



# 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	Amoxycillin & Potassium Clavulanate Injection IP 1.2gm		
Batch No.	B24122	Batch Size	25,005 Vials
Mfg. Date	09/2024	Exp. Date	08/2026
Date of Sample	16/10/2024	Sample Qty.	25 Vials
Date of Analysis	16/10/2024	Date of Release	30/10/2024
Stage	Finished	A.R.No.	QC/FP/BP/24297

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.  Complies.
3.	Appearance of Solution	Solution should be clear and leaving no visible residue as un-dissolved matter	Complies
4.	pH (10.0 % of Amoxycillin)	Between 8.0 to 10.0	8.76
5.	Average fill weight	1362.5 mg $\pm$ 3 %	1357.72mg
6.	Uniformity of weight	$\pm$ 10.0 %w/w of Average weight	Mini: 1340.3 mg Maxi: 1367.5 mg
7.	Water (By KF)	NMT 3.5 %	0.42%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.	Complies
11.	Assay Each Vial Contains:		
	Amoxycillin Sodium IP eq. to Amoxycillin 1000 mg	900.0mg to 1075.0mg (NLT 90.0 % & NMT 107.5 %)	1012.36 mg 101.24% of Amoxycillin
	Potassium Clavulanate IP eq. to Clavulanic Acid 200 mg	180.0 mg to 215.0 mg (NLT 90.0 % & NMT 107.5 %)	198.05 mg 99.02 % of Clavulanic Acid

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

	Analysis By	Checked By	Approved By
Name	SHAMEEM	AWANEESH	SANDEEP KUMAR
Signature			
Date	30/10/2024	30/10/2024	30/10/2024