

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

: R. Vanlalsiama,

Asst Director (F & D)

Sr. CMO Office, Lunglei Pin: 796701

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

:8

Date 27.01.25

Number of Sample

:MS-17

Date of receipt

: 07-FEB-2025

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- 25/1753	GUW/LS/2024- 25/1779	TMR-222129	NOV. 2022	OCT, 2025	PROCHEM PHARMACEUTICALS PVT. LTD. 140-141, Makkanpur, Bhagwanpur,
			1 - Salah 1	72	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 20-Feb-2025 To 24-Feb-2025

COMPOSITION

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

Protocol Applied: IP 202

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 0.18121 gm.		NA		
4	Dissolution	Complies (Release of all six units were found above 'Q' 75+5%).	NLT 75 % of Claim		

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Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Cetirizine Hydrochloride	10.143 mg/Tablet	10 mg/Tablet	101.43	90 % to 110 %	IP 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: 25-FEB-2025

GOVERNMENT ANALYST

Dilip Kr. Sarkar

Government Analyst

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

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

