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Pace Biotech

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

Title	:	Certificate of Analysis Finished Product

Product Name	**FOXATIM 1G** Injection	**A.R. No.**	BD/FP/24/247
Generic Name	Cefotaxime for Injection IP 1gm	**Sampled qty.**	45 Vials
Batch No.	B24210A	**Sampled by**	Vineet
Batch Size	36,236 Vials	**Sampled on**	14/08/2024
Mfg. Date	07/2024	**Date of Testing**	14/08/2024
Exp. Date	06/2026	**Date of Release**	28/08/2024

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 IR)	**A.** The absorption spectrum of the test preparation should exhibits maxima at same wavelength with that obtained with similar preparation of Cefotaxime working standard.	Complies
	(By HPLC)	**B.** 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)	**C.** Gives the reactions of sodium salts.	Complies
3.	Uniformity of weight	Average weight ±10%	-1.46% & +1.77%
4.	Average weight	Informative.	1102.28 mg
5.	pH	4.5 to 6.5	5.92
6.	Water	NMT-3.0%	1.70%
7.	Related Substances		
	Single impurities	NMT-1.0%	0.25%
	Total impurities	NMT-4.0%	0.71%
8.	Particulate Matter (IHS)		
	(a.) Sub-Visible particle count		
	(1.) Particles ≥10µm	NMT-6000/vial	173/vial
	(2.) Particles ≥25µm	NMT-600/vial	19/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

Analysis by	Checked by	Approved by

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

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10.	Bacterial Endotoxins	NMT- 0.20 EU/mg of Cefotaxime.		Less than- 0.20 EU/mg of Cefotaxime.	
11.	Assay: Each glass vial Contains :				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Cefotaxime Sodium (Sterile) IP Eq. to Anhydrous Cefotaxime		1000 mg	976.25 mg	97.63%	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.~~

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

Analysis by	**Checked by**	**Approved by**