

Regional Drugs Testing Laboratory Directorate General of Health Services, Guwahati (India)-781022 Fax: 0361-2338555/2330555 Phone No.0361 2338555

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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

Name of Inspector from whom received

Lalruatadika varte

Drugs Inspector

Office of the Senior Chief Medical Officer

Kolasib, Mizoram-796082

Serial No. and date of Inspector's memorandum

: KLB/08/2024/DRUGS

Dated Kolasib, the 22nd November, 2024

Number of Sample

: Nil

Date of receipt

: 09-DEC-2024

Names of drugs purporting to be contained in the sample: Amoxycillin Capsules I.P. 250 mg.

| Lab. Sample No. | Report No. | Batch No. | Date of Mfg. | Date of Exp. | Mfg. By |
|--------------------------|-------------------------|-----------|----------------|--------------|--|
| LSD/GUW/2024- 25/1759 | GUW/LS/2024- 25/1787 | Z23-1203 | ARD (10/2023V) | 09/2025 O | Zee Laboratories Ltd. Behind 47,Industrial Area, Paonta Sahib-173025 |

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 06-Feb-2025 To 25-Feb-2025

COMPOSITION

Each hard gelatin capsule contains:

Amoxycillin Trihydrate I.P.

Eq. to Anhydrous Amoxycillin 250 mg

| Sr No. | Test Name | Result | Limits | |
|---------------|------------------------|---|-------------------|--|
| 1 Description | | Bi- colour (dark blue & white) hard gelatin capsule filled with white crystalline powder in blister pack. | NA | |
| 2 | Identification | Gives positive test for Amoxycillin. | NA | |
| 3 | Average filled content | 0.2960 gm. | NA | |
| 4 | Uniformity of weight | Complies. | NA | |
| 5 | Dissolution | Complies (Release of each unit was found above 'Q' 80 + 5%). | NLT 80 % of claim | |

Assay

| Sr.No | Ingredient Name | Found | Claim | % of claim | Limits | Procedure / Method |
|-------|-----------------|-------|-------|------------|--------|-----------------------|
| | | N 2-1 | | | | |

| 1122 | Amoxycillin Trihydrate Eq. to Amoxycillin | 263.12 mg/Capsule | 250 mg/Capsule | 105.248 | 90 % to 110 % | I.P. 2022 |
|--------|---|---------------------|----------------|---------|---------------|-----------|
| 200 14 | | REAL REAL PROPERTY. | 30) | | | |

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: 27-FEB-2025

GOVERNMENT ANALYST

Dilip Kr. Sarkar

Government Analyst

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

--- END OF REPORT -----

