ALERIS PHARMACEUTICALS

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/24A0030
Generic Name	Ceftriaxone Injection IP 1 g	**Sample Quantity**	65 Vials
Batch No.:	ACD40802	**Sample Received on**	29/08/2024
Batch Size:	0.50 Lac	**Analysis Date**	29/08/2024
Mfg. Date.	08/2024	**Release Date**	NA
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 blue coloured flip off having aluminium seal.	White powder filled in a transparent 10 ml molded glass vial sealed with rubber stopper blue coloured 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 should corresponds to the peak in the chromatogram obtained with the reference solution (a).	Complies
	c) **By Chemically**	It gives reaction A of Sodium Salts: A dense white precipitate should be formed.	Complies
3.	**Average filled weight**	± 7.5% of Target filled weight.	1177.75 mg
4.	**Uniformity of filled weight**	± 10% of its average filled weight.	Min: 1159.81 mg ; Max: 1197.68 mg -1.52% ; +1.69%
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 BYS5 or YS5.	A Solution is clear and not more intense than reference solution BYS5
7.	**pH**	Between 6.0 to 8.0, determine in a 10 % w/v solution.	7.18
8.	**Water**	NMT 11.0%w/w	10.06 %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	Tanveej	Gautam Singh
Designation	Executive	Sr. Executive	Head-QA
Signature		Tanveej	
Date	06/09/2024	06/09/2024	06/09/2024

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11.	**Sterility**	Should be sterile		Under Test	
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.	975.61 mg	97.56%

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