

AMERICAN REMEDIES HEALTHCARE PVT. LTD.

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Certificate of Analysis Finished Product

Product Name	AZTREOCAN Injection	A.R. No.	ARB/FP/25/021
Generic Name	Aztreonam for Injection USP 1gm	Sampled qty.	45 vials
Batch No.	ARB2524A	Sampled by	Aakash
Package Size	5,000 Vials	Sampled on	24/12/2025
Expiry Date	12/2025	Date of Testing	24/12/2025
Release Date	11/2027	Date of Release	07/01/2026

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 $\pm 10\%$	-4.92% & +1.13%
4.	Average weight	Informative $\pm 2\%$.	1811.5 mg
5.	pH	4.5 to 7.5	5.62
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.	56/vial 2/vial Complies
7.	Water	NMT 2.0%w/w	0.59%w/w
8.	Contents of Arginine	42% to 46%	45.54%
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	985.3398 mg	98.53%	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.

Analysis by NAME: NIKHIL SHARMA	Checked by NAME: RAMANJEET SINGH	Approved by NAME: MRS. SWATI DHAWAN
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