Pace

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Pace Biotech

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

Title	:	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	**A.**The absorption spectrum of the test preparation should exhibits maxima at same wavelength with that obtained with similar preparation of Ceftriaxone working standard. **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). **C.** It gives the reaction A of sodium salts.	Complies Complies Complies
3.	Uniformity of Weight	Average weight ±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	A1.2 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 to11% w/w	9.49%w/w
9.	Particulate Matter		
	a.) Sub-Visible particle count		
	(1.) Particles ≥10µm	NMT-6000/vial	218/vial
	(2.) Particles ≥25µm	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	Approved by

PACE BIOTECH PAONTA SAHIB (H.P.) Quality Control Manager