



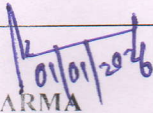
AMERICAN REMEDIES HEALTHCARE PVT. LTD.

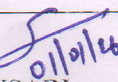
Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

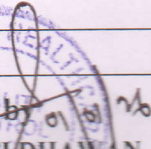
Title : Certificate of Analysis Finished Product

Product Name	FOXATIM Injection	A.R. No.	ARB/FP/25/020
Generic Name	Cefotaxime for Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	ARB2527A	Sampled by	Anuj Verma
Batch Size	25,000 Vials	Sampled on	18/12/2025
Mfg. Date	12/2025	Date of Testing	18/12/2025
Exp. Date	11/2027	Date of Release	01/01/2026

S. No.	Tests	Specifications	Observations
1.	Description	An Off-white to pale yellow, crystalline powder filled in clear glass vial.	A white dry powder filled in clear glass vial.
2.	Identification (By HPLC)	A. 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)	B. Gives the reactions of sodium salts.	Complies
3.	Uniformity of weight	Average weight $\pm 10\%$	-5.26% & +2.32%
4.	Average weight	Informative $\pm 2\%$.	1077.5 mg
5.	pH	4.5 to 6.5	5.54
6.	Water	NMT 3.0%	2.40%
7.	Related Substances (By HPLC)		
	Area secondary peak	NMT 1.0%	Not Detected
	Sum of all secondary peak	NMT 4.0%	Not Detected
8.	Particulate Matter (IHS)		
	(A.) Light Obscuration Particle Count test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	NMT 6000/vial NMT 600/vial The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	68/vial 1/vial Complies
9.	Sterility	No microbial growth should be observed.	Complies
10.	Bacterial Endotoxins	NMT 0.20 EU/mg of Cefotaxime.	Less than 0.20 EU/mg of Cefotaxime.
11.	Assay: (By HPLC) Each glass vial contains:		

Analysis by 
NAME: NIKHIL SHARMA

Checked by 
NAME: SUFIYAN ANSARI

Approved by 
NAME: MRS. SWATI DHAWAN



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Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Cefotaxime Sodium (Sterile) IP Eq. to Anhydrous Cefotaxime	1000 mg	978.7544 mg	97.88 %	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/...
✓

Analysed by NAME: NIKHIL SHARMA	Checked by NAME: SUFIYAN ANSARI	Approved by NAME: MRS. SWATI DHAWAN
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