

Title : Certificate of Analysis Finished Product

Product Name	AONE Injection	A.R. No.	BD/FP/25/041
Generic Name	Ceftriaxone Injection IP 2gm	Sampled qty.	45 Vials
Batch No.	B25037F	Sampled by	Rakesh
Batch Size	1000 Vials	Sampled on	23/04/2025
Mfg. Date	04/2025	Date of Testing	23/04/2025
Exp. Date	03/2027	Date of Release	08/05/2025

S. No.	Tests	Specifications	Observations
1.	Description	A white dry powder filled in clear glass vial.	A white dry powder filled in clear glass vial.
2.	Identification By I.R	A. The absorption spectrum of the test preparation should exhibit maxima at same wavelength with that obtained with similar preparation of Ceftriaxone working standard.	Complies
	By HPLC	B. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution (a).	Complies
	By Chemical	C. It gives the reaction A of sodium salts.	Complies
3.	Uniformity of weight	Average weight $\pm 10\%$	-3.15% & +5.21%
4.	Average weight	Informative $\pm 2\%$.	2419.9 mg
5.	Related Substance (By HPLC)		
	Any secondary peak	NMT 1.0%	Not detected
	Sum of all secondary peaks	NMT 5.0%	Not detected
6.	Appearance of solution	A 1.2 percent w/v solution in carbon dioxide-free water is clear and not more intensely coloured than reference solution by S5 or YS5.	Complies
7.	pH	6.0 to 8.0	7.01
8.	Water	NMT 11%w/w	8.37%w/w

Analysis by NAME: NIKHIL SHARMA	Checked by NAME: SUFIYAN ANSARI	Approved by NAME: MRS. SWATI BHAWAN
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Surajpur, Paonta sahib Dist. Sirmour (H.P)

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9.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	NMT 6000/vial NMT 600/vial The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that cannot be seen with naked eye.	73/vial 1/vial Complies
10.	Sterility	No microbial growth should be observed.	Complies
11.	Bacterial Endotoxins	NMT 0.2 EU/mg of Ceftriaxone Sodium.	Less than 0.2 EU/mg of Ceftriaxone Sodium.
12.	Assay: Each vial contains :		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Sterile Ceftriaxone Sodium IP Eq. to anhydrous Ceftriaxone	2000 mg	2099.01 mg	104.95%	90.0 to 115.0%

Remarks: In the opinion of the undersigned the sample referred to above is/ is ~~not~~ of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ ~~not~~ complies as per IP/BP/USP/HS.

Analysis by NAME: NIKHIL SHARMA	Checked by NAME: SUFIYAN ANSARI	Approved by NAME: MRS. SWATI BHAWAN
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