



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/57 , 26-MAR-2025
3. Number of Sample : SMP/MZ/TMT/2024-2025/055
4. Date of receipt : 02-APR-2025
5. Names of drugs purporting to be contained in the sample : Azithromycin Oral Suspension IP (AZAL SUSPENSION)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0541	GUW/LS/2025-26/547	DL4F035	Jun-2024 May-2026	NA	DR PATEL PHARMACEUTICALS PVT. LTD., PLOT NO. 4 SHAH INDUSTRIAL, PHASE-2, LAMDAPURA, MANJUSAR. DOST. VADODARA- 391775 (GUJARAT)

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 02-Jul-2025 To 09-Jul-2025

COMPOSITION : Each 5ml. contains:
Azithromycin I.P. (As dihydrate) equivalent to Anhydrous 200mg.

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Yellow colored suspension in amber colored plastic bottles.	NA
2	Identification	Gives positive test for Azithromycin.	NA
3	Weight per ml	1.3045 g/ml	NA
4	pH	7.65	7.5 to 11 .

Assay

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

1	Azithromycin (As dihydrate) equivalent to Azithromycin anhydrous	202.97 mg/5ml	200 mg/5ml	101.485	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: 06-AUG-2025

GOVERNMENT ANALYST

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

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

