



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 : Mrs. C. Ramdinmawii  
Assistant Director (Food & Drugs)  
C.M.O. Office, Champhai-796321  
Mizoram.
2. Serial No. and date of Inspector's memorandum : 034/IPA-CPI/24 Date: 17/01/2025
3. Number of Sample : Nil
4. Date of receipt : 03-FEB-2025
5. Names of drugs purporting to be contained in the sample: Dicyclomine Hydrochloride Injection IP; (2ml)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1894	GUW/LS/2024-25/1918	I-1390	July-2023	June-2025	Jackson Laboratories Pvt.Ltd. 22-24, Majitha Road, Bye Pass, Amritsar-143 001(India)

6. 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

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

Date of Testing : From 18-Feb-2025 To 17-Mar-2025

COMPOSITION : Each ml contains:  
Dicyclomine Hcl IP 10 mg

**Protocol Applied: I.P. 2022**

Sr No.	Test Name	Result	Limits
1	Description	Colorless solution in sealed amber colour glass ampoule with blue dot mark on the neck in paper carton.	NA
2	Identification	Gives positive test for Dicyclomine Hydrochloride.	NA
3	Sterility	Complies.	NA
4	Bacterial endotoxins	Complies.	NA
5	Extractable volume	Complies.	NA
6	Particulate matter	Complies.	NA

**Assay**

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Dicyclomine Hydrochloride	9.72 mg/ml	10 mg/ml	97.2	93.0 to 107.0 %	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: 21-MAR-2025



GOVERNMENT ANALYST

**Dilip Kr. Sarkar**

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

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

