

Regional Drugs Testing Laboratory

Directorate General of Health Services, Guwahati (India) - 78102 Fax: 0361-2338555/2330555 Phone No.0361 2338555

Email:rdtlguwahati@cdsco.nic.in

FORM 13

(See rule 46)

CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER: (1)
SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

1. Name of Inspector from whom received

: Mrs. C. Ramdinmawii, Assistant Director (Food and

Drugs)

C.M.O. Office,

Champhai-796321 Mizoram

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

: 023/IPA-CPI/24, 16-DEC-2024

3. Number of Sample

: NIL

4. Date of receipt

: 31-DEC-2024

5. Names of drugs purporting to be contained in the sample: Ciprofloxacin Eye Drops IP (CIPLOX Eye / Ear Drops)

| Lab. Sample No. | Report No. | Batch No. | Date of Mfg. | Date of Exp. | Mfg. By |
|--------------------------|-------------------------|-----------|--------------|--------------|--|
| LSD/GUW/2024- 25/1890 | GUW/LS/2024- 25/1912 | 4L80704 | Jun-2024 | May-2027 | CIPLA LTD, Ambica Estate, National Highway No. 8, Aslali, Ahmedabad 382427 INDIA. At: Village Sachana, Tal Viramgam, Dist. Ahmedabad 382150 INDIA |

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 20-Jan-2025 To 13-Mar-2025

COMPOSITION

Ciprofloxacin Hydrochloride IP Equivalent to Ciprofloxacin 0.3% w/v

Benzalkonium Chloride IP 0.01% w/v

Protocol Applied: I.P. 2022

| Sr No. | Test Name | Result | Limits | |
|---------------|--------------------|--|--------------|--|
| 1 Description | | Clear and colorless liquid filled in colorless translucent sealed plastic ampoules with screw cap, supplied in paper carton. | NA | |
| 2 | Identification | Gives positive test for Ciprofloxacin. | NA | |
| 3 | Sterility | Passes the test. | NA | |
| 4 | Extractable volume | Complies. | NA | |
| 5 | Particulate matter | Passes the test. | NA . | |
| 6 | pH | 4.3 . | 3.5 to 5.5 . | |
| | 4 | | . 12 | |

Assay

| Sr.No | Ingredient Name | Found | Claim | % of claim | Limits | Procedure / Method |
|-------|---|------------|-----------|------------|---------------|--------------------|
| 1 | Ciprofloxacin Hydrochloride equivalent to Ciprofloxacin | 0.31 % w/v | 0.3 % w/v | 103.333 | 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: 20-MAR-2025

GOVERNMENT ANALYST

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

CDSCO CDSCO