

**RICA ENTERPRISES**

(A WHO- GMP Certified Company)

Village Khari, Mauza Ogli, Kala-Amb, Distt. Sirmour H.P.

**QUALITY CONTROL DEPARTMENT****CERTIFICATE OF ANALYSIS**

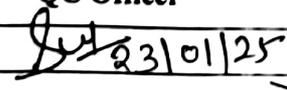
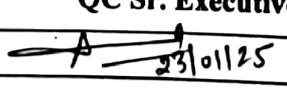
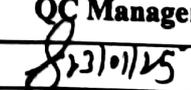
(The Drugs &amp; Cosmetics act 1940 &amp; the rules there under)

Mfg. Lic . No: N-MB/17/193

Product name	AONE- SB 1.5GM		
Generic Name	Ceftriaxone & Sulbactam Injection 1.5 gm IP		
Batch No.	R24421B	Batch Size	6,025 Vials
Mfg. Date	11/2024	Exp.Date	10/2026
Date of Sample	09/01/2025	Sample Qty.	45 Vials
Date of Analysis	09/01/2025	Date of Release	23/01/2025
Stage	Finished	A.R.No.	QC/FP/CG/25019

S. No.	Test	Specification	Result
1.	Description	A white to off white Powder.	A White Powder.
2.	Identification: By HPLC	Retention time of principal peaks in the chromatogram obtained of the assay preparation correspond to that of the standard preparation as obtained in the assay.	Complies.
3.	pH (10 % w/v )	Between 4.5 to 8.0	6.62
4.	Average fill weight	1760.0 mg $\pm$ 3.0 %	1771.80 mg.
5.	Uniformity of weight	$\pm$ 10.0 % w/w of Average weight	Mini: 1744.9mg & Maxi: 1788.5 mg
6.	Related Substances: Any Secondary impurity The sum of all Impurities	NMT-1.0% NMT-5.0%	0.02% 0.06%
7.	Particulate Matter	The solution shall be essentially free from particles of foreign matter that can be seen on visual.	Complies.
8.	Bacterial Endotoxins	NMT 0.20 EU /mg.	Less than 0.20 EU/ mg .
9.	Sterility	Complies with the test of sterility.	Complies .
10.	Assay Each Vial Contains: Ceftriaxone Sodium IP eq. to Ceftriaxone      1000 mg Sulbactam Sodium IP eq. to Sulbactam      500 mg	900.0 mg to 1100.0 mg (NLT 90.0 % & NMT 110.0 %) 450.0 mg to 550.0 mg (NLT 90.0 % & NMT 110.0 %)	1005.94 mg 100.59 % of $C_{18}H_{18}N_8O_7S_3$ 498.31 mg 99.66 % of $C_8H_{11}NO_3S$

Remark: The sample is complies / does not comply as per IP/EP/USP/ In-House Specification.

Name	Prepared By(QC)	Checked By(QC)	Approved by(QC)
	Shameem	Awaneesh	Mr. Sandeep Kumar
Designation	QC Officer	QC Sr. Executive	QC Manager
Signature & Date:	 23/01/25	 23/01/25	 23/01/25
Degree			M. Sc
Enrolment No.			D C LS(C) 2008-197
Name & place of Institute			Punjabi University, Patiala

F/QC-017-03