

Title

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Certificate of Analysis Finished Product

<b>Product Name</b>	AFIPIME Injection	<b>A.R. No.</b>	BD/FP/23/777
<b>Generic Name</b>	Cefepime Injection I.P. 1gm	<b>Sampled qty.</b>	45 vials
<b>Batch No.</b>	B23698B	<b>Sampled by</b>	Snehal
<b>Batch Size</b>	10,000 Vials	<b>Sampled on</b>	05/03/2024
<b>Mfg. Date</b>	02/2024	<b>Date of Testing</b>	05/03/2024
<b>Exp. Date</b>	01/2026	<b>Date of Release</b>	20/03/2024

S. No.	Tests	Specifications	Observations
1.	Description	A white 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 $\pm 10\%$	-0.68% & +0.49%
4.	Average weight	Informative.	1885.2 mg
5.	pH	4.0 to 6.0	4.96
6.	N-methylpyrrolidine	Not more than 1.0%	Complies
7.	Water	NMT- 4.0%	2.43%
8.	Related Substances		
	(a) Area of any secondary peak due to Cefepime impurity A,%	Not more than 0.50%	Complies
	(b) Area of any secondary peak due to Cefepime impurity B,%	Not more than 0.20%	Complies
(c) Sum of all the secondary peaks,%	Not more than 1.0%	Complies	
9.	Particulate Matter		
	(a.) Sub-Visible particle count		
	(1.) Particles $\geq 10\mu\text{m}$	NMT-6000/vial	119/vial
(2.) Particles $\geq 25\mu\text{m}$	NMT-600/vial	10/vial	
(b.) Visual	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	Complies	

# Pace

Add Pace To Health

# Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title

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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: 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	1014.150 mg	101.42%	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.

Analysis by

*Supriya*

Checked by

*Omika*

Approved by

*[Signature]*