

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/23/090
Generic Name	Ceftriaxone Injection I.P 250mg	Sampled qty.	45 Vials
Batch No.	B23026B	Sampled by	Vineet
Batch Size	5000 Vials	Sampled on	30/04/2023
Mfg. Date	04/2023	Date of Testing	30/04/2023
Exp. Date	03/2025	Date of Release	15/05/2023

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 exhibits 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	Fill weight $\pm 10\%$	-3.81% & +3.58%
4.	Average fill	Average weight $\pm 2\%$	297.6mg
5.	Related Substance	In the chromatogram obtained with the test solution the area of any secondary peak is not greater than the area of the principal peak in the chromatogram obtained with working standard solution (1.0 per cent) and the sum of the areas of all the secondary peaks is not greater than 5 times the area of the principal peak in the chromatogram obtained with working standard solution.	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	7.56
8.	Water	NMT-11% w/w	10.65% w/w

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9.	Particulate Matter	NMT-6000/vial NMT-600/vial The solution is free from particles of foreign matter particles that can be observed on visual inspection.	49/vial 2/vial Complies		
	(a.) Sub-Visible particle count				
	(1.) Particles $\geq 10\mu\text{m}$				
	(2.) Particles $\geq 25\mu\text{m}$				
	(b.) Visual				
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 glass vial Contains :				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Sterile Ceftriaxone Sodium I.P Eq. to anhydrous Ceftriaxone		250 mg	246.10mg	98.44%	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/PHS.

Analysis by

Checked by

