



ALVENTA PHARMA LIMITED

VILL. KISHANPURA, TEHSIL BADDI- NALAGARH ROAD, DISTT.- SOLAN (H.P) 174101

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Clavcan 1.2 g	A.R. No.	FG/B/26A0042
Generic Name	Amoxycillin and Potassium Clavulanate Injection IP	Sample Quantity	65 Vials
Batch No.:	ABD60501	Sample Received on	06/05/2026
Batch Size:	31000 Vials	Analysis Date	06/05/2026
Mfg. Date.	05/2026	Release Date	20/05/2026
Exp. Date	04/2028	Page No.:	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result
1.	Description	A White or almost white powder filled in a transparent 20 ml molded glass vial sealed with rubber stopper green coloured flip off having aluminium seal.	A White powder filled in a transparent 20 ml molded glass vial sealed with rubber stopper green coloured flip off having aluminium seal.
2.	Identification	In the assay, the principal peak in the chromatogram obtained with the test solution should corresponds to the peak in the chromatogram obtained with the reference solution.	Complies
3.	Average filled weight	$\pm 7.5\%$ of Target filled weight.	1304.38 mg
4.	Uniformity of filled weight	$\pm 10\%$ of its average filled weight.	Min: 1272.17 mg ; Max: 1323.34 mg -2.47% ; +1.45%
5.	pH	Between 8.0 to 10.0	8.91
6.	Particulate matter	The Sample Solution should be clear and free from any visible particles	The Sample Solution is clear and free from any visible particles.
7.	Reconstitution Solution	When reconstitution with the sterile water for injection the sample solution should be clear and free from suspended matters.	Complies
8.	Clarity of Solution	Solid should dissolve completely when, leaving no visible residue as undissolved matter.	Complies
9.	Sterility	Should be sterile	Sterile
10.	Bacterial Endotoxins Tests	NMT 0.25 EU/mg	Less than 0.25 EU/mg
11.	Water	NMT 3.5%w/w	0.84%w/w

Particulars	Prepared By	Checked By	Approved By
Name	Barveen Kumar	Subheet Kaur	Subheet Kaur
Designation	Executive	Head QC.	Head QC.
Signature			
Date	20/05/2026	20/05/2026	20/05/2026



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12.	Assay:				
	Each Vial contains:	Claim	Limit	mg	%
	Sterile Amoxycillin Sodium IP Eq. to Amoxycillin	1000 mg	Between 90.0 % to 107.5 % of stated amount of Amoxycillin (Between 900.0 mg to 1075.0 mg)	982.30 mg	98.23%
	Sterile Potassium Clavulanate IP Eq. to Clavulanic Acid	200 mg	Between 90.0 % to 107.5 % of stated amount Clavulanic acid (Between 180.0 mg to 215.0 mg)	203.08 mg	101.54%

Remarks: The above test parameters are ~~complies/ not complies~~ as per IP/BP/USP & In-House Specification.

Particulars	Prepared By	Checked By	Approved By
Name	Barveen Kumar	Subheet Kaur	Subheet Kaur
Designation	Executive	Head QC	Head QC
Signature			
Date	20/05/2026	20/05/2026	20/05/2026