

Title

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Certificate of Analysis Finished Product

Product Name	AFIPIIME Injection	A.R. No.	BD/FP/23/638
Generic Name	Cefepime Injection IP 1g	Sampled qty.	45 Vials
Batch No.	B23614A	Sampled by	Arvind
Batch Size	7220 Vials	Sampled on	07/01/2024
Mfg. Date	12/2023	Date of Testing	07/01/2024
Exp. Date	11/2025	Date of Release	22/01/2024

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 $\pm 10\%$	-2.93% & +2.05%
4.	Average weight	Informative.	1906.2 mg
5.	pH	4.0 to 6.0	4.33
6.	N-methylpyrrolidine	NMT- 1.0%	Complies
7.	Water	NMT- 4.0%	2.26%
8.	Related Substances		
	Area of any secondary peak due to Cefepime impurity A,%	NMT- 0.50%	Complies
	Area of any secondary peak due to Cefepime impurity B,%	NMT- 0.20%	Complies
	Sum of all the secondary peaks,%	NMT-1.0%	Complies
9.	Particulate Matter (IHS)		
	(a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$	NMT-6000/vial NMT-600/vial	1343/vial 24/vial
	(b.) Visual	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	Complies
10.	Sterility	No microbial growth should be observed.	Complies

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Pace Biotech

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

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11.	Bacterial Endotoxins	NMT- 0.06 EU/mg of Cefepime.	Less than- 0.06 EU/mg of Cefepime.
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12.	Assay: Each glass vial Contains :		
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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	985.52 mg	98.55%	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/HHS.

Analysis by

Checked by

