



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 : B.LALZAMLIANA, Drug Inspector (F and D)
CMO West Office
Kulikawn, Aizawl- 796005
- Serial No. and date of Inspector's memorandum : B.11012/5/2024-CMO (W)/DRUGS/47 , 25-FEB-2025
- Number of Sample : SMP/MZ/TMT/2024-2025/042
- Date of receipt : 06-MAR-2025
- Names of drugs purporting to be contained in the sample : azithromycin Suspension I.P. (Azirift-200)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0160	GUW/LS/2025-26/167	AL-24857	Oct-2024 Sep-2026	NA	Altop Healthcare, Vill. Juddi Kalan, P.O. Baddi, Distt. Solan (H.P.) 173205

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 29-Apr-2025

COMPOSITION : Each 5ml contains:
Azithromycin Dihydrate I.P. Anhydrous Azithromycin 200 mg.

Protocol Applied : I.P.2022

Sr No.	Test Name	Result	Limits
1	Description	Orange colored liquid filled in amber colored plastic bottles along with measuring cups.	NA
2	Identification	Gives positive test for Azithromycin.	NA
3	Weight per ml	1.1751 g/ml	NA
4	pH	8.03 .	7.5 to 11 .

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
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1	Azithromycin Dihydrate equivalent to anhydrous Azithromycin	180 mg/5ml	200 mg/5ml	90	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: 05-MAY-2025

GOVERNMENT ANALYST

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

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

