

Regional Drugs Testing Laboratory

Directorate General of Health Services, Guwahati (India)- 7810/22 Fax: 0361-2338555/2330555 Phone No.0361 2338555

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FORM 13 (See rule 46)

Wahali 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

: R. Vanlalsiama. Asst Director (F&D), Sr. CMO Office, Lunglei.

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

: 8 , Date: 10-DEC-2024

3. Number of Sample

: MS-2

4. Date of receipt

: 23-DEC-2024

5. Names of drugs purporting to be contained in the sample : Amoxycillin Trihydrate with Lactic acid bacillus Capsules

(Mimox LB-500 CAPSULES)

| Lab. Sample No. | Report No. | Batch No. | Date of Mfg. | Date of Exp | Mfg. By |
|--------------------------|-------------------------|-----------|--------------|-------------|--|
| LSD/GUW/2024- 25/1939 | GUW/LS/2024- 25/1961 | CI-23005 | Sep-2023 | Aug-2025 | Horizone Bioceuticals Pvt. Ltd., Plot No 3A, Industrial Area Trilokpur Road, kala Amb,Distt. Sirmour (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

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7. Result of test or analysis with protocols or test or analysis applied : Please see below

Date of Testing: 24-Mar-2025, 25-Mar-2025

COMPOSITION

Each hard gelatin capsule contains:

Amoxycillin Trihydrate I.P.

Equivalent to Amoxycillin 500 mg Lactic Acid Bacillus 90 million spores

Protocol Applied: Validated Method

| Sr No. Test Name | | Result | Limits | |
|------------------|------------------------------|--|----------------|--|
| 1 | Description | Yellow colour, hard gelatin capsule containing light yellow crystalline powder in blister strip. | NA | |
| 2 | Identification | Gives positive test for Amoxycillin. | NA | |
| 3 | Average filled content | 0.5944 g | NA | |
| 4 | Uniformity of filled content | Complies. (Method I.P.) | NA | |
| 5 Disintegration | | Passes the test. (Method I.P.) (Time taken for disintegration 07 minutes 45 seconds) | NMT 30 minutes | |

| r.No ِ | Ingredient Name | Found | Claim | % of claim | Limits | Procedure / Method |
|--------|---|------------------|-------------------|------------|---------------|--------------------|
| 1 | Amoxycillin Trihydrate eq. to Amoxycillin | 472.4 mg/Capsule | 500 mg/Capsule | 94.48 | 90 % to 110 % | Validated Method |

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 conforms to claim with respect to the above tests only.

Date: 26-MAR-2025

GOVERNMENT ANALYST Amar Jyofi Chamuah Government Analyst R.D.T.L., Guwahati-22

- END OF REPORT -

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