



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 & Cosmetics act 1940 & the rules there under)

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

Product name	AONE- SB 1.5GM		
Generic Name	Ceftriaxone & Sulbactam For Injection 1.5 gm IP		
Batch No.	R24320R	Batch Size	6,025 Vials
Mfg. Date	09/2024	Exp. Date	08/2026
Date of Sample	04/10/2024	Sample Qty.	25 Vials
Date of Analysis	04/10/2024	Date of Release	18/10/2024
Stage	Finished	A.R.No.	QC/FP/CG/24461

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	6.69
4.	Average fill weight	1750.0 mg \pm 3.0 %	1757.15 mg
5.	Uniformity of weight	\pm 10.0 % w/w of Average weight	Mini: 1745.6 mg & Maxi: 1765.9 mg
6.	Related Substances: Any Secondary impurity The sum of all Impurities	NMT-1.0% NMT-5.0%	Not detected. Not detected.
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 %)	1014.61 mg 101.46% of C ₁₈ H ₁₈ N ₈ O ₇ S ₃ 499.19 mg 99.84% of C ₈ H ₁₁ NO ₅ S

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

	Analysis By	Checked By	Approved by
Name	SHAMEEM	AWANEESH	SANDEEP KUMAR
Signature			
Date	18/10/2024	18/10/2024	18/10/2024

F/QC-017-03