ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Aone 1 g	**A.R. No.**	FG/C/24A0011
Generic Name	Ceftriaxone Injection IP 1 g	**Sample Quantity**	65 Vials
Batch No.:	ACD40202	**Sample Received on**	01/03/2024
Batch Size:	49,875 Vials	**Analysis Date**	01/03/2024
Mfg. Date.	02/2024	**Release Date**	15/03/2024
Exp. Date	01/2026	**Page No.:**	Page 1 of 1

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 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
	By Chemically	It gives reaction A of Sodium Salts: A dense white precipitate should be formed.	A dense white precipitate is formed.
3.	**Average filled weight**	1202.00 mg ± 7.5 %	1192.19 mg
4.	**Uniformity of filled weight**	±10 % of its average filled weight	Min: 1144.71 mg ; Max: 1285.14 mg -3.98% ; +7.80%
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.	7.21
8.	**Water**	NMT 11.0%w/w	8.35 %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
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.	972.39 mg	97.24%

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	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head - QA
Signature			
Date	15/03/2024	15/03/2024	15/03/2024

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