

Title

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Certificate of Analysis Finished Product

Product Name	AONE Injection	A.R. No.	ARB/FP/25/016
Generic Name	Ceftriaxone Injection IP 2gm	Sampled qty.	45 Vials
Batch No.	ARB2516A	Sampled by	Anuj Verma
Batch Size	5,000Vials	Sampled on	05/11/2025
Mfg. Date	11/2025	Date of Testing	06/11/2025
Exp. Date	10/2027	Date of Release	20/11/2025

S. No.	Tests	Specifications	Observations
1.	Description	A white or almost white dry powder filled in clear glass vial.	A white dry powder filled in clear glass vial.
2.	Identification By I.R	A. Determine by infrared absorption spectrophotometry. Compare the spectrum with that obtained with Ceftriaxone sodium IPRS or with the reference spectrum of ceftriaxone sodium.	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 $\pm 10\%$	-0.47% & +0.53%
4.	Average weight	Informative $\pm 2\%$.	2397.8 mg
5.	Related Substance (By HPLC)		
	Any secondary peak	NMT 1.0%	0.13%
	Sum of all secondary peaks	NMT 5.0%	0.13%
6.	Appearance of solution	1.2 per cent w/v solution in carbon dioxide-free water is clear and not more intensely coloured than reference solution BY55 or YS5.	Complies
7.	pH	6.0 to 8.0	7.30
8.	Water	NMT 11%w/w	9.33%w/w

Analysis by *Nikhil Sharma*
NAME: NIKHIL SHARMA

Checked by *Sufiyan Ansari*
NAME: SUFIYAN ANSARI

Approved by *Mrs. Swati Dhawan*
NAME: MRS. SWATI DHAWAN

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9.	Particulate Matter	NMT 6000/vial NMT 600/vial The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	80/vial 3/vial Complies		
	(A.) Light obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle				
10.	Sterility	No microbial growth should be observed.	Complies		
11.	Bacterial Endotoxins	NMT 0.2 EU/mg of Ceftriaxon.	Less than 0.2 EU/mg of Ceftriaxone.		
12.	Assay: (By HPLC) Each glass vial contains:				
Ingredients		Labelled Claim	Found	% of labelled amount	Limits % of labelled amount
Sterile Ceftriaxone Sodium IP Eq. to anhydrous Ceftriaxone		2000 mg	2125.55 mg	106.28%	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/THS.

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