



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 Senior Chief Medical
Officer Kolasib, Mizoram- 796082
- Serial No. and date of Inspector's memorandum : KLB/04/2025/IPA/DRUGS , 17-JAN-2025
- Number of Sample : NIL
- Date of receipt : 05-FEB-2025
- Names of drugs purporting to be contained in the sample : Ampicillin Sodium Injection I.P. AMPIVEE-500
Injection

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-GUW/LS/2025-26/0050	26/65	TGDI08231904	Aug-2023 Jul-2025	NA	T & G Medicare, Village Kunjahal, PO Baddi, Distt. Solan (H.P.)

- 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.

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

Date of Testing : From 19-Feb-2025 To 08-Apr-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 colorless transparent sealed glass vials.	NA
2	Identification	Gives positive test for Ampicillin.	NA
3	Average filled content	0.4942 gm	NA
4	Sterility	Does not pass the test.	NA
5	BET	Complies.	NA
6	pH	8.77	8 to 10
7	Specific optical rotation	+ 260°	+258° to +287°
8	Appearance of solution	Complies. Abs. 0.135	NMT 0.15

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Ampicillin Sodium eq. to Anhydrous Ampicillin	485.14 mg/vial	500 mg/vial	97.028	95 % to 105 %	I.P. 2022

In the opinion of the undersigned the sample referred to above **is not of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules there under for the reasons given below:-

The sample does not conform as per I.P. 2022 with respect to the test for "Sterility".

Date: 09-APR-2025

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

Report in red color paper indicates the sample is not of standard quality.

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

