

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

Gevt. Of India

Guwahati-22

FORM 13

(See rule 46)

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

1. Name of Inspector from whom received

· Mrs. C. Ramdinmawii

Assistant Director (Food & Drugs) C.M.O. Office, Champhai-796321

Mizoram

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

:008/IPA-CPI/24

Date:27/11/2024

3. Number of Sample

:Nil

4. Date of receipt

:11-DEC-2024

5. Names of drugs purporting to be contained in the sample: Co- trimoxazole Tablets I.P. (Trimzole- SS)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1410	GUW/LS/2024- 25/1438	ZSRT-003	10/2022	09/2025	Laborate Pharmaceuticals India Ltd. 51,Industrial Area, Paonta Sahib (H.P.)

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 23-Dec-2024

COMPOSITION

Each Uncoated Tablets Contains:

Trimethoprim I.P. 80 mg.

Sulphamethoxazole I.P. 400mg.

Protocol Applied: I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	White, round, bi-convex, scored on one side, uncoated tablet, having engraved "COTRIMOXAZOLE" on the unscored surface and "400" and "80" on the scored surface, packed in blister pack.	NA
2	Identification	Gives positive test for Trimethoprim and Sulphamethoxazole.	NA
3	Average weight	0.5373 gm.	NA
4	Uniformity of weight	Complies.	NA
5	Dissolution	Complies.	NA
6	Dissolution	Complies for Trimethoprim (Release of all six units found above 'Q' 70+5%).	NLT 70 % of claim
7	Dissolution	Complies for Sulphamethoxazole (Release of all six units found above 'Q' 70+5%).	NLT 70 % of claim

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1.	Trimethoprim	80.47 mg/Tablet	80 mg/Tablet	100.587	92.5 % to 107.5%	I.P. 2022
2	Sulphamethoxazole	395.501 mg/Tablet	400 mg/Tablet	98.875	92.5 % to 107.5%	I.P. 2022

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: 24-DEC-2024

GOVERNMENT ANALYST

Dilip Kr. Sarkar

Government Analyst

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

TA END OF REPORT-FROLOACY

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