Regional Drugs Testing Laboratory
Directorate General of Health Services, Guwahati (India)-781022
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Regional Drugs Testing Laboratory Govt. Of India Guwahati-22

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** : SARAH LALDINTLUANGI
   ASSISTANT DIRECTOR (FOOD AND DRUGS)
   Sr. CMO OFFICE, SERCHHIP-796181,
   SERCHHIP
2. **Serial No. and date of Inspector's memorandum** : 028/IPA/2025 Date 16.01.2025
3. **Number of Sample** : Nil
4. **Date of receipt** : 28-FEB-2025
5. **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/2025-26/0056	GUW/LS/2025-26/63	TGDI08231904	08/2023 07/2025	NA	T & G Medicare Village Kunjahal PO Baddi, Distt. Solan (HP)

6. **Condition of seals on** [the packet or on portion of sample or container] : Seals were intact & identical to the 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 11-Mar-2025 To 02-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	Off- white crystalline powder filled in a transparent glass vial, plugged with rubber & sealed with aluminium flip off seal in paper carton.	NA
2	Identification	Gives positive test for Ampicillin.	NA
3	Filled Content	0.49328 gm.	NA
4	Sterility	**Does not comply with I.P.**	NA
5	Bacterial endotoxins	Complies.	NA
6	pH	Complies (Found: 8.75).	8.0 to 10.0
7	Appearance of solution	Complies (Found: 0.135).	NMT 0.15 of claim
8	Specific optical rotation	Complies (Found: +260^0).	+258° to +287°.

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Ampicillin Sodium eq. to Anhydrous Ampicillin	480.97 mg/vial	500 mg/vial	96.194	95 % to 105 %	I.P. 2022

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

The sample does not conform to I.P. with respect to the tests for "Sterility".

Date: 09-APR-2025

GOVERNMENT ANALYST
Dilip Kr. Sarkar
Government Analyst
R.D.T.L., Guwahati-22

Report in red coloured paper indicates the sample is Not of Standard Quality

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