

## Regional Drugs Testing Laboratory Directorate General of Health Services, Guwahati (India)-781022 Fax: 0361-2338555/2330555 Phone No.0361 2338555 Email: rdtlguwahati@cdsco.nic.in



FORM 13

(See rule 46)

CERTIFICATE OF TESTOR ANALYSIS BY GOVERNMENT ANALYST UNDER SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

1. Name of Inspector from whom received

mail feld quiet,

: K.Lalngilneia

Asst. Director (F & D)

CMO Office, Mamit Distric: Mamit

Pin- 796441

2. Serial No. and date of Inspector's memorandum

: B.17011/12/09-CMO(M)/DRUGS/26 Date 28<sup>th</sup> Nov,2024

3. Number of Sample

:MD08/26

4. Date of receipt

:09-DEC-2024

5. Names of drugs purporting to be contained in the sample: Trimethoprim and Sulphamethoxazole Tablets IP

(Co-Trimoxazole DS)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1387	GUW/LS/2024- 25/1411	T-2974	Jan-2024	Dec-2025	Jackson Laboratories Pvt. Ltd. 22-24, Majitha Road, Bye Pass Amritsar-143 001 (India)

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 16-Dec-2024 To 18-Dec-2024

COMPOSITION

Each uncoated tablet contains:

Trimethoprim

**IP** 160 mg

Sulphamethoxazole

800mg

Protocol Applied: I P 2022

Sr No.	Test Name	Result	Limits		
1	Description	White, elongated, bi-convex, scored on one side, uncoated tablet having engraved "D" and "S" on the scored surface in blister pack.			
2	Identification	Gives positive test for Trimethoprim and Sulphamethoxazole.	NA		
3	Average weight 1.004325 gm.		NA		
4	Uniformity of weight Complies.		NA		
5	Dissolution	Complies.	NA		
6	Dissolution for Trimethoprim	Complies (Release of all six units were found above 'Q' 70+5%).	NLT 70 % of		
7	Dissolution for Sulphamethoxazole	Complies (Release of all six units were found above 'Q' 70+5%).	NLT 70 % of claim		

## Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Trimethoprim	158.54 mg/Tablet	160 mg/Tablet	99.087	92.5 % to 107.5%	I.P. 2022
2	Sulphamethoxazole	791.16 mg/Tablet	800 mg/Tablet	98.895	92.5 % to 107.5%	

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 thereunder for the reasons given below:-

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

Date: 19-DEC-2024

GOVERNMENT ANALYST

Dilip Kr. Sarkar

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

CDSCO

CDSCO

CDSCO