

# **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

: Mr.R.Vanlalruata, Assistant Director (F and Drugs)

Govt.0

India

Guwaha

Assistant Director (F&D)

Office of Chief Medical Officer, Aizwal, Mizoram-

796017

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

: MZ/24/AE/10, 15-OCT-2024

3. Number of Sample

: NIL

4. Date of receipt

: 01-NOV-2024

5. Names of drugs purporting to be contained in the sample : Amlodipine Tablets IP 5mg (Amlojack-5)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1417	GUW/LS/2024- 25/1444	T-2117	Oct-2023	Sep-2026	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 Please see below

Date of Testing: From 13-Dec-2024 To 20-Dec-2024

COMPOSITION

Each uncoated tablet contains: Amlodipine Besilate IP eq. to Amlodipine 5 mg

### Protocol Applied: I.P. 2022

Sr No. Test Name  1 Description		Result	Limits	
		White, round shaped, flat, scored on one surface, uncoated tablets, in blister pack.	NA	
2	Identification	Gives positive test for Amlodipine.	NA	
3	Average weight	0.2082 g	NA	
4 Dissolution		Complies.	NLT 75 % of claim	

#### Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Amlodipine Besilate equivalent to Amlodipine	5.12 mg/Tablet	5 mg/Tablet	102.4	90 % to 110 %	I.P. 2022

In the opinion of the undersigned the sample referred to above is of standard quality as defined in the Drugs and Cosmetics Act, 1940, and Rules there under for the reasons given below:
The sample conforms to claim as per I.P. 2022 in respect of test performed.

Date: 23-DEC-2024

GOVERNMENT ANALYST

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

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