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/24A0029
Generic Name	Ceftriaxone Injection USP 1 g	**Sample Quantity**	65 Vials
Batch No.:	ACD40801	**Sample Received on**	14/08/2024
Batch Size:	0.25 Lac	**Analysis Date**	14/08/2024
Mfg. Date.	08/2024	**Release Date**	06/09/2024
Exp. Date	07/2026	**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 red coloured flip off having aluminium seal.	White powder filled in a transparent 10 ml molded glass vial sealed with rubber stopper red coloured flip off having aluminium seal.
2.	**Identification:**		
	a) **By IR**	Compare the spectrum with that obtained with Ceftriaxone sodium RS or with the reference spectrum of Ceftriaxone sodium.	Complies
	b) **By HPLC**	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.	Complies
3.	**Average filled weight**	± 7.5% of Target filled weight.	1168.09 mg
4.	**Uniformity of filled weight**	± 10% of its average filled weight.	Min: 1156.50 mg ; Max: 1182.87 mg -0.99% ; +1.27%
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.	**pH**	Between 6.0 to 8.0 (10% w/v solution in water)	6.98
7.	**Water content**	8.0 % to 11.0 % w/w	10.05 %w/w
8.	**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.
9.	**Crystallinity**	Particles should show birefringence and exhibit extinction positions.	Complies
10.	**Bacterial Endotoxins Tests**	NMT 0.20 Endotoxin Unit per mg of Ceftriaxone.	Less than 0.20 EU/mg
11.	**Uniformity of dosage units**	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	2.74
12.	**Sterility**	Should meet the requirement when tested as directed for "Membrane Filtration Method"	Sterile

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Tanveej	Gautam Singh
Designation	Executive	Sr. Executive	Head- QA
Signature			
Date	06/09/2024	06/09/2024	06/09/2024

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13.	**Assay:**				
	Each Vial contains:	**Claim**	**Limit**	**mg**	**%**
	Sterile Ceftriaxone Sodium USP eq. to Ceftriaxone	**1000 mg**	NLT 90.00% and NMT 115.00% of the labeled amount of Ceftriaxone	970.95 mg	97.09%

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	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head- QA
Signature			
Date	06/09/2024	06/09/2024	06/09/2024