ₃) is: 9.76% of claim (<70%). ii). Drug release of all 24 units are found less than 55% of claim (<Q- 15%). iii). Drug release of all 24 units are found less than 45% of claim (<Q- 25%).	Average of 24 units (S ₁ +S ₂ +S ₃) ≥ 70% (≥Q), Not more than 2 units are <Q-15% (i.e. 55%) and no unit is <Q-25% (i.e. 45%)
		Does not Comply for Trimethoprim.	NA
S ₁	6	Release of each individual unit obtained are as follows: Unit 1=26.03%; Unit 2=26.78%; Unit 3=45.70%; Unit 4=26.05%; Unit 5=13.14%; Unit 6=13.34% 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 ₂	6	Release of each individual unit obtained are as follows: Unit 1=26.99%; Unit 2=26.27%; Unit 3=26.25%; Unit 4=13.49%; Unit 5=45.92%; Unit 6=13.58% i) Average drug release of 12 units (S ₁ +S ₂) is: 25.29% of claim (<70%) ii). Drug release of all 12 units are found less than 55% of claim (<Q- 15%).	Average of 12 units (S ₁ +S ₂) is ≥ 70% (≥Q) and no unit is < 55% of claim (Q-15%).
S ₃	12	Release of each individual unit obtained are as follows: Unit 1=26.19%; Unit 2=27.12%; Unit 3=46.55%; Unit 4=26.39%; Unit 5=13.66%; Unit 6=13.67%; Unit 7= 26.51%; Unit 8=27.18%; Unit 9=46.61%; Unit 10=26.51%; Unit 11=13.84%; Unit 12=13.71% i). Average drug release of 24 units (S ₁ +S ₂ +S ₃) is: 25.48% of claim (<70%). ii). Drug release of all 24 units are found less than 55% of claim (<Q- 15%). iii). Out of 24 units drug release of 20 units are found less than 45% of claim (<Q- 25%).	Average of 24 units (S ₁ +S ₂ +S ₃) ≥ 70% (≥Q), Not more than 2 units are <Q-15% (i.e. 55%) and no unit is <Q-25% (i.e. 45%)

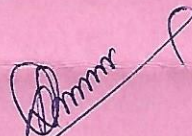
Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Sulphamethoxazole	771.81 mg/Tablet	800 mg/Tablet	96.476	92.5 % to 107.5%	I.P. 2022
2	Trimethoprim	164.34 mg/Tablet	160 mg/Tablet	102.712	92.5 % to 107.5%	

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 thereunder for the reasons given below:-

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

Date: 05-FEB-2025


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 -----