

## 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

: Mrs. C. Ramdinmawii

Assistant Director (Food & Drugs) C.M.O. Office, Champhai-796321

Mizoram

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

: 015/IPA-CPI/24

Date: 16/12/2024

3. Number of Sample

:Nil

Date of receipt

: 31-DEC-2024

5. Names of drugs purporting to be contained in the sample: Diazepam Injection IP (Cerejack);2ml.

Lab. Sample No.	Report No.	Batch No.	Pate of Mig.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1809	GUW/LS/2024- 25/1844	SI≥1839	Sept. 2024	Aug. 2025	Jackson Laboratories Pvt.Ltd. 22-24, Majitha Road, Bye Pass, Amritsar-143 001(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

Date of Testing: From 16-Jan-2025To 03-Mar-2025

COMPOSITION

Each ml contains: Diazepam IP 5 mg

Protocol Applied: I.P. 2022

Sr No.	Test Name	Result				
1 Description		Colorless solution in sealed amber colour glass ampoule with blue dot mark on the neck.				
2	Identification	Gives positive test for Diazepam.	NA			
3	Sterility	Complies.	NA			
4	Bacterial endotoxins	Complies.	NA NA			
5	Particulate Matter	Complies.	NA			
6	Extractable volume	Complies.	NA			
7	рН	Complies (Found: 6.45).	6.2 to 6.9			

## **Assay**

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Diazepam	4.88 mg/ml	5 mg/ml	97.6	90 % to 110 %	I.P. 2022
The s	-/-					

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: 11-MAR-2025

**GOVERNMENT ANALYST** 

Dilip Kr. Sarkar Government Analyst R.D.T.L., Guwahati-22

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

