

Regional Drugs Testing Laboratory

Directorate General of Health Services, Guwahati (India) - 781022 385ting

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## 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

: K.Lalngilneia, Asst. Director (F and D) Asst. Director (F&D), CMO Office, Mamit Distric: Mamit, Mizoram- 796441.

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

: B.17011/12/09-CMO (M)/DRUGS/48, 09-JAN-2025

3. Number of Sample

: MD08/48

4. Date of receipt

: 23-JAN-2025

5. Names of drugs purporting to be contained in the sample : Trimethoprim & Sulphamethoxazole Oral Suspension

I.P. (Maxtrim Suspension)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1764	GUW/LS/2024- 25/1783	ML-23J15	Oct-2023	Sep-2025	Martin & Brown Bio-sciences K. No. 918/419, Malkumajra,
	<u> </u>			192	Nalagarh Road, Baddi, Distt. Solan (H.P.)-173205

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 18-Feb-2025 To 26-Feb-2025

COMPOSITION

Each 5 ml contains:

Trimethoprim I.P. 40 mg

Sulphamethoxazole I.P. 200 mg

## Protocol Applied: I.P. 2022

Sr No.	Test Name	Result	Limits	
1	Description	Pink colored suspension filled in amber colored plastic bottles.	NA	
2	Identification	Gives positive test for Trimethoprim & Sulphamethoxazole.	NA	
3	pH	Found 5.67	5.0 to 6.5 .	

## <u>Assay</u>

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Trimethoprim	40.56 mg/5ml	40 mg/5ml	101.4	90 % to 110 %	I.P. 2022
						3.

2	Sulphamethoxazole	199.15 mg/5ml	200 mg/5ml	99.575	90 % to 110 %	I.P. 2022	2
			mg/om				1

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-FEB-2025

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GOVERNMENT ANALYST

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

END OF REPORT -----