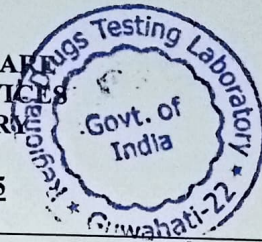


GOVERNMENT OF INDIA  
MINISTRY OF HEALTH AND FAMILY WELFARE  
DIRECTORATE GENERAL OF HEALTH SERVICES  
REGIONAL DRUGS TESTING LABORATORY  
SIX-MILE, GUWAHATI-781 022  
Tel. No-0361-2338555, Fax No. 0361-2330555  
Email: rdtlguwahati@cdsco.nic.in



No. RDTL/Report/S/2026-2027/A.N. 30014/ 203

Date: 27/05/2026

To,

Lalruatdika varte  
Drugs Inspector  
Office of the Senior Chief Medical Officer  
Kolasib, Mizoram -796082

Subject: Test report in Form 13 of sample under Drugs and Cosmetics Act, 1940 and Rules, 1945 thereunder-regarding.

Ref. No.: KLB/02/2026/DRUGS

Date- 18.03.2026

Sir,

With reference to above, please find herewith the enclosed test report in Form 13 (in triplicate) of the sample received by the laboratory.

Kindly acknowledge the receipt of the same.

Yours sincerely,

(Rinku Kalita)  
Government Analyst  
RDTL, Guwahati

Copy for information to: The Drugs Controller, Mizoram.

(Rinku Kalita)  
Government Analyst  
RDTL, Guwahati



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 : Lalruatdika Varte (Drugs Inspector)  
O/o the Sr. CMO, Kolasib, Mizoram- 796082
2. Serial No. and date of Inspector's memorandum : KLB/02/2026/DRUGS , 18-MAR-2026
3. Number of Sample : Not mentioned.
4. Date of receipt : 30-MAR-2026
5. Names of drugs purporting to be contained in the sample : Co-trimoxazole Tablets IP 960 mg (Clinpod-DS Tablets)

| Lab. Sample No.                   | Report No. | Batch No. | Date of Mfg. & Exp   | Marketed By | Mfg. By                                                                                                                                                                 |
|-----------------------------------|------------|-----------|----------------------|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| LSD/GUWI/2026-GUW/LS/2026-27/0025 | 27/108     | OMT25087  | Jun-2025<br>May-2027 | NA          | Omish Laboratories Pvt. Ltd.,<br>Plot No.: D-10, Gallops<br>Industrial Park-1,<br>Ahmedabad- Rajkot Highway,<br>NH-8A, Rajoda, Bavla,<br>Ahmedabad- 382220<br>(Gujarat) |

6. 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

7. Result of test or analysis with protocols or test or analysis applied : Please see below  
Date of Testing : From 06-May-2026 To 14-May-2026

COMPOSITION : Each uncoated tablet contains:  
Trimethoprim IP 160 mg  
Sulphamrthoxazole IP 800 mg

Protocol Applied : I.P. 2022

| Sr No. | Test Name                      | Result                                                                                 | Limits                 |
|--------|--------------------------------|----------------------------------------------------------------------------------------|------------------------|
| 1      | Description                    | White, elongated, bi-convex, scored on one surface, uncoated tablets, in blister pack. | NA                     |
| 2      | Identification                 | Gives positive test for Trimethoprim and Sulphamrthoxazole.                            | NA                     |
| 3      | Average weight                 | 1.10488 g                                                                              | NA                     |
| 4      | Uniformity of weight           | Complies.                                                                              | +5 % of Average weight |
| 5      | Dissolution (For Trimethoprim) | Complies.                                                                              | NLT 70 % of claim      |

|   |                                     |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                            |
|---|-------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 6 | Dissolution (For Sulphamethoxazole) | Does not comply.                                                                                                                                                                                                                                                                                                                                                           | NLT 70% of claim                                                                                                                                           |
| 7 | Level S1 (6 units)                  | Does not comply. Release of Sulphamethoxazole of each individual unit is found as follows: Unit 1=33.13%; Unit 2=37.91%; Unit 3=35.08%; Unit 4=34.63%; Unit 5=39.68%; Unit 6=27.78% . Release of Sulphamethoxazole of all 06 units are found less than 75% of claim i.e. (Q+5%) where Q is 70% of claim.                                                                   | Each unit is not less than Q+5% of claim where Q is 70%                                                                                                    |
| 8 | Level S2 (6 units)                  | Does not comply. Release of Sulphamethoxazole of each individual unit is found as follows: Unit 1=24.84%; Unit 2=33.66%; Unit 3=36.84%; Unit 4=28.30%; Unit 5=36.34%; Unit 6=37.84% . Average release of Sulphamethoxazole of 12 units (S1+S2) is 33.84 % of claim which is less than Q i.e. 70% of claim. Release of all 12 units are found less than 55% of claim(Q-15%) | Average of 12 units (S1+S2) $\geq$ 70% of claim and no unit is less than 55% of claim (Q-15%)                                                              |
| 9 | Level S3                            | Does not comply. Release of Sulphamethoxazole of all 12 units are found less than (Q-15%) i.e. 55% as well as less than (Q-25%) i.e. 45% of claim.                                                                                                                                                                                                                         | Average of 24 units (S1+S2+S3) $\geq$ 70% of claim, not more than 2 units are less than 55% of claim (Q-15%) and no unit is less than 45% of claim (Q-25%) |

### Assay

| Sr.No | Ingredient Name  | Found            | Claim         | % of claim | Limits            | Procedure / Method |
|-------|------------------|------------------|---------------|------------|-------------------|--------------------|
| 1     | Trimethoprim     | 156.64 mg/Tablet | 160 mg/Tablet | 97.9       | 92.5 % to 107.5 % | I.P. 2022          |
| 2     | Sulfamethoxazole | 825.85 mg/Tablet | 800 mg/Tablet | 103.231    | 92.5 % to 107.5 % | I.P. 2022          |
|       |                  |                  |               |            |                   |                    |
|       |                  |                  |               |            |                   |                    |

In the opinion of the undersigned 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 comply as per I.P. 2022 with respect to the test for "Dissolution" of Sulphamethoxazole.

Date: 27-MAY-2026

Report in the red colored paper indicates the sample is not of standard quality.

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

