Pacé
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/24/010
Generic Name	Ceftriaxone Injection IP 500mg	**Sampled qty.**	45 Vials
Batch No.	B23787B	**Sampled by**	Arvind
Batch Size	5000 Vials	**Sampled on**	04/04/2024
Mfg. Date	03/2024	**Date of Testing**	04/04/2024
Exp. Date	02/2026	**Date of Release**	19/04/2024

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	**A.**The absorption spectrum of the test preparation should exhibits 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 ±10%	-1.15% & +0.80%
4.	Average weight	Informative.	599.1 mg
5.	Related Substance (By HPLC)		
	Any Impurity	NMT-1.0%	Complies
	The sum of all such Impurities	NMT- 4.0%	Complies
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	6.37
8.	Water	NMT-11% w/w	10.40% w/w

Analysis by	Checked by	Approved by

Pacé
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/24/010
Generic Name	Ceftriaxone Injection IP 500mg	**Sampled qty.**	45 Vials
Batch No.	B23787B	**Sampled by**	Arvind
Batch Size	5000 Vials	**Sampled on**	04/04/2024
Mfg. Date	03/2024	**Date of Testing**	04/04/2024
Exp. Date	02/2026	**Date of Release**	19/04/2024

9.	Particulate Matter (a.) Sub-Visible particle count (1.) Particles ≥10µm (2.) Particles ≥25µm (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.	 82/vial 1/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	528.80 mg	105.76%	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	Approved by