Pace Biotech

Surajpur, Paonta Sahib, Distt. Sirmour (H.P)

Certificate of Analysis Finished Product

Name	FOXATIM 1g Injection	A.R. No.	BD/FP/25/118
Name	Cefotaxime for Injection IP 1gm	Sampled qty.	45 Vials
No.	B25111A	Sampled by	Rakesh
Batch Size	20,100 Vials	Sampled on	26/05/2025
Mfg. Date	05/2025	Date of Testing	26/05/2025
Exp. Date	04/2027	Date of Release	10/06/2025

S. No.	Tests	Specifications	Observations
1.	Description	An Off-white to pale yellow, crystalline powder filled in clear glass vial.	An Off-white to pale yellow, crystalline powder filled in clear glass vial.
2.	Identification (By HPLC)	**A.** In, assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the working reference solution.	Complies
	(By Chemical)	**B.** Gives the reactions of sodium salts.	Complies
3.	Uniformity of weight	Average weight ±10%	-3.64% & +2.64%
4.	Average weight	Informative.	1088.4 mg
5.	pH	4.5 to 6.5	5.83
6.	Water	NMT- 3.0%	1.93%
7.	Related Substances		
	Area of any other secondary peak	NMT-1.0%	0.43%
	Sum of areas of the principal peak	NMT-4.0%	0.43%
8.	Particulate Matter (IHS)		
	(a.) Sub-Visible particle count		
	(1.) Particles ≥10µm	NMT-6000/vial	388/vial
	(2.) Particles ≥25µm	NMT-600/vial	8/vial
	(b.) Visual	The solution is free from particles of foreign matter particles that can be observed on visual inspection.	Complies
9.	Sterility	No microbial growth should be observed.	Complies
10.	Bacterial Endotoxins	NMT 0.20 EU/mg of Cefotaxime.	Less than 0.20 EU/mg of Cefotaxime.
11.	Assay: Each glass vial Contains :		

Analysis by	Checked by	Approved by
NAME: NIKHIL SHARMA	NAME: SUFIYAN ANSARI	NAME: SWATI DHAWAN

PACE BIOTECH PAONTA SAHIB (H.P.) Quality Assurance Department

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Product Name	**FOXATIM 1g** Injection	**A.R. No.**	BD/FP/25/118
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Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Cefotaxime Sodium (Sterile) IP Eq. to Anhydrous Cefotaxime	1000 mg	986.56 mg	98.66%	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
NAME: NIKHIL SHARMA	NAME: SUFIYAN ANSARI	NAME: SWATI DHAWAN

PACE BIOTECH PAONTA SAHIB Quality Manager