

Pace

Add Pace To Health

Pace Biotech

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

Title

:

Certificate of Analysis Finished Product

Product Name	AZIDIME AVB Injection	A.R. No.	BD/FP/24/395
Generic Name	Ceftazidime & Avibactam Powder for Concentrate for Solution for Infusion 2.5gm	Sampled qty.	45 Vials
Batch No.	B24326D	Sampled by	Boby Kumar
Batch Size	1000 Vials	Sampled on	26/10/2024
Mfg. Date	09/2024	Date of Testing	26/10/2024
Exp. Date	08/2026	Date of Release	10/11/2024

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 HPLC)	In the Assay, the principal peak of Ceftazidime & Avibactam Sodium in the chromatogram obtained with the test solution corresponds to the peak of Ceftazidime & Avibactam Sodium in the Chromatogram obtained with the working standard solution.	Complies
3.	Uniformity of Weight	Average weight $\pm 10\%$	-0.52% & +0.33%
4.	Average weight	Informative.	3144.2 mg
5.	Particulate Matter		
	(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	233/vial 52/vial
	(b.) Visual	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	Complies
6.	Sterility	No microbial growth should be observed.	Complies
7.	Bacterial Endotoxins	NMT- 0.1 EU/mg of Ceftazidime & Avibactam.	Less than- 0.1 EU/mg of Ceftazidime & Avibactam.
8.	Assay: Each glass vial Contains :		

Analysis by

NAME: SUFIYAN ANSARI

Checked by

NAME: SANDHYA

Approved by

NAME: P. N. TRIPATHI



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Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Ceftazidime Pentahydrate (Sterile) IP Eq. to Anhydrous Ceftazidime (A sterile mixture of Ceftazidime & Sodium Carbonate)	2000 mg	2026.82 mg	101.34%	90.0% to 110%
Avibactam Sodium Eq. to Avibactam	500 mg	497.81 mg	99.56%	90.0% to 110%

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

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NAME: P.N. TRIPATHI

