AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

Title	:	Certificate of Analysis Finished Product

Product Name	**AFIPIME** Injection	**A.R. No.**	ARB/FP/25/009
Generic Name	Cefepime for Injection IP 1g	**Sampled qty.**	45 Vials
Batch No.	ARB2509A	**Sampled by**	Rakesh
Batch Size	19,980 Vials	**Sampled on**	19/09/2025
Mfg. Date	09/2025	**Date of Testing**	19/09/2025
Exp. Date	08/2027	**Date of Release**	04/10/2025

S. No.	Tests	Specifications	Observations
1.	Description	A white to pale yellow dry powder filled in clear glass vial.	A white dry powder filled in clear glass vial.
2.	Identification (By TLC)	A.The principal spots in the chromatogram obtained with the test solution correspond to those in the chromatogram obtained with the reference solution.	Complies
	(By HPLC)	B. 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
3.	Uniformity of Weight	Average weight ±10%	-1.35% & +2.30%
4.	Average weight	Informative ±2%.	1880.6 mg
5.	pH	4.0 to 6.0	4.52
6.	N- methylpyrrolidine	NMT 1.0%	Not detected
7.	Water	NMT 4.0%	2.16%
8.	Related Substances		
	Area of any secondary peak due to Cefepime impurity A,%	NMT 0.5%	Not detected
	Area of any secondary peak due to Cefepime impurity B,%	NMT 0.5%	Not detected
	Total impurities,%	NMT 1.5%	0.25%
9.	Particulate Matter (IHS)		
	(A.) Light Obscuration Particle Count Test		
	(1.) Particles ≥10µm	NMT 6000/vial	1527.33/vial
	(2.) Particles ≥25µm	NMT 600/vial	214.00/vial
	(B.) Visual Particle	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be observed on visual inspection.	Complies

Analysis by	Checked by	Approved by
04/10/2025	04/10/25	for 04/10/25
NAME: NIKHIL SHARMA	NAME: SUFIYAN ANSARI	NAME: MRS. SWATI DHAWAN

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10.	Sterility	No microbial growth should be observed.	Complies
11.	Bacterial Endotoxins	NMT 0.06 EU/mg of Cefepime.	Less than 0.06 EU/mg of Cefepime.
12.	Assay: (By HPLC) Each glass vial contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Cefepime Hydrochloride (Sterile) IP Eq. to anhydrous Cefepime (A sterile mixture of Cefepime Hcl & Arginine)	1000 mg	1049.15 mg	104.92%	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	Checked by	Approved by
04/10/2025	04/10/25	for 04/10/25
NAME: NIKHIL SHARMA	NAME: SUFIYAN ANSARI	NAME: MRS. SWATI DHAWAN

AMERICAN REMEDIES HEALTHCARE PVT. LTD. COMPANY SEAL