



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 : Lalruatdika Varte, Drugs Inspector
Office of the Chief Medical Officer
Kolasib, Mizoram- 796082
- Serial No. and date of Inspector's memorandum : 010/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 : Ampicillin Sodium Injection I.P.. (Ampicin 500 mg)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/1040	GUW/LS/2025-26/1027	DAMA516	Jan-2025 Dec-2026	NA	REGAIN LABORATORIES,, 134/5, H.T.M. RD., RAIPUR LANE, HISAR-125001

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 09-Oct-2025 To 04-Dec-2025

COMPOSITION : Each vial contains:
Sterile Ampicillin Sodium I.P. Eq. to Anhydrous Ampicillin 500 mg

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	White powder filled in sealed glass vials.	NA
2	Identification	Gives positive test for Ampicillin Sodium.	NA
3	Sterility	Passes the test.	NA
4	BET	Complies.	NA
5	pH	8.7 .	8 to 10 .

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
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1	Sterile Ampicillin Sodium Eqv. to Anhydrous Ampicillin	519.62 mg/vial	500 mg/vial	103.924	95 % to 105 %	I.P. 2022
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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 -----

