

Pace

Add Pace To Health

Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title

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Certificate of Analysis Finished Product

Product Name	AONE Injection	A.R. No.	BD/FP/24/634
Generic Name	Ceftriaxone Injection IP 500mg	Sampled qty.	45 Vials
Batch No.	B24597A	Sampled by	Rakesh
Batch Size	30,500 Vials	Sampled on	03/02/2025
Mfg. Date	02/2025	Date of Testing	03/02/2025
Exp. Date	01/2027	Date of Release	19/02/2025

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 $\pm 10\%$	-2.37% & +1.75%
4.	Average weight	Informative.	593.0 mg
5.	Related Substance (By HPLC)		
	Any Individual Impurity	NMT-1.0%	Not detected
	Total Impurities	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	6.58
8.	Water	NMT-11% w/w	7.02% w/w

Analysis by

NAME: SUFIYAN ANSARI

Checked by

NAME: SANDHYA

Approved by

NAME: P. N. TRIPATHI



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9.	Particulate Matter (a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (b.) Visual	NMT-6000/vial NMT-600/vial The solution is free from particles of foreign matter particles that can be observed on visual inspection.	105/vial. 3/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 I.P Eq. to anhydrous Ceftriaxone	500 mg	510.97 mg	102.19%	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 NAME: SUFIYAN ANSARI	Checked by NAME: SANDHYA	Approved by NAME: P. N. TRIPATHI
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