



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 : K. Lalngilneia, Asst. Director (F and D)
Asst. Director (F&D), CMO Office,,
Mamit Distric: Mamit, Pin- 796441
- Serial No. and date of Inspector's memorandum : B.17011/12/09-CMO(M)/DRUGS/50 , 09-JAN-2025
- Number of Sample : MD08/50
- Date of receipt : 04-FEB-2025
- 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. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0152	GUW/LS/2025-26/162	E3E0365	May-2023 Apr-2025	NA	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
[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 28-Mar-2025 To 29-Apr-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 packing.	NA
2	Identification	Gives positive test for Amlodipine Besylate.	NA
3	Average weight	0.1342 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	4.8 mg/Tablet	5 mg/Tablet	96	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 conform to claim as per I.P. 2022 in respect of test performed.

Date: 02-MAY-2025

Rinku Kalita
GOVERNMENT ANALYST

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

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

