

Pace

Add Pace To Health

Pace Biotech

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

Title

:

Certificate of Analysis Finished Product

Product Name	AFIPIIME Injection	A.R. No.	BD/FP/24/710
Generic Name	Cefepime Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	B24674A	Sampled by	Rakesh
Batch Size	10,000 Vials	Sampled on	24/03/2025
Mfg. Date	03/2025	Date of Testing	24/03/2025
Exp. Date	02/2027	Date of conditionally Release	02/04/2025

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.	Under process
	(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 $\pm 10\%$	-1.10% & +1.16%
4.	Average weight	Informative.	1851.6 mg
5.	pH	4.0 to 6.0	5.61
6.	N- methylpyrrolidine	NMT- 1.0%	Under process
7.	Water	NMT- 4.0%	1.76%
8.	Related Substances		
	Area of any secondary peak due to Cefepime impurity A,%	NMT- 0.5%	Under process
	Area of any secondary peak due to Cefepime impurity B,%	NMT- 0.5%	Under process
	Sum of any secondary peaks,%	NMT- 1.5%	Under process
9.	Particulate Matter (IHS)		
	(a.) Sub-Visible particle count		
	(1.) Particles $\geq 10\mu\text{m}$	NMT-6000/vial	169/vial
	(2.) Particles $\geq 25\mu\text{m}$	NMT-600/vial	6/vial
	(b.) Visual	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	Complies

Analysis by

NAME: SUFIYAN ANSARI

Checked by

NAME: SANDHYA

Approved by

NAME: P. N. TRIPATHI

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10.	Sterility	No microbial growth should be observed.	Under process		
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	968.25 mg	96.83%	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: SUFIYAN ANSARI	Checked by  NAME: SANDHYA	Approved by  NAME: P. N. TRIPATHI
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