

Title

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Certificate of Analysis Finished Product

Product Name	AONE Injection	A.R. No.	ARB/FP/26/022
Generic Name	Ceftriaxone Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	ARB2619A	Sampled by	Rakesh
Batch Size	30,000 Vials	Sampled on	13/08/2026
Mfg. Date	08/2026	Date of Testing	14/08/2026
Exp. Date	07/2028	Date of Release	28/08/2026

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 $\pm 10\%$	-1.30% & +1.10%
4.	Average weight	Informative $\pm 2\%$.	1212.1 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	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	7.11
8.	Water	NMT 11%w/w	9.93%w/w

Analysis by

NAME: SHAHRUKH KHAN

Checked by

NAME: SURJEET KAUR

Approved by

NAME: MRS. SWATI DHAWAN

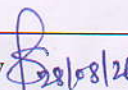
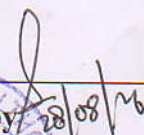
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9.	Particulate Matter (A.) Light obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	NMT 6000/vial NMT 600/vial The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	223/vial 4/vial Complies
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	1000 mg	1031.6766 mg	103.17%	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: SHAHRUKH KHAN	Checked by  NAME: SURJEET KAUR	Approved by  NAME: MRS. SWATI DHAWAN
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