

Title

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Certificate of Analysis Finished Product

Product Name	AFIPIIME Injection	A.R. No.	ARB/FP/26/020
Generic Name	Cefepime Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	ARB2616A	Sampled by	Rakesh
Batch Size	10,000 Vials	Sampled on	10/07/2026
Mfg. Date	07/2026	Date of Testing	11/07/2026
Exp. Date	06/2028	Date of Release	25/07/2026

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 $\pm 10\%$	-1.30% & +1.23%
4.	Average weight	Informative $\pm 2\%$.	1845.6 mg
5.	pH	4.0 to 6.0	4.85
6.	N- methylpyrrolidine	NMT 1.0%	Not detected
7.	Water	NMT 4.0%	2.28%
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 $\geq 10\mu\text{m}$	NMT 6000/vial	486/vial
	(2.) Particles $\geq 25\mu\text{m}$	NMT 600/vial	6/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

NAME: NIKHIL SHARMA

Checked by

NAME: SURJEET KAUR

Approved by

NAME: MRS. SWATI DHAWAN



AMERICAN REMEDIES HEALTHCARE PVT. LTD.
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Title

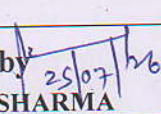
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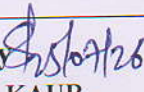
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10.	Sterility	No microbial growth should be observed.	Complies		
11.	Bacterial Endotoxins	NMT 0.06 EU/mg of Cefepime.	Less than 0.06 EU/mg of Cefepime.		
12.	Assay: (By HPLC) Each glass vial contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Cefepime Hydrochloride (Sterile) IP Eq. to anhydrous Cefepime (A sterile mixture of Cefepime Hcl & Arginine)		1000 mg	974.7378 mg	97.47%	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/PHS.

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