

**Title : Certificate of Analysis Finished Product**

<b>Product Name</b>	AZTREOCAN Injection	<b>A.R. No.</b>	BD/FP/24/454
<b>Generic Name</b>	Aztreonam for Injection USP 1000mg	<b>Sampled qty.</b>	45 vials
<b>Batch No.</b>	B24379J	<b>Sampled by</b>	Boby Kumar
<b>Batch Size</b>	2000 Vials	<b>Sampled on</b>	27/11/2024
<b>Mfg. Date</b>	10/2024	<b>Date of Testing</b>	27/11/2024
<b>Exp. Date</b>	09/2026	<b>Date of Release</b>	12/12/2024

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	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 $\pm 10\%$	-0.82% & +0.66%
4.	Average weight	Informative.	1800.3 mg
5.	pH	4.5 to 7.5	5.34
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	NMT-6000/vial NMT-600/vial The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	193/vial 1/vial Complies
7.	Water	NMT- 2.0% w/w	0.43%w/w
8.	Contents of Arginine	38 to 42%	40.74%
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: 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	970.49 mg	97.05%	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/IHS.**

<b>Analysis by</b> NAME: SUFIYAN ANSARI	<b>Checked by</b> NAME: SANDHYA	<b>Approved by</b> NAME: P. N. TRIPATHI
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