

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

Testing India Guwahati

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 AND DRUGS) Sr. CMO OFFICE, SERCHHIP-796181, SERCHHIP

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

: 020/IPA/2024

Date 13.12.2024

3. Number of Sample

:Nil

4. Date of receipt

:02-JAN-2025

5. Names of drugs purporting to be contained in the sample: CIPROFLOXACIN TABLETS IP 250 mg (Ciprodac 250)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1603	GUW/LS/2024- 25/1641	CT23015	08/2023	07/2026	CADILA PHARMACEUTICALS LIMITED, 1389, Dholka- 382 225, Dist.: Ahmedabad.

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 17-Jan-2025 To 29-Jan-2025

COMPOSITION

Each film-coated tablet contains: Ciprofloxacin Hydrochloride IP equivalent to Ciprofloxacin 250 mg

Sr No. Test Name		Result	Limits	
1	Description	White, round.bi-convex, film coated tablet, having a dosage line on one side packed in blister pack.	NA	
2	Identification	Gives positive test for Ciprofloxacin.	NA	
3	Average weight	0.333195 gm.	NA	
4	Uniformity of weight	Complies.	NA	
5	Dissolution	Complies {Average drugs release (S ₁ +S ₂₎ found: 83.75%}.	Average of 12 units (S_1+S_2) is $\geq 80\%$ ($\geq Q$ and no unit is $< 65\%$ of claim (Q-15%).	

<u>Assay</u>

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

1	Ciprofloxacin	251.06 mg/Tablet	250 mg/Tablet	100.424	90 % to 110 %	I.P. 2022
0.50	Hydrochloride	let a let	a fabrual ish a	H -	00 70 10 110 70	1.1. 2022
*ibm)	equivalent to	a new dispersion	est times in the			
	Ciprofloxacin	TA BUTTO ON GREAT	Manual Control			

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: 03-FEB-2025

GOVERNMENT ANALYST

Dilip Kr. Sarkar

Government Analyst

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

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

