

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

1. Name of Inspector from whom received

· Lalruatadika varte

Drugs Inspector

Office of the Senior Chief Medical Officer

Kolasib, Mizoram-796082

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

: KLB/17/2025/IPA/DRUGS

Dated Kolasib, the 3rd March, 2025

3. Number of Sample

: Nil

4. Date of receipt

: 10-MAR-2025

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

ARD ((MimoxLB-250 CAPSULES))

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-	GUW/LS/2025-	CH-23027	AUG.2023	70	Horizon Bioceuticals Pvt.Ltd.
26/0074	26/82	CH-23027	JUL.2025	NA 🦠	Plot No.: 3A,Ind.Area, Trilokpur Road,
	_	3			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

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

Date of Testing: From 24-Mar-2025 To 26-Mar-2025

COMPOSITION

Each hard gelatin capsule contains:

Amoxycillin Trihydrate I.P.

Equivalent Amoxicillin 250 mg Lactic acid bacillus 60 million Spores.

Protocol Applied: Validated Method

Sr No.	Test Name	Result	Limits
1	Description	Light yellow colour crystalline powder filled in bi-colour (red & white) hard gelatin capsule having printed 'CUREWELL' and 'MIMOX-LB 250' on either half of the capsule shells in blister pack	NA
2	Identification	Gives positive test for Amoxycillin.	NA
3	Filled content	0.3204 gm.	»NA
4	Uniformity of filled content	Passes the test (Method: I.P.).	NA
5	Disintegration	Passes the test {All six units disintegrated within 7 minutes 11 seconds; (Method: I.P.)}.	NMT 30 minutes

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
	1	4				

	1	Amoxicillin Trihydrate Equivalent to Amoxicillin	250 mg/Capsule	101.816	90 % to 110 %	HPLQ (Ref:Validated
	1 100 11					Method)
-	In the onin	ion of the under size at the				

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 claim with respect to the above tests only.

Date: 17-APR-2025

GOVERNMENT ANALYST

Dilip Kr. Sarkar

Government Analyst

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

CDSCO / CDSCO

END OF REPORT -