

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/24/180
Generic Name	Ceftazidime & Avibactam Powder for Concentrate for Solution for Infusion	Sampled qty.	45 Vials
Batch No.	B24004L	Sampled by	Aakash
Batch Size	1000 Vials	Sampled on	03/07/2024
Mfg. Date	04/2024	Date of Testing	03/07/2024
Exp. Date	03/2026	Date of Conditionally Release	10/07/2024

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 $\pm 10\%$	-0.95% & +0.64%
4.	Average weight	Informative.	3154.1 mg
5.	Particulate Matter (a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (b.) Visual	NMT-6000/vial NMT-600/vial The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	495/vial 192/vial Complies
6.	Sterility	No microbial growth should be observed.	Under Process
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 :		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Ceftazidime Pentahydrate (Sterile) IP Eq. to Ceftazidime	2000 mg	2050.59 mg	102.53%	90.0% to 110%
Avibactam Sodium (Sterile) Eq. to Avibactam	500 mg	496.99 mg	99.40%	90.0% to 110%

Remarks: In the opinion of the undersigned the sample referred to above is/ is-not-of-the-standard quality as per The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ not complies as per IP/BP/USP/IHS.

Analysis by

Checked by

Approved by

