



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 Chief Medical Officer  
Kolasib, Mizoram- 796082
2. Serial No. and date of Inspector's memorandum : KLB/11/2025/IPA/DRUGS , 03-FEB-2025
3. Number of Sample : NIL
4. Date of receipt : 13-FEB-2025
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. & Exp	Marketed By	Mfg. By
LSD/GUW/2024-25/1943	GUW/LS/2025-26/41	TI-23090	Sep-2023 Aug-2025	NA	Horizon Bioceuticals Pvt. Ltd., Plot No. 3A, Ind. Area, Trilokpur Road, Kala Amb, Distt, Sirmour (H.P.).

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 27-Feb-2025 To 27-Mar-2025

COMPOSITION : Each film coated tablet contains: Azithromycin IP eq. to Anhydrous Azithromycin 250 mg.

**Protocol Applied : I.P. 2022**

Sr No.	Test Name	Result	Limits
1	Description	White, oval shaped, bi-convex, scored on one surface, film coated tablets, in blister pack.	NA
2	Identification	Gives positive test for Azithromycin.	NA
3	Average weight	0.3644 g	NA
4	Uniformity of weight	Complies.	NA
5	Dissolution	Complies.	NLT 75 % of claim

**Assay**

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

1	Azithromycin Eq. to Anhydrous Azithromycin	241.8 mg/Tablet	250 mg/Tablet	96.72	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 conform to claim as per I.P. 2022 in respect of test performed.

Date: 07-APR-2025

*Rinku Kalita*  
GOVERNMENT ANALYST

Rinku Kalita  
Government Analyst  
R.D.T.L., Guwahati-22

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

