



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 : Mr. R. Vanlalruata, Assistant Director (Food and Drugs)
ASSISTANT DIRECTOR(F&D)
OFFICE OF CHIEF MEDICAL OFFICER, AIZAWL,
MIZORAM, PIN-769017
2. Serial No. and date of Inspector's memorandum : MZ/2025/CMO E/IPA/10 , 20-JAN-2025
3. Number of Sample : NIL
4. Date of receipt : 29-JAN-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/2025-26/0045 | GUW/LS/2025-26/47 | L3L010 | Dec-2023 Nov-2025 | NA | Smayan Healthcare Pvt. Ltd., Plot No. 26-27, HPSIDC Indl. Area, Vill. Davni, Baddi, Distt. Solán (H.P.) 173 205 |

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 25-Mar-2025 To 04-Apr-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 ember colored plastic bottles. | NA |
| 2 | Identification | Gives positive test for Azithromycin. | NA |
| 3 | Weight per ml | 1.2425 g/ml | NA |
| 4 | pH | 8.01 . | 7.5 to 11 . |

Assay

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

| | | | | | | |
|---|---|---------------|------------|--------|---------------|-----------|
| 1 | Azithromycin Dihydrate equivalent to Azithromycin | 184.95 mg/5ml | 200 mg/5ml | 92.475 | 90 % to 110 % | I.P. 2022 |
|---|---|---------------|------------|--------|---------------|-----------|

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: 07-APR-2025

Rinku Kalita
GOVERNMENT ANALYST

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

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

