

## **Regional Drugs Testing Laboratory** Directorate General of Health Services, Guwahati (India)-781022 Fax: 0361-2338555/2330555 Phone No.0361 2338555

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**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

: B. LALZAMLIANA,

Drugs Inspector (F & D),

CMO West Office.

Kulikawn, Aizawl- 796005

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

:B.11012/5/2024-CMO(W)/DRUGS/12

Dated Aizawl, the 18th October, 2024

3. Number of Sample

: SMP/MZ/TMT/2024-2025/017

4. Date of receipt

: 28-OCT-2024

5. Names of drugs purporting to be contained in the sample: Amoxycillin & Potassium Clavulanate Tablets I.P.

(Clavorid-625)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1400	GUW/LS/2024- 25/1417	TB240284D	08/2024	04/2026	M/s. Polestar Power Industries (Pharma Division) Vill. Damuwala, Haripur Road, Barotiwala, Baddi, Distt. Solan (H.P.) - 174 103

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 05-Dec-2024 To 17-Dec-2024

COMPOSITION

Each film coated tablet contains:

Amoxycillin Trihydrate I.P.

eq. to Amoxycillin

500mg

Potassium Clavulanate Diluted I.P.

equivalent to Clavulanic Acid

Protocol Applied: I.P.

Sr No.	Test Name	Result		
1	Description	in aluminium strip pack in paper box.		
2	Identification			
3	Average weight	1.04188 gm.	NA	
4	Uniformity of weight	Complies.	NA	
5	Dissolution	Complies.	NA	
6	Dissolution (for Amoxycillin)	Complies (Release of all 6 units were found above 'Q' 85 + 5%).	NLT 85 % of claim	
7	Dissolution (for Clavulanic Acid)	Complies (Release of all 6 units were found above 'Q' 80 + 5%)	NLT 80% of claim	

## Assav

Date: 19-DEC-2024

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
71 ···	Amoxycillin Trihydrate eq. to Amoxycillin	484.55 mg/Tablet	500 mg/Tablet	96.91	90 % to 120 %	Carte Valley
2	Potassium Clavulanate Diluted equivalent to Clavulanic Acid	137.47 mg/Tablet	125 mg/Tablet	109.976	90 % to 120 %	I.P. 2022

In the opinion of the under signed 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.

GOVERNMENT ANALYST

Dilip Kr. Sarkar Government Analyst R..... Guwahati-22