



Rica Enterprises

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 -1.2 GM		
Generic Name	Amoxycillin & Potassium Clavulanate Injection 1.2gm IP		
Batch No.	B23090	Batch Size	10,200 Vials
Mfg. Date	10/2023	Exp.Date	09/2025
Date of Sample	08/12/2023	Sample Qty.	25 Vials
Date of Analysis	08/12/2023	Date of Release
Stage	Finished	A.R.No.	QC/FP/BP/23219

S. No.	Test	Specification	Result
1.	Descriptions	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	9.14
5.	Average fill weight	1356.0 mg \pm 3 %	1340.06 mg
6.	Uniformity of weight	\pm 10.0 %w /w of Average weight	Mini: 1330.2 mg Maxi: 1345.7 mg
7.	Water (by KF)	NMT 3.5 %	1.18 %
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	Complies
10.	Sterility	Complies with the test of sterility.	Complies
11.	Assay Each Vial Contains		Complies
	Amoxycillin Sodium IP eq. to Amoxycillin 1000 mg	900.00 mg to 1075.0 mg (NLT 90.0 % & NMT 107.5 %	997.55 mg 99.75 % of Amoxycillin
	Potassium Clavulanate IP eq. to Clavulanic Acid 200 mg	180 mg to 215.0 mg (NLT 90.0 % & NMT 107.5 %	198.42 mg 99.21 % of Clavulanic Acid

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

Name	Analysis By	Checked By	Approved By
Signature	VINEET	AWNEESH	SANDEEP KUMAR
Date	19/12/2023	19/12/2023	19/12/2023