

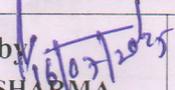
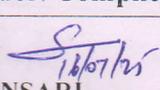
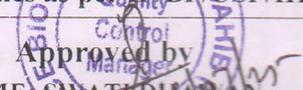
Title : Certificate of Analysis Finished Product

Product Name	AONE SB 1.5g Injection	A.R. No.	BD/FP/25/191
Generic Name	Ceftriaxone & Sulbactam for Injection IP 1.5gm	Sampled qty.	45 Vials
Batch No.	B25125F	Sampled by	Rakesh
Batch Size	6000 Vials	Sampled on	01/07/2025
Mfg. Date	06/2025	Date of Testing	01/07/2025
Exp. Date	05/2027	Date of Release	16/07/2025

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 $\pm 10\%$	-1.66% & +1.65%
4.	Average weight	Informative $\pm 2\%$.	1733.6 mg
5.	pH	4.5 to 8.0	6.71
6.	Related Substance		
	Any secondary peak	NMT 1.0%	Not detected
	Sum of all secondary peaks	NMT 5.0%	Not detected
7.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$	NMT 6000/vial NMT 600/vial	556/vial 5/vial
	(B.) Visual Particle	The reconstituted solution should be essentially free from extraneous, mobile, undissolved particles, other than gas bubbles, unintentionally that cannot be seen with naked eye.	Complies
8.	Sterility	Powder for injection should comply with test for sterility.	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	Labelled Claim	Found	% of labelled amount	Limits % of labelled amount
Sterile Ceftriaxone Sodium IP Eq. to anhydrous Ceftriaxone	1000 mg	1060.47 mg	106.05%	90.0 to 110%
Sterile Sulbactam Sodium IP Eq. to anhydrous Sulbactam	500 mg	476.59 mg	95.32%	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  NAME: NIKHIL SHARMA	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: SWATI DHARAN
--	---	---

