



# AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

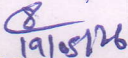
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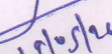
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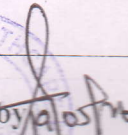
Certificate of Analysis Finished Product

Product Name	AFIPIME Injection	A.R. No.	ARB/FP/26/009
Generic Name	Cefepime Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	ARB2606A	Sampled by	Rakesh
Batch Size	10,000 Vials	Sampled on	01/05/2026
Mfg. Date	04/2026	Date of Testing	02/05/2026
Exp. Date	03/2028	Date of Release	19/05/2026

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 $\pm 10\%$	-1.16% & +0.84%
4.	Average weight	Informative $\pm 2\%$ .	1852.7 mg
5.	pH	4.0 to 6.0	4.46
6.	N- methylpyrrolidine	NMT 1.0%	Not detected
7.	Water	NMT 4.0%	2.51%
8.	Related Substances		
	Area of any secondary peak due to Cefepime impurity A,%	NMT 0.5%	0.006%
	Area of any secondary peak due to Cefepime impurity B,%	NMT 0.5%	0.014%
	Total impurities,%	NMT 1.5%	0.020%
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	67/vial 3/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: SACHIN KUMAR

Checked by   
NAME: SUFIYAN ANSARI

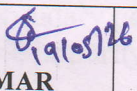
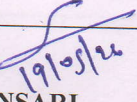
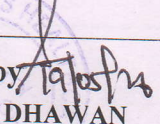
Approved by   
NAME: MRS. SWATI DHAWAN

**Title : Certificate of Analysis Finished Product**

<b>Product Name</b>	AFIPIME Injection	<b>A.R. No.</b>	ARB/FP/26/009
<b>Generic Name</b>	Cefepime Injection IP 1gm	<b>Sampled qty.</b>	45 Vials
<b>Batch No.</b>	ARB2606A	<b>Sampled by</b>	Rakesh
<b>Batch Size</b>	10,000 Vials	<b>Sampled on</b>	01/05/2026
<b>Mfg. Date</b>	04/2026	<b>Date of Testing</b>	02/05/2026
<b>Exp. Date</b>	03/2028	<b>Date of Release</b>	19/05/2026

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:				
<b>Ingredients</b>		<b>Labeled Claim</b>	<b>Found</b>	<b>% of labeled amount</b>	<b>Limits % of labeled amount</b>
Cefepime Hydrochloride (Sterile) IP Eq. to anhydrous Cefepime (A sterile mixture of Cefepime Hcl & Arginine)		1000 mg	966.2797 mg	96.63%	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/HS.

<b>Analysis by</b>  NAME: SACHIN KUMAR	<b>Checked by</b>  NAME: SUFIYAN ANSARI	<b>Approved by</b>  NAME: MRS. SWATI DHAWAN
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