



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 : K.Lalngilneia
Asst. Director (F& D)
CMO Office, Mamit Distric: Mamit,
Pin- 796441
- Serial No. and date of Inspector's memorandum : B.17011/12/09-CMO(M)/DRUGS/16 Date 10th Sept. 24
- Number of Sample : MD08/16
- Date of receipt : 19-SEP-2024
- 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/2024-25/1145	GUW/LS/2024-25/1168	TF-23211	JUN. 2023	MAY 2025	M/s. 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 15-Oct-2024 To 29-Oct-2024

COMPOSITION : Each film coated tablet contains:
Azithromycin I.P. 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 side, film coated tablet in aluminium blister pack.	NA
2	Identification	Gives positive test for Azithromycin.	NA
3	Average weight	0.3714 gm.	NA
4	Uniformity of weight	Complies.	NA
5	Dissolution	Complies (Release of all six units found above 'Q' 75+5%).	NLT 75 % of Claim

Assay

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

11 Standard Sample
 ABC (70) Azithromycin
 Mon 20/09/2024

1	Azithromycin eq.to Anhydrous Azithromycin	246.46 mg/Tablet	250 mg/Tablet	98.584	90 % to 110 %	I.P.
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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 thereunder for the reasons given below:-

The sample conforms to I.P. with respect to the above tests only.



GOVERNMENT ANALYST

Dilip Kr. Sarkar
Government Analyst
R.D.T.L., Guwahati-22

Date: 08-NOV-2024

.....END OF REPORT.....

