



FORM 13
 (See rule 46)

CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER
 SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

- Name of Inspector from whom received : Mrs. C. Ramdinmawii
Assistant Director (Food & Drugs)
C.M.O. Office, Champhai-796321
Mizoram.
- Serial No. and date of Inspector's memorandum :032/IPA-CPI/24 Date: 17/01/2025
- Number of Sample :Nil
- Date of receipt :03-FEB-2025
- Names of drugs purporting to be contained in the sample: Cetirizine Hydrochloride Tablets IP (EZICETRI Tablets)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1716	GUW/LS/2024-25/1741	GT2406010	JUN. 2024	MAY 2026	M/s. Roseate Medicare Village Anji, P.O. Barog, Distt. Solan, 173211 (HP) INDIA

- Condition of seals on : Seals were intact & identical to the
[the packet or on portion of sample or container] Specimen impression of the seal
received from Drugs Inspector

- Result of test or analysis with protocols or test or analysis applied :Please see below

Date of Testing : From 12-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	Limits
1	Description	White, round, bi-convex, film coated tablet packed in blister pack.	NA
2	Identification	Gives positive test for Cetirizine Hydrochloride.	NA
3	Average weight	0.161395 gm.	NA
4	Dissolution	Complies (Release of all six units were found above 'Q' 75+5%).	NLT 75 % of claim

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Cetirizine Hydrochloride	10.26 mg/Tablet	10 mg/Tablet	102.6	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: 19-FEB-2025



GOVERNMENT ANALYST

Dilip Kr. Sarkar

Government Analyst

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

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

