



# RICA ENTERPRISES

Village Khari, Mauza Ogli, Kala-Amb, Distt. Sirmour H.P.

QUALITY CONTROL DEPARTMENT

## CERTIFICATE OF ANALYSIS

(The Drugs & Cosmetics act 1940 & the rules there under)

Mfg. Lic.No.: N-MB/17/193

Name of Product	CLAVCAN -1.2GM		
Generic Name	Amoxicillin & Potassium Clavulanate Injection IP 1.2GM		
Batch No.	B24115	Batch Size	15,097 Vials
Mfg. Date	09/2024	Exp. Date	08/2026
Date of Sample	03/10/2024	Sample Qty.	25 Vials
Date of Analysis	03/10/2024	Date of Release	.....
Stage	Finished	A.R.No.	QC/FP/BP/24284

S. No.	Test	Specification	Result
1.	Description	A white or almost white powder.	Almost white powder.
2.	Identification (A) By TLC  (B) By HPLC	The principal spots in the chromatogram obtained with the test solution correspond to those in the chromatogram obtained with the reference solution. Retention time of principal peaks in the chromatogram obtained of the assay preparation correspond to that of the standard preparation as obtained in the assay.	Complies.
3.	Appearance of Solution	Solution should be clear and Leaving no visible residue as un-dissolved matter	Complies.
4.	pH (10.0 % of Amoxicillin)	Between 8.0 to 10.0	9.11
5.	Average fill weight	1397.5 mg ± 3 %	1385.81 mg
6.	Uniformity of weight	± 10.0 %w/w of Average weight	Mini:1372.3 mg Maxi: 1403.8 mg
7.	Water (By KF)	NMT 3.5 %	0.29% w/w
8.	Particulate Matter	The solution shall be essentially free from particles of foreign matter that can be seen on visual.	Complies.
9.	Bacterial Endotoxins	NMT 0.25 EU /mg	Less than 0.25 EU/mg.
10.	Sterility	Complies with the test of sterility.	Under test.
11.	Assay Each Vial Contains:		
	Amoxicillin Sodium IP eq. to Amoxicillin 1000 mg	900.0 mg to 1075.0 mg (NLT 90.0 % & NMT 107.5 %)	999.37 mg 99.94 % of Amoxicillin
	Potassium Clavulanate IP eq. to Clavulanic Acid 200 mg	180.0 mg to 215.0 mg (NLT 90.0 % & NMT 107.5 %)	199.78 mg 99.89% of Clavulanic Acid

Remark: The sample is complies / does not comply as per IP/BP/USP/ In-House Specification

Name	Analysis By SHAMEEM	Checked By AWANEESH	Approved By SANDEEP KUMAR
Signature			
Date	09/10/2024	09/10/2024	09/10/2024

F/QC-017-03