

Title

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Certificate of Analysis Finished Product

Product Name	AONE Injection	A.R. No.	BD/FP/23/707
Generic Name	Ceftriaxone Injection IP 250mg	Sampled qty.	45 Vials
Batch No.	B23632C	Sampled by	Vineet
Batch Size	5000 Vials	Sampled on	04/02/2024
Mfg. Date	01/2024	Date of Testing	04/02/2024
Exp. Date	12/2025	Date of Conditionally Release	09/02/2024

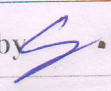
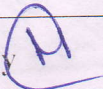

S. No.	Tests	Specifications	Observations
1.	Description	A white dry powder filled in clear glass vial.	A white dry powder filled in clear glass vial.
2.	Identification by I.R	<p>A. The absorption spectrum of the test preparation should exhibit maxima at same wavelength with that obtained with similar preparation of Ceftriaxone working standard.</p> <p>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).</p> <p>C. It gives the reaction A of sodium salts.</p>	<p>Complies</p> <p>Complies</p> <p>Complies</p>
3.	Uniformity of Weight	Average weight $\pm 10\%$	-1.76% & +2.50%
4.	Average weight	Informative.	302.9 mg
5.	Related Substance		
	Any peak other than the principal peak, %	NMT- 0.2%	Under process
	The sum of all such peak, %	NMT- 2.5%	Under process
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	6.90
8.	Water	NMT- 8.0 to 11% w/w	9.49%w/w
9.	Particulate Matter		
	a.) Sub-Visible particle count		
	(1.) Particles $\geq 10\mu\text{m}$	NMT-6000/vial	218/vial
	(2.) Particles $\geq 25\mu\text{m}$	NMT-600/vial	2/vial
	(b.) Visual	The solution is free from particles of foreign matter particles that can be observed on visual inspection.	Complies

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10.	Sterility	No microbial growth should be observed.	Under process		
11.	Bacterial Endotoxins	NMT- 0.2 EU/mg of Ceftriaxone Sodium.	Less than- 0.2 EU/mg of Ceftriaxone Sodium.		
12.	Assay: Each glass vial Contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Sterile Ceftriaxone Sodium IP Eq. to anhydrous Ceftriaxone		250 mg	250.10 mg	100.04%	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/IHS.

Analysis by 	Checked by 	
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