



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 : Lianhmingthangi, Assistant Drugs Inspector (F and D)
CMO Office
Siaha District, Mizoram- 796901
2. Serial No. and date of Inspector's memorandum : SD/19/038N-DRUGS , 24-MAR-2025
3. Number of Sample : NIL
4. Date of receipt : 04-APR-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/2025-26/0522	GUW/LS/2025-26/533	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 21-May-2025 To 17-Jul-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, elongated, slightly bi-convex, having a dosage line on one surface, film coated tablets, in blister pack.	NA
2	Identification	Gives positive test for Azithromycin.	NA
3	Average weight	0.3622 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
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1	Azithromycin Eq. to Anhydrous Azithromycin	226.2 mg/Tablet	250 mg/Tablet	90.48	90 % to 110 %	I.P. 2022
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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: 31-JUL-2025

GOVERNMENT ANALYST

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

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

