

Certificate of Analysis Finished Product

Title	:		
Product Name	AFIPIME Injection	A.R. No.	BD/FP/24/492
Generic Name	Cefepime Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	B24485C	Sampled by	Rakesh
Batch Size	7000 Vials	Sampled on	09/12/2024
Mfg. Date	12/2024	Date of Testing	09/12/2024
Exp. Date	11/2026	Date of Release	24/12/2024

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 $\pm 10\%$	-0.61% & +0.80%
4.	Average weight	Informative.	1878.6 mg
5.	pH	4.0 to 6.0	4.65
6.	N- methylpyrrolidine	NMT- 1.0%	Not detected
7.	Water	NMT- 4.0%	1.88%
8.	Related Substances		Not detected
	Area of any secondary peak due to Cefepime impurity A,%	NMT- 0.5%	Not detected
	Area of any secondary peak due to Cefepime impurity B,%	NMT- 0.5%	Not detected
	Sum of any secondary peaks,%	NMT- 1.5%	Not detected
9.	Particulate Matter (IHS)		
	(a.) Sub-Visible particle count		436/vial
	(1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$	NMT-6000/vial NMT-600/vial	25/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	Quality Control Manager NAME: P. N. TRIPATHI
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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	1001.89 mg	100.19%	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: Manoj TRIPATHI

