

Title	:	Certificate of Analysis Finished Product
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Product Name	FUXORIME Injection	A.R. No.	ARB/FP/26/024
Generic Name	Cefuroxime Injection IP 1.5gm	Sampled qty.	45 vials
Batch No.	ARB2620A	Sampled by	Rakesh
Batch Size	20,000 vials	Sampled on	30/08/2026
Mfg. Date	08/2026	Date of Testing	31/08/2026
Exp. Date	07/2028	Date of Release	15/09/2026

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 $\pm 10\%$	-0.51% & +1.12%
4.	Average weight	Informative $\pm 2\%$.	1654.4 mg
5.	Related Substance (By HPLC)		
	Descarbamoyl-cefuroxime	NMT 1.0%	0.252%
	Area of any other secondary peak	NMT 1.0%	0.163%
	Sum of areas of all the secondary peaks	NMT 3.0%	0.919%
6.	pH	6.0 to 8.5	6.96
7.	Water (By K.F.)	NMT 3.5%w/w	3.17%w/w
8.	Particulate Matter		
	(A.) Light Obscuration		
	Particle Count Test		
	(1.) Particles $\geq 10\mu\text{m}$	NMT 6000/vial	715/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 SHARMA

Checked by
NAME: SURJEET KAUR

Name: Mrs. Swati Dhawan
Designation: QC HOD
Qualification: M.Sc. Clinical Microbiology
Registration No.: 580106099503
Approved by
NAME: MRS. SWATI DHAWAN
Punjab Technical University, Jalandhar



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

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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	1500 mg	1514.4458 mg	100.96%	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.

Name : Mrs. Swati Dhawan

Designation : QC HOD

Qualification : M.Sc. Clinical Microbiology

Registration No. : 589483038593

Approved by :
NAME: MRS. SWATI DHAWAN
Sample Technical University, Jalandhar

Analysis by NAME: NIKHIL SHARMA	15/09/26	Checked by NAME: SURJEET KAUR	15/09/26
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