

## **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

: Mr.R.VANLALRUATA,

Assistant Director (F&D)

Office of the Chief Medical Officer, Aizawl, Mizoram, PIN - 796001

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

: MZ/24/AE/25/IPA , 19-DEC-2024

3. Number of Sample

4. Date of receipt

: 31-DEC-2024

5. Names of drugs purporting to be contained in the sample: AZITHROMYCIN TABLETS I.P. (ZAX 250)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1885	GUW/LS/2024- 25/1905	TI-23090	Sep-2023	Aug-2025	Horizon Bioceuticals Pvt. Ltd., Plot No.3A, Ind. Area, Trilokpur Road, Kala Amb,
	Q'			77	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: 19-Mar-2025, 20-Mar-2025

COMPOSITION

Each film coated tablet contains:

Azithromycin IP eq. to Anhydrous Azithromycin 250 mg.

Protocol Applied: I.P. 2022

सत्यमंब ज्ञान

Sr No.	Test Name	Result	g NA NA	
1	Description	White, elongated, bi-convex, film coated tablet having a dosage line on one side in blister strip.		
2	Identification	Gives positive test for Azithromycin.		
3	Average weight	0.3631 g	NA	
4 Uniformity of weight		Complies.	NA	
5	Dissolution	Complies.	NLT 75%	

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ŝr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Azithromycin eq. to Anhydrous Azithromycin	239.02 mg/Tablet	250 mg/Tablet	95.608	90 % to 110 %	I.P. 2022

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 I.P. with respect to the above tests only.

Date: 20-MAR-2025

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

**END OF REPORT** 

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