



# 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 1G Injection	A.R. No.	ARB/FP/25/014
Generic Name	Cefotaxime for Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	ARB2514A	Sampled by	Anuj Verma
Batch Size	25,000 Vials	Sampled on	11/10/2025
Mfg. Date	10/2025	Date of Testing	12/10/2025
Exp. Date	09/2027	Date of Release	12/11/2025

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 $\pm 10\%$	-6.12% & +2.21%
4.	Average weight	Informative $\pm 2\%$ .	1090.6 mg
5.	pH	4.5 to 6.5	5.90
6.	Water	NMT 3.0%	1.91%
7.	Related Substances (By HPLC)		
	Area secondary peak	NMT 1.0%	0.31%
	Sum of all secondary peak	NMT 4.0%	0.31%
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.	35/vial 0/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



# 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 1G Injection	A.R. No.	ARB/FP/25/014
Generic Name	Cefotaxime for Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	ARB2514A	Sampled by	Anuj Verma
Batch Size	25,000 Vials	Sampled on	11/10/2025
Mfg. Date	10/2025	Date of Testing	12/10/2025
Exp. Date	09/2027	Date of Release	12/11/2025

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Cefotaxime Sodium (Sterile) IP Eq. to Anhydrous Cefotaxime	1000 mg	982.73 mg	98.27%	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/IHS.

Analysis by *Nikhil Sharma* 12/11/2025  
NAME: NIKHIL SHARMA

Checked by *Sufiyan Ansari* 12/11/25  
NAME: SUFIYAN ANSARI

Approved by *Swati Dhawan* 12/11/25  
NAME: MRS. SWATI DHAWAN

