

Regional Drugs Testing Laboratory Directorate General of Health Services, Guwahati (India)-781022 Fax: 0361-2338555/2330555 Phone No.0361 2338555

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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

: Mrs. C. Ramdinmawii

Assistant Director (Food & Drugs) C.M.O. Office, Champhai-796321

Mizoram

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

:005/IPA-CPI/24

Date: 27/11/2024

3. Number of Sample

:Nil

4. Date of receipt

:11-DEC-2024

5. Names of drugs purporting to be contained in the sample: Cetirizine Hydrochloride Tablets IP (Microcet)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1541	GUW/LS/2024- 25/1566	TMR-222129	NOV. 2022	OCT. 2025	Prochem Pharmaceuticals Pvt. Ltd.,140-141,
23/1341	23/1300			70,	Makkanpur, Bhagwanpur, Roorkee, Dist. Haridwar (UK)

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 06-Jan-2025 To 17-Jan-2025

COMPOSITION

Each film-coated tablet contains: Cetirizine Hydrochloride IP 10 mg

Protocol Applied: I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	White, elongated, bi-convex, film coated tablet, one side scored, plain on the other side, packed in blister strip.	NA
2	Identification	Gives positive test for Cetirizine Hydrochloride.	NA
3	Average weight	0.18409 gm.	NA
4	Dissolution	Complies (Release of all six units were found above 'Q' 75+5%).	NLT 75 % of Claim

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Cetirizine Hydrochloride	10.73 mg/Tablet	10 mg/Tablet	107.3	90 % to 110 %	I.P. 2022
		\$ M				

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: 21-JAN-2025

GOVERNMENT ANALYST

Dilip Kr. Sarkar

Government Analyst

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

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

