



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Aone 1 g	A.R. No.	FG/C/25A0004
Generic Name	Ceftriaxone Injection IP 1 g	Sample Quantity	65 Vials
Batch No.:	ACD50101	Sample Received on	10/01/2025
Batch Size:	25500 Vials	Analysis Date	10/01/2025
Mfg. Date.	01/2025	Release Date	25/01/2025
Exp. Date	12/2026	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 10 ml molded glass vial sealed with rubber stopper bluecoloured flip off having aluminium seal.	White powder filled in a transparent 10 ml molded glass vial sealed with rubber stopper bluecoloured flip off having aluminium seal.
2.	Identification:		
	a) By IR	The IR Spectrum obtained with test should be concordant with that spectrum obtained from the Ceftriaxone Sodium WS/RS or with the reference spectrum of Ceftriaxone Sodium.	Complies
	b) By HPLC	In the assay, the principal peak in the chromatogram obtained with the test solution shouldcorresponds to the peak in the chromatogram obtained with the referencesolution (a).	Complies
	c) By Chemically	It gives reaction A of Sodium Salts: A dense white precipitate should be formed.	Complies
3.	Average filled weight	$\pm 7.5\%$ of Target filled weight.	1182.25 mg
4.	Uniformity of filled weight	$\pm 10\%$ of its average filled weight.	Min: 1161.10 mg ; Max: 1223.87 mg -1.79% ; +3.52%
5.	Clarity of Solution	Solid should dissolve completely when, leaving no visible residue as undissolved matter.	Solid dissolve completely when, leaving no visible residue as undissolved matter.
6.	Appearance of Solution	A Solution is clear and not more intense than reference solution BY55 or YS5.	A Solution is clear and not more intense than reference solution BY55
7.	pH	Between 6.0 to 8.0, determine in a 10 % w/v solution.	7.16
8.	Water	NMT 11.0%w/w	10.22 %w/w
9.	Particulate matter	The Sample Solution should be clear and free from any visible particles when examine visually against black background.	The Sample Solution is clear and free from any visible particles.
10.	Bacterial Endotoxins Tests	NMT 0.20 EU/mg of Ceftriaxone	Less than 0.20 EU/mg

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Kuljeet Kaur	Kavita Nandwani
Designation	Executive	Head QC	QA Manager
Signature			
Date	25/01/2025	25/01/2025	25/01/2025



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11.	Sterility	Should be sterile	Sterile		
12.	Assay:				
	Each Vial contains:	Claim	Limit	mg	%
	Sterile Ceftriaxone Sodium IP eq. to Ceftriaxone	1000 mg	Between 90.0 % to 115.0 % of stated amount of Ceftriaxone.	992.72 mg	99.27%

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	Kuljeet Kaur	Kavita Nandwani
Designation	Executive	Head QC	QA Manager
Signature			
Date	25/01/2025	25/01/2025	25/01/2025