



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 : Lalruatadika Varte, Drugs Inspector
Office of the Chief Medical Officer
Kolasib, Mizoram- 796082
- Serial No. and date of Inspector's memorandum : 011/IPA-KLB/III-25, 21-JUL-2025
- Number of Sample : NIL
- Date of receipt : 26-AUG-2025
- Names of drugs purporting to be contained in the sample : Amitriptyline Tablets IP 10mg (AMITRIP-10)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/1041	GUW/LS/2025-26/1028	T-4519	Feb-2025 Jan-2027	N/A	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 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 26-Nov-2025 To 05-Dec-2025

COMPOSITION : Each film coated tablet contains:
Amitriptyline Hydrochloride IP 10

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	White, round, slightly bi-convex, film coated tablets, in blister pack.	NA
2	Identification	Gives positive test for Amitriptyline Hydrochloride.	NA
3	Average weight	0.1535 g	NA
4	Dissolution	Complies.	NLT 75 % of claim

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
-------	-----------------	-------	-------	------------	--------	--------------------

1	Amitriptyline Hydrochloride	9.761 mg/Tablet	10 mg/Tablet	97.61	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: 22-DEC-2025

GOVERNMENT ANALYST

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

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

