



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 Chief Medical Officer
Kolasib, Mizoram- 796082
- Serial No. and date of Inspector's memorandum : KLB/19/2025/IPA/DRUGS , 03-MAR-2025
- Number of Sample : NIL
- Date of receipt : 10-MAR-2025
- 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/2025-26/0329	GUW/LS/2025-26/339	TH-23128	Aug-2023 Jul-2025	NA	Horizon Bioceticals 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 specimen impression of the seal received from Drugs Inspector
[the packet or on portion of sample or container]

7. Result of test or analysis with protocols or test or analysis applied : Please see below
Date of Testing : From 25-Mar-2025 To 09-Jun-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 with four corner, biconvex, scored on one surface, film coated tablets, in blister packing.	NA
2	Identification	Gives positive test for Azithromycin.	NA
3	Average weight	0.3586 g	NA
4	Uniformity of weight	Complies.	+5 % of Average weight
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	237.8 mg/Tablet	250 mg/Tablet	95.12	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: 11-JUN-2025

GOVERNMENT ANALYST

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

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

26/6/25

