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/25A0138
Generic Name	Amoxycillin and Potassium Clavulanate Injection IP	**Sample Quantity**	65 Vials
Batch No.:	ABD51002	**Sample Received on**	17/10/2025
Batch Size:	30200 Vials	**Analysis Date**	17/10/2025
Mfg. Date.	10/2025	**Release Date**	31/10/2025
Exp. Date	09/2027	**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 blue coloured flip off having aluminium seal.	A White powder filled in a transparent 20 ml molded glass vial sealed with rubber stopper blue 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**	± 7.5% of Target filled weight.	1361.19 mg
4.	**Uniformity of filled weight**	± 10% of its average filled weight.	Min: 1338.87 mg ; Max: 1391.68 mg -1.64% ; +2.24%
5.	**pH**	Between 8.0 to 10.0	9.4
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	2.80%w/w

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Manibel	Kuljeet Kaur
Designation	Executive	Sr. Executive	Head QC
Signature	[illegible]	[illegible]	[illegible]
Date	31/10/2025	31/10/2025	31/10/2025

Format No.: SOP/QC/029/F02-01

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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)	979.85 mg	97.98%
	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)	197.71 mg	98.86%

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	Praveen Kumar	Manilal	Kuljeet Kaur
Designation	Executive	Sr. Executive	Head QC
Signature			
Date	31/10/2025	31/10/2025	31/10/2025

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