

# Pace

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# Pace Biotech

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

**Title : Certificate of Analysis Finished Product**

<b>Product Name</b>	<b>FUXORIME 750mg Injection</b>	<b>A.R. No.</b>	<b>BD/FP/25/122</b>
<b>Generic Name</b>	<b>Cefuroxime Injection IP 750mg</b>	<b>Sampled qty.</b>	<b>45 vials</b>
<b>Batch No.</b>	<b>B25083C</b>	<b>Sampled by</b>	<b>Rakesh</b>
<b>Batch Size</b>	<b>10,000 vials</b>	<b>Sampled on</b>	<b>27/05/2025</b>
<b>Mfg. Date</b>	<b>05/2025</b>	<b>Date of Testing</b>	<b>27/05/2025</b>
<b>Exp. Date</b>	<b>04/2027</b>	<b>Date of Release</b>	<b>11/06/2025</b>

S. No.	Tests	Specifications	Observations
1.	Description	A white or faintly yellow dry powder filled in clear glass vial.	A white dry powder filled in clear glass vial.
2.	Identification By HPLC	a).The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the working standard solution.	Complies
	By Chemical	b). Gives the reaction of Sodium salt.	Complies
3.	Uniformity of weight	Average weight $\pm 10\%$	-1.39% & +1.52%
4.	Average weight	Informative.	833.6 mg
5.	Related Substance (By HPLC)		
	Descarbamoyl cefuroxime	NMT- 1.0%	Not detected
	Any other secondary peak	NMT- 1.0%	0.31%
	Sum of all secondary peaks	NMT- 3.0%	0.31%
6.	Appearance of solution	A 1.2 per cent w/v solution in carbon dioxide-free water is clear (2.4.1) and not more intensely coloured than working standard solution.	Complies
7.	pH	6.0 to 8.5	6.83
8.	Water	NMT-3.5% w/w	2.55% w/w
9.	Particulate Matter		
	a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (b.) Visual	NMT-6000/vial NMT-600/vial The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	110/vial 1/vial Complies
10.	Sterility	No microbial growth should be observed.	Complies
11.	Bacterial Endotoxins	NMT 0.1 EU/mg of Cefuroxime.	Less than 0.1 EU/mg of Cefuroxime

Analysis by NAME: NIKHIL SHARMA 11/06/2025	Checked by NAME: SUFIYAN ANSARI 11/06/25	Approved by NAME: SWATI DHAWAN 11/06/25
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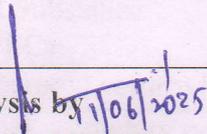
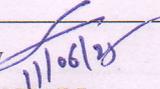
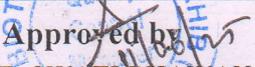
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Product Name	FUXORIME 750mg Injection	A.R. No.	BD/FP/25/122
Generic Name	Cefuroxime Injection IP 750mg	Sampled qty.	45 vials
Batch No.	B25083C	Sampled by	Rakesh
Batch Size	10,000 vials	Sampled on	27/05/2025
Mfg. Date	05/2025	Date of Testing	27/05/2025
Exp. Date	04/2027	Date of Release	11/06/2025

12. Assay: Each vial contains				
Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Sterile Cefuroxime Sodium IP Eq. to Cefuroxime	750 mg	760.16 mg	101.35%	90.0 to 120.0%

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/HS.

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