

# **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), CMO Office, Lunglei.

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

: 8

Date 12/12/24

**Number of Sample** 

:MS-12

4. Date of receipt

:23-DEC-2024

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

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-	GUW/LS/2024-	EPD2Al2001	APR. 22	MAR. 25	IBN Herbals, Khasra No. 63,
25/1532	25/1552	EPDZAIZ001	AFN. 22 *	WAR. 23	Vill.JuddiKalan, Baddi-173 205,
		(0,2)		~ O.	Distt. Solan (H.P.), 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-Jan-2025To 17-Jan-2025

COMPOSITION

Each film coated tablet contains:

Cetirizine Hydrochloride IP

10 ma

## Protocol Applied: I.P. 2022

Sr No. Test Name		Result	Limits	
1 Description		White, elongated, bi-convex, film coated tablet, one side scored,	NA	
		plain on the other side, packed in blister strip.		
2	Identification	Gives positive test for Cetirizine Hydrochloride.	NA	
3	Average weight	0.14817 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	10.69 mg/Tablet	10 mg/Tablet	106.9	90 % to 110 %	I.P. 2022
		\$ 18				

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: 20-JAN-2025

GOVERNMENT ANALYST

Dilip Kr. Sarkar

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

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

