

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/24/381
Generic Name	Cefepime Injection IP 1g	Sampled qty.	45 Vials
Batch No.	B24328A	Sampled by	Aakash
Batch Size	6000 Vials	Sampled on	24/10/2024
Mfg. Date	09/2024	Date of Testing	24/10/2024
Exp. Date	08/2026	Date of conditionally Release	07/11/2024

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 $\pm 10\%$	-0.94% & +0.82%
4.	Average weight	Informative.	1854.3 mg
5.	pH	4.0 to 6.0	4.52
6.	N- methylpyrrolidine	NMT- 1.0%	Not detected
7.	Water	NMT- 4.0%	2.81%
8.	Related Substances		
	Area of any secondary peak due to Cefepime impurity A,%	NMT- 0.50%	Not detected
	Area of any secondary peak due to Cefepime impurity B,%	NMT- 0.50%	Not detected
	Sum of all the secondary peaks,%	NMT- 1.5%	Not detected
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	542/vial 1/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	1064.06 mg	106.41%	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 NAME: SUFIYAN ANSARI	Checked by NAME: SANDHYA	Approved by NAME: P. N. TRIPATHI
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