

## Regional Drugs Testing Laboratory Directorate General of Health Services, Guwahati (India)-781022 Fax: 0361-2338555/2330555 Phone No.0361 2338555 Email: rdtlguwahati@cdsco.nic.in

Govt. Of India

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

: SARAH LALDINTLUANGI

ASSISTANT DIRECTOR (FOOD & DRUGS) Sr. CMO OFFICE, SERCHHIP-796181,

**SERCHHIP** 

2. Serial No. and date of Inspector's memorandum

:012/IPA/2024

Date 27-11-2024

3. Number of Sample

:Nil

4. Date of receipt

:26-DEC-2024

5. 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-<br>25/1661 | GUW/LS/2024-<br>25/1685 | TI-23090  | SEP. 2023     | AUG. 2025    | Horizon Bioceuticals Pvt.Ltd. Plot No. 3A, Ind. Area, Trilokpur Road, Kala Amb, Distt, Sirmour (H.P.). |

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 21-Jan-2025 To 07-Feb-2025

**COMPOSITION:** 

Each film coated tablet contains:

Azithromycin IP

eq. to Anhydrous Azithromycin 250 mg

Protocol Applied: I.P. 2022

| Sr No. Test Name  1 Description |                      | Result  White, oval shaped, bi-convex, scored on one side, film coated tablet in aluminium blister strip in paper box. |                   |  |
|---------------------------------|----------------------|--|-------------------|--|
|                                 |                      |  |                   |  |
| 3                               | Average weight       | 0.3679 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 /<br>Method |
|-------|-----------------|-------|-------|------------|--------|-----------------------|
|       |                 |       |       |            |        |                       |

| Azithromycin eq.to Anhydrous Azithromycin | 250.44 mg/Tablet | 250 mg/Tablet | 100.176 | 90 % to 110 % | I.P. 2022 |
|---|------------------|---------------|---------|---------------|-----------|
| 7.0/                                      | th Dallas        |               |         |               |           |

In the opinion of the under signed 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.

Date: 10-FEB-2025

GOVERNMENT ANALYST

Dilip Kr. Sarkar

Government Analyst

R.D.T.L., Guwahati-22

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

