



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 and Drugs)  
C.M.O. Office,  
Champhai-796321 Mizoram
2. Serial No. and date of Inspector's memorandum : 011/IPA-CPI/24 , 27-NOV-2024
3. Number of Sample : NIL
4. Date of receipt : 11-DEC-2024
5. Names of drugs purporting to be contained in the sample : Amlodipine Besylate Tablets I.P. 5 mg.. (Amlopen 5)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1529	GUW/LS/2024-25/1558	E3E0365	May-2023	Apr-2025	MOREPEN LABORATORIES LTD, Plot No. 12-B, Sector-2, Parwanoo, Distt. Solan (H.P) 173 220

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

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

Date of Testing : From 07-Jan-2025 To 09-Jan-2025

COMPOSITION : Amlodipine Besylate I.P. eq. to Amlodipine 5 mg.

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

Sr No.	Test Name	Result	Limits
1	Description	White, round, flat, uncoated tablets, in blister pack.	NA
2	Identification	Gives positive test for Amlodipine Besylate.	NA
3	Average weight	0.1337 g	NA
4	Dissolution	Complies.	NLT 75 % of claim

**Assay**

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Amlodipine Besylate equivalent to Amlodipine	4.72 mg/Tablet	5 mg/Tablet	94.4	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.

*Rinku Kalita*

Date: 17-JAN-2025

GOVERNMENT ANALYST

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

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

