

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

: SARAH LALDINTLUANGI

ASSISTANT DIRECTOR (FOOD & DRUGS) Sr. CMO OFFICE, SERCHHIP-796181

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

: 005/2024

Date 3.10.2024

3. Number of Sample

: Nil

4. Date of receipt

: 28-OCT-2024

5. Names of drugs purporting to be contained in the sample : Cetirizine Tablets I.P. (10 mg)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1249	GUW/LS/2024- 25/1277	Z23-816	07/2023	06/2025	Zee Laboratories Ltd. Behind 47, Industrial Area, Paonta Sahib-173025

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-Nov-2024 To 21-Nov-2024

COMPOSITION

Each film coated tablet contains: Cetirizine Hydrochloride I.P. 10 mg

Protocol Applied: I.P.

Sr No. Test Name 1 Description		Result	Limits NA	
		White, elongated, bi-convex, film coated tablet having a dosage line on one side in blister pack.		
2	Identification	Gives positive test for Cetirizine Hydrochloride.	NA	
3	Average weight	0.14039 gm.	NA	
4	Dissolution	Complies (Release of all six units found above 'Q' 75+5%).	NLT 75 % of Claim	

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Cetirizine Hydrochloride	9.48 mg/Tablet	10 mg/Tablet	94.8	90 % to 110 %	I.P.2022

In the opinion of the undersigned 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: 27-NOV-2024

GOVERNMENT ANALYST

Dilip Kr. Sarkar Government Analyst R.D.T.L., Guwahati-22

END OF REPORT