



Rica Enterprises

## RICA ENTERPRISES

(A WHO- GMP Certified Company)

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

QUALITY CONTROL DEPARTMENT

## PROVISIONAL CERTIFICATE OF ANALYSIS (FINISH)

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

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

Product Name	AONE-500		
Generic Name	Ceftriaxone Injection IP 500 mg		
Batch No.	R23200A	Batch Size	5,059 Vials
Mfg. Date	08/2023	Exp. Date	07/2025
Date of Sample	06/09/2023	Sample Qty.	25 Vials
Date of Analysis	07/09/2023	Date of Release	20/09/2023
Stage	Finished	A.R.No.	QC/FP/CG/23259

S. No.	Test	Specification	Result
1.	Description	A white or almost white powder.	Almost white powder.
2.	Identification (A) By IR  (B) By HPLC  (C) Chemically	The IR absorption spectrum obtained with sample should concordant to the IR absorption spectrum obtained with RS/WS of Ceftriaxone. 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. Gives the reaction with sodium salt.	Complies.  Complies.  Complies.
3.	Appearance of Solution	Solution should be clear and Leaving no visible residue as un-dissolved matter	Complies
4.	pH (100 mg/ml)	Between 6.0 to 8.0	6.82
5.	Average fill weight	603.5 mg $\pm$ 3 %	606.56 mg
6.	Uniformity of weight	$\pm$ 10.0 %w /w of Average weight	Mini: 597.1 mg & Maxi: 615.0 mg
7.	Related Substance Any secondary impurity The sum of all impurities	NMT 1.0 % NMT 5.0 %	Not Detected Not Detected
8.	Water	NMT 11.0 %	9.07 %
9.	Particulate Matter	The solution shall be essentially free from particles of foreign matter that can be seen on visual.	Complies
10.	Bacterial Endotoxins	NMT 0.2 EU /mg of Ceftriaxone.	Complies
11.	Sterility	Complies with the test of sterility.	Complies
12.	Assay Each Vial Contains Ceftriaxone Sodium IP eq. to Ceftriaxone 500 mg	450.0 mg to 575.0 mg (NLT 90.0 % & NMT 115.0 %)	509.18 mg 101.84 % of $C_{18}H_{18}N_8O_7S_3$

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

Name	Analysis By	Checked By	Approved By
Signature	BINDU	LAKSHAY	SANDEEP KUMAR
Date	20/09/2023	20/09/2023	20/09/2023

F/QC-017-03