

Regional Drugs Testing Laboratory Directorate General of Health Services, Guwahati (India) - 781022 Fax: 0361-2338555/2330555 Phone No.0361 2338555 Email: rdtlguwahati@cdsco.nic.in

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

and the state of

: SARAH LALDINTLUANGI

ASSISTANT DIRECTOR (FOOD AND DRUGS) Sr. CMO OFFICE, SERCHHIP-796181, SERCHHIP

2. Serial No. and date of Inspector's memorandum

: 011/2024

Date 10/10/2024

3. Number of Sample

: Nil

4. Date of receipt

: 30-OCT-2024

5. Names of drugs purporting to be contained in the sample : Amoxycillin Capsules I.P. 250 mg

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1234	GUW/LS/2024- 25/1276	Z23-1203	10/2023	09/2025	Zee Laboratories Ltd. Behind 47, Industrial Area, Paonta Sahib- 173025

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-Nov-2024 To 20-Nov-2024

COMPOSITION

Each hard gelatin capsule contains:

Amoxycillin Trihydrate IP

Eq. to Anhydrous Amoxycillin 250 mg

Protocol Applied: I.P. 2022

Sr No.	Test Name	Result	Limits	
1 Description		Bi-colour (white and dark blue) hard gelatin capsule filled with yellowish crystalline powder in blister pack.	NA	
2	Identification	Gives positive test for Amoxycillin.	NA	
3	Average filled content	0.2977 gm.	NA	
4	Uniformity of weight	Complies.	NA	
5	Dissolution	Complies (Release of each unit was found above 'Q' 80 + 5%).	NLT 80 % of claim	

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
		2.00				

1 Amoxycillin Trihydrate	257.03 mg/Capsule	250 mg/Capsule	102.812	90 % to 110 %	I.P. 2022
Eq. to Anhydrous Amoxycillin		redictor (inc.			

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 thereunder for the reasons given below:
The sample conforms to I.P. with respect to the above tests only.

Date: 28-NOV-2024

GOVERNMENT ANALYST

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

END OF REPORT