



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 : B.LALZAMLIANA, Drugs Inspector (F and D)
CMO West Office
Kulikawn, Aizawl- 796005
2. Serial No. and date of Inspector's memorandum : B.11012/5/2024-CMO (W)/DRUGS/62 , 22-APR-2025
3. Number of Sample : 007/IPA-AZL W/II-25
4. Date of receipt : 05-MAY-2025
5. Names of drugs purporting to be contained in the sample : Azithromycin Oral Suspension I.P.. . (Afdiz- DS.)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0664	GUW/LS/2025-26/666	L3L010	Dec-2023 Nov-2025	NA	Smayan Healthcare Pvt. Ltd., Plot No. 26-27, HPSIDC Indl. Area, Vill. Davni, Baddi, Distt. Solan (H.P.) 173 205

6. Condition of seals on :
[the packet or on portion of sample or container] : Seals were intact & identical to the
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 02-Jul-2025 To 04-Sep-2025

COMPOSITION : Each 5 ml contains:
Azithromycin Dihydrate IP Eq. to Azithromycin 200 mg.

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Orange colored suspension filled in amber colored plastic bottles.	NA
2	Identification	Gives positive test for Azithromycin.	NA
3	Weight per ml	1.2304 gm	NA
4	pH	8.11 .	7.5 to 11 .

Assay

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

1	Azithromycin Dihydrate equivalent to Azithromycin	183.78 mg/5ml	200 mg/5ml	91.89	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: 08-SEP-2025

GOVERNMENT ANALYST

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

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

