

**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/26/014
Generic Name	Cefotaxime for Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	ARB2608A	Sampled by	Dhananjay
Batch Size	15,000 Vials	Sampled on	03/06/2026
Mfg. Date	05/2026	Date of Testing	04/06/2026
Exp. Date	04/2028	Date of Release	18/06/2026

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 $\pm 10\%$	-7.05% & +2.11%
4.	Average weight	Informative $\pm 2\%$.	1082.6 mg
5.	pH	4.5 to 6.5	5.82
6.	Water	NMT 3.0%	1.92%
7.	Related Substances (By HPLC)		
	Area secondary peak	NMT 1.0%	0.260%
	Sum of all secondary peak	NMT 4.0%	0.755%
8.	Particulate Matter (IHS)		
	(A.) Light Obscuration Particle Count test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$	NMT 6000/vial NMT 600/vial	137/vial 3/vial
	(B.) Visual Particle	The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	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: SACHIN KUMARChecked by
NAME: SUFIYAN ANSARIApproved 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 Injection	A.R. No.	ARB/FP/26/014
Generic Name	Cefotaxime for Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	ARB2608A	Sampled by	Dhananjay
Batch Size	15,000 Vials	Sampled on	03/06/2026
Mfg. Date	05/2026	Date of Testing	04/06/2026
Exp. Date	04/2028	Date of Release	18/06/2026

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Cefotaxime Sodium (Sterile) IP Eq. to Anhydrous Cefotaxime	1000 mg	1077.1398 mg	107.71%	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

NAME: SACHIN KUMAR

Checked by

NAME: SUFIYAN ANSARI

Approved by

NAME: MRS. SWATI DHAWAN