



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 : TIMOTHY THANCHUNGUNGA, Assistant Director (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/39 , 21-JAN-2025
3. Number of Sample : SMP/MZ/TMT/2024-2025/034
4. Date of receipt : 03-FEB-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. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-GUW/LS/2025-26/0101	GUW/LS/2025-26/132	CT24001	Feb-2024 Jan-2027	NA	CADILA PHARMACEUTICALS LIMITED, 1389, Dholka-382225, Dist. Ahmedabad

6. Condition of seals on : Seals were intact & identical to the specimen impression of the seal received from Drugs Inspector.
(the packet or on portion of sample or container)

7. Result of test or analysis with protocols or test or analysis applied : Please see below

Date of Testing : From 25-Mar-2025 To 11-Apr-2025

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

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	White, round, biconvex, scored on one surface, film coated tablets, in blister pack.	
2	Identification	Gives positive test for Ciprofloxacin Hydrochloride.	NA
3	Average weight	0.3338 g	NA
4	Uniformity of weight	Complies.	±5% of average weight
5	Dissolution	Does not comply.	NLT 80% of claim
6	Level S1 (6 units)	Does not comply. Release of Ciprofloxacin of each individual unit is found as follows: Unit 1=57.3%; Unit 2=57.5%; Unit 3=57.3%; Unit 4=49.0%; Unit 5=52.3%; Unit 6=48.2% . Release of Ciprofloxacin of all 06 units are found less than 85% of claim i.e. (Q+5%), where Q is 80% of claim.	Each unit is not less than Q+5% i.e., 85% of claim, where Q is 80%.

7	Level S2 (6 units)	Does not comply. Release of Ciprofloxacin of each individual unit is found as follows: Unit 1=66.1%; Unit 2=69.3%; Unit 3=62.1%; Unit 4=61.5%; Unit 5=65.1%; Unit 6=64.5% . Average release of Ciprofloxacin of 12 units (S1+S2) is 59.2% of claim which is less than Q i.e. 80% of claim. Release of Ciprofloxacin of 09 units are found less than 65% of claim(Q-15%).	Average of 12 units (S1+S2) \geq 80% of claim and no unit is less than 65% of claim (Q-15%)
8	Level S3	Out of 12 units 09 units are found less than Q-15% i.e 65% as well as 03 units are found less than Q-25% i.e. 55%.	Average of 24 units (S1+S2+S3) \geq 80% of claim, not more than 2 units are less than 65% of claim (Q-15%) and no unit is less than 55% of claim (Q-25%)

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Ciprofloxacin Hydrochloride Eq. to Ciprofloxacin	268.69 mg/Tablet	250 mg/Tablet	107.476	90 % to 110 %	I.P. 2022

In the opinion of the undersigned the sample referred to above is **not of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules there under for the reasons given below:-

The sample does not comply as per I.P. 2022 with respect to the test for "Dissolution" of Ciprofloxacin.

Date: 25-APR-2025

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

Report in red color paper indicates the sample is not of standard quality.

END OF REPORT