

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)

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Sr. CMO Office SERCHHIP-796181 SERCHHIP

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

: 014/IPA/2024 , Date: 27-NOV-2024

3. Number of Sample

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4. Date of receipt

: 26-DEC-2024

5. Names of drugs purporting to be contained in the sample : Cetirizine Hydrochloride Tablets IP 10 mg (Cetispan)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1702	GUW/LS/2024- 25/1722	CNA23003	Dec-2023	Nov-2025	DANISH HEALTH CARE (P) LTD., 76/27-29, Industrial Estate, Maxi Road, UJJAIN 456 010, INDIA

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 10-Feb-2025 To 14-Feb-2025

COMPOSITION

Each film coated tablet contains: Cetirizine Hydrochloride IP 10 mg

Protocol Applied: I.P. 2022

Sr No.	Test Name	Result		
1	Description	White, elongated, bi-convex, film coated tablet having scored on one side in blister strip.	NA	
2	Identification	Gives positive test for Cetirizine Hydrochloride.	NA	
3	Average weight	0.16716 g	NA	
4	Dissolution	Complies.	NLT 75 %	

<u>తay</u> Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Cetirizine Hydrochloride	9.81 mg/Tablet	10 mg/Tablet	98.1	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 there under for the reasons given below:-

The sample conforms to I.P. with respect to the above tests only.

Date: 14-FEB-2025

GOVERNMENT ANALYST Amar Jyofi Chamuah Government Analyst R.D.T.L., Guwahati-22

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