




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 BYSS or YSS.	A Solution is clear and not more intense than reference solution BYSS
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	Braveen Kumar	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head-QA
Signature			
Date	06/09/2024	06/09/2024	06/09/2024

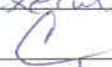

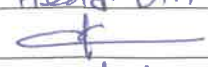
Quality Control Department

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 2 of 2

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