

**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 1.5g Injection	A.R. No.	ARB/FP/25/013
Generic Name	Ceftriaxone & Sulbactam for Injection IP 1.5gm	Sampled qty.	45 Vials
Batch No.	ARB2513A	Sampled by	Dhananjay
Batch Size	20,160 Vials	Sampled on	06/10/2025
Mfg. Date	10/2025	Date of Testing	06/10/2025
Exp. Date	09/2027	Date of Release	23/10/2025

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 $\pm 10\%$	-0.70% & +1.47%
4.	Average weight	Informative $\pm 2\%$.	1742.9 mg
5.	pH	4.5 to 8.0	6.84
6.	Related Substance		
	Any secondary peak	NMT 1.0%	0.25%
	Sum of all secondary peaks	NMT 5.0%	0.63%
7.	Particulate Matter		
	(a.) Sub-Visible particle count		
	(1.) Particles $\geq 10\mu\text{m}$	NMT 6000/vial	73/vial
	(2.) Particles $\geq 25\mu\text{m}$	NMT 600/vial	1/vial
	(b.) Visual	The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	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	1035.39 mg	103.54%	90.0 to 110%
Sterile Sulbactam Sodium IP Eq. to Sulbactam	500 mg	483.89 mg	96.78%	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/BP/SP/US.

Analysis by NAME: NIKHIL SHARMA	Checked by NAME: SUFIYAN ANSARI	Approved by NAME: MRS. SWATI DHAWAN
------------------------------------	------------------------------------	--