

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



FORM 13 (See rule 46)

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

Name of Inspector from whom received

: MR. R. VANLALRUATA

ASSISTANT DIRECTOR (F & D)

OFFICE OF CHIEF MEDICAL OFFICER,

AIZAWL, MIZORAM, PIN: - 796017

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

: MZ/24/A 'E'/15/IPA

Date 17.12. 2024

3. Number of Sample

:Nil

4. Date of receipt

:02-JAN-2025

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

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1773	GUW/LS/2024- 25/1796	TMR-222129	NOV. 2022	OCT. 2025	Prochem Pharmaceuticals Pvt. Ltd. 140-141, 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 05-Feb-2025 To 27-Feb-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 having a dosage line on one side in blister pack.	NA		
2	Identification	Gives positive test for Cetirizine Hydrochloride.			
3	Average weight	0.18231 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	10.32 mg/Tablet	10 mg/Tablet	103.2	90 % to 110 %	I.P.2022

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: 28-FEB-2025

GOVERNMENT ANALYST

Dilip Kr. Sarkar

Government Analyst

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

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

