



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

Title : Certificate of Analysis Finished Product

Product Name	AONE-SB 1.5 Injection	A.R. No.	ARB/FP/25/024
Generic Name	Ceftriaxone & Sulbactam for Injection IP	Sampled qty.	45 Vials
Batch No.	ARB2530A	Sampled by	Aakash
Batch Size	25,000 Vials	Sampled on	08/01/2026
Mfg. Date	01/2026	Date of Testing	09/01/2026
Exp. Date	12/2027	Date of Release	24/01/2026

S.No.	Tests	Specifications	Observations
1.	Description	A white to off white powder filled in clear glass vial.	A white dry powder filled in clear glass vial.
2.	Identification	In the Assay, the principal peaks in the chromatogram obtained with the test solution correspond to the peak in the chromatogram obtained with reference solution (c).	Complies
3.	Uniformity of Weight	Average weight $\pm 10\%$	-0.72% & +1.89%
4.	Average weight	Informative $\pm 2\%$.	1773.9 mg
5.	pH	4.5 to 8.0	6.71
6.	Related Substance		
	Any secondary peak	NMT 1.0%	0.28%
	Sum of all secondary peaks	NMT 5.0%	0.28%
7.	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 reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	103/vial 1/vial Complies
8.	Sterility	No microbial growth should be observed.	Complies
9.	Bacterial Endotoxins	NMT 0.2 EU/mg of Ceftriaxone.	Less than 0.2 EU/mg Ceftriaxone.
10.	Assay: (By HPLC) Each vial Contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Sterile Ceftriaxone Sodium IP Eq. to anhydrous Ceftriaxone	1000 mg	1033.4052 mg	103.34%	90.0 to 110%
Sterile Sulbactam Sodium IP Eq. to Sulbactam	500 mg	504.3367 mg	100.87%	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/BB/USP/THS.

Analysis by NAME: NIKHIL SHARMA 24/01/26	Checked by NAME: SUFIYAN ANSARI 24/01/26	Approved by NAME: MRS. SWATI DHAWAN 24/01/26
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