

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

: K.Lalngilneia,

Asst. Director (F & D)

CMO Office, Mamit Distric: Mamit,

Pin - 796441

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

:B.17011/12/09-CMO(M)/DRUGS/32

Date 9th Dec. 24

3. Number of Sample

:MD08/32

4. Date of receipt

:20-DEC-2024

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

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-	GUW/LS/2024-	GLL22021	ARP COM	NOV OF	IBN Herbals
25/1555	25/1583	GLLZ2021	DEC. 22	NOV. 25	Khasra No. 63, Vill. JuddiKalan,
		(C)		× 0.	Baddi-173 205, Distt. Solan (H.P.)

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-2025 To 16-Jan-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	0.12317 gm	NA
4 Dissolution Complies (Release of all six units found a		Complies (Release of all six units found above 'Q' 75+5%)	NLT 75 % of claim

<u>Assay</u>

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
.1	Cetirizine Hydrochloride	9.9 mg/Tablet	10 mg/Tablet	99	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: 23-JAN-2025

GOVERNMENT ANALYST

Dilip Kr. Sarkar

Government Analyst

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

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

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MINISTRAL HICHARD GOVERNMENT OF MEALTH, GOVERNMENT