

Title

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Certificate of Analysis Finished Product

Product Name	AONE-SB Injection	A.R. No.	ARB/FP/26/006
Generic Name	Ceftriaxone & Sulbactam for Injection IP 1.5gm	Sampled qty.	45 Vials
Batch No.	ARB2601A	Sampled by	Aakash
Batch Size	20,000 Vials	Sampled on	27/04/2026
Mfg. Date	04/2026	Date of Testing	28/04/2026
Exp. Date	03/2028	Date of Release	12/05/2026

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 $\pm 10\%$	-6.40% & +5.41%		
4.	Average weight	Informative $\pm 2\%$.	1754.6 mg		
5.	pH	4.5 to 8.0	6.69		
6.	Related Substance				
	Any secondary peak	NMT 1.0%	0.322%		
	Sum of all secondary peaks	NMT 5.0%	0.736%		
7.	Particulate Matter	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.	36/vial 5/vial Complies		
	(a.) Sub-Visible particle count				
	(1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$				
	(b.) Visual				
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	1022.0369 mg	102.20%	90.0 to 110%
Sterile Sulbactam Sodium IP Eq. to Sulbactam		500 mg	514.7103 mg	102.94%	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/USP/HS.

Analysis by 12/05/2026
NAME: NIKHIL SHARMA

Checked by 12/05/26
NAME: SUFIYAN ANSARI

Approved by
NAME: MRS. SWATI BHAWAN