



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

Title

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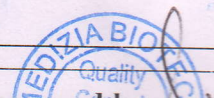
Certificate of Analysis Finished Product

Product Name	AFIPIME Injection	A.R. No.	ARB/FP/25/029
Generic Name	Cefepime Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	ARB2537A	Sampled by	Anuj Verma
Batch Size	10,000 Vials	Sampled on	21/02/2026
Mfg. Date	02/2026	Date of Testing	22/02/2026
Exp. Date	01/2028	Date of Release	09/03/2026

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 $\pm 10\%$	-0.92% & +0.91%
4.	Average weight	Informative $\pm 2\%$.	1848.9mg
5.	pH	4.0 to 6.0	4.65
6.	N- methylpyrrolidine	NMT 1.0%	Not detected
7.	Water	NMT 4.0%	2.36%
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%	Not detected
9.	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	146/vial 1/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





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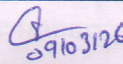
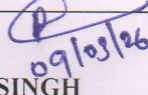
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Certificate of Analysis Finished Product

Product Name	AFIPIIME Injection	A.R. No.	ARB/FP/25/029
Generic Name	Cefepime Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	ARB2537A	Sampled by	Anuj Verma
Batch Size	10,000 Vials	Sampled on	21/02/2026
Mfg. Date	02/2026	Date of Testing	22/02/2026
Exp. Date	01/2028	Date of Release	09/03/2026

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	974.9556 mg	97.50%	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: RAMANJEET SINGH	Approved by  NAME: MRS. SWATI DHAWAN
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