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 ±10%	-2.24% & +2.88%
4.	Average weight	Informative ±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 ≥10µm (2.) Particles ≥25µm	 NMT 6000/vial NMT 600/vial	 304/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	Checked by	Approved by
19/05/2026	19/05/26	19/05/26
NAME: NIKHIL SHARMA	NAME: SUFIYAN ANSARI	NAME: MRS. SWATI DHAWAN

AMERICAN REMEDIES HEALTHCARE PVT. LTD. ★ QUALITY CONTROL MANAGER

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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/IHS.~~

Analysis by	Checked by	Approved by
19/05/2026	19/05/26	19/05/26
NAME: NIKHIL SHARMA	NAME: SUFIYAN ANSARI	NAME: MRS. SWATI DHAWAN

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