



Add Pace To Health

Pace Biotech

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

Title : Certificate of Analysis Finished Product

Product Name	AONE Injection	A.R. No.	BD/FP/26/215
Generic Name	Ceftriaxone Injection IP 250mg	Sampled qty.	45 Vials
Batch No.	B26205B	Sampled by	Rakesh
Batch Size	5,000 Vials	Sampled on	18/07/2026
Mfg. Date	07/2026	Date of Testing	19/07/2026
Exp. Date	06/2028	Date of Release	03/08/2026

S. No.	Tests	Specifications	Observations
1.	Description	A white or almost white 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 $\pm 10\%$	-1.11% & +1.51%
4.	Average weight	Informative $\pm 2\%$.	297.7 mg
5.	Related Substance (By HPLC)		
	Any individual impurity	NMT 1.0%	0.139%
	Total impurity	NMT 5.0%	0.139%
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 BYS5 or YS5.	Complies
7.	pH	6.0 to 8.0 , determined in a 10.0 per cent w/v solution.	7.00
8.	Water	Not more than 11.0 per cent, determined on 0.1g.	9.70%w/w

Name : Mrs. Swati Dhawan
Designation : QC HOD

Qualification : M.Sc. Clinical Microbiology
Registration No. : 580402030703
Approved by
NAME: MRS. SWATI DHAWAN
Punjab Technical University, Jalandhar

Analysis by
NAME: NIKHIL SHARMA

Checked by
NAME: SURJEET KAUR

Title : Certificate of Analysis Finished Product

Product Name	AONE Injection	A.R. No.	BD/FP/26/215
Generic Name	Ceftriaxone Injection IP 250mg	Sampled qty.	45 Vials
Batch No.	B26205B	Sampled by	Rakesh
Batch Size	5,000 Vials	Sampled on	18/07/2026
Mfg. Date	07/2026	Date of Testing	19/07/2026
Exp. Date	06/2028	Date of Release	03/08/2026

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.	604/vial 5/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 Ceftriaxone.	Less than 0.2 EU/mg of Ceftriaxone.		
12.	Assay: (By HPLC) Each vial contains:				
Ingredients		Labelled Claim	Found	% of labelled amount	Limits % of labelled amount
Sterile Ceftriaxone Sodium IP Eq. to anhydrous Ceftriaxone		250 mg	252.1791 mg	100.87%	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: SURJEET KAUR	Approved by NAME: MRS. SWATI DHAWAN
------------------------------------	----------------------------------	--

Name : Mrs. Swati Dhawan
Designation : QC HOD

Qualification : M.Sc. Clinical Microbiology
Registration No. 55001321000100
Punjab Technical University, Jalandhar