

**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title : Certificate of Analysis Finished Product

Product Name	FUXORIME Injection	A.R. No.	ARB/FP/26/010
Generic Name	Cefuroxime Injection IP 750mg	Sampled qty.	45 vials
Batch No.	ARB2607A	Sampled by	Aakash
Batch Size	15,000 vials	Sampled on	01/05/2026
Mfg. Date	04/2026	Date of Testing	02/05/2026
Exp. Date	03/2028	Date of Release	19/05/2026

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. 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. B. It gives the reactions of sodium salts.	Complies Complies
3.	Uniformity of weight	Average weight $\pm 10\%$	-2.24% & +2.88%
4.	Average weight	Informative $\pm 2\%$.	831.8 mg
5.	Related Substance (By HPLC)		
	Descarbamoyl-cefuroxime	NMT 1.0%	0.063%
	Area of any other secondary peak	NMT 1.0%	0.168%
	Sum of areas of all the secondary peaks	NMT 3.0%	0.232%
6.	pH	6.0 to 8.5	7.31
7.	Water (By K.F.)	NMT 3.5%w/w	2.47%w/w
8.	Particulate Matter		
	(A.) Light Obscuration		
	Particle Count Test		
	(1.) Particles $\geq 10\mu\text{m}$	NMT 6000/vial	304/vial
	(2.) Particles $\geq 25\mu\text{m}$	NMT 600/vial	2/vial
	(B.) Visual Particle	The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be observed on visual inspection.	Complies
9.	Sterility	No microbial growth should be observed.	Complies
10.	Bacterial Endotoxins	NMT 0.1 EU/mg of Cefuroxime.	Less than 0.1 EU/mg of Cefuroxime

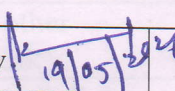
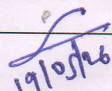
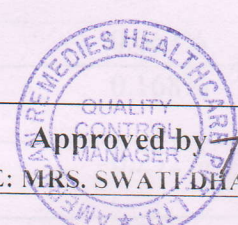
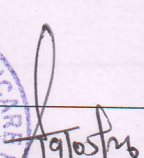
Analysis by
NAME: NIKHIL SHARMAChecked by
NAME: SUFIYAN ANSARIApproved by
NAME: MRS. SWATI DHAWAN

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11.	Assay: (By HPLC) Each glass vial contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Cefuroxime Sodium (Sterile) IP Eq. to Cefuroxime		750 mg	785.7130 mg	104.76%	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: MRS. SWATI DHAWAN
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