

Title

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Certificate of Analysis Finished Product

Product Name	AZTREOCAN Injection	A.R. No.	ARB/FP/25/012
Generic Name	Aztreonam for Injection USP 1000mg	Sampled qty.	45 vials
Batch No.	ARB2511A	Sampled by	Anuj Verma
Batch Size	5000 Vials	Sampled on	30/09/2025
Mfg. Date	09/2025	Date of Testing	30/09/2025
Exp. Date	08/2027	Date of Release	17/10/2025

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	The retention times the major peaks of the sample solution correspond to those of the working standard solution.	Complies		
3.	Uniformity of Weight	Average weight $\pm 10\%$	-1.66% & +0.99%		
4.	Average weight	Informative $\pm 2\%$.	1827.2 mg		
5.	pH	4.5 to 7.5	6.34		
6.	Particulate Matter (A.) Light Obscuration Particle Count Test 1. Particles $\geq 10 \mu\text{m}$ 2. Particles $\geq 25 \mu\text{m}$ (B.) Visual Particle	NMT 6000/vial NMT 600/vial The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be observed on visual inspection.	38/vial 0/vial Complies		
7.	Water	NMT 2.0%w/w	0.36%w/w		
8.	Contents of Arginine	42% to 46%	45.68%		
9.	Sterility	No microbial growth should be observed.	Complies		
10.	Bacterial Endotoxins	NMT 0.17 USP EU/mg of Aztreonam.	Less than 0.17 USP EU/mg of Aztreonam.		
11.	Assay: (By HPLC) Each glass vial contains				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Aztreonam (Sterile) USP Eq. to anhydrous Aztreonam (A mixture of Aztreonam & L-Arginine)		1000 mg	1041.79 mg	104.18%	90.0% to 105.0%

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/HIS~~.

Analysis by

NAME: NIKHIL SHARMA

Checked by

NAME: SUFIYAN ANSARI

Approved by

NAME: MRS. SWATI DHAWAN

