

**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-1 GM		
Generic Name	Ceftriaxone Injection IP 1000 mg		
Batch No.	R23319	Batch Size	50,300 Vials
Mfg. Date	10/2023	Exp. Date	09/2025
Date of Sample	04/12/2023	Sample Qty.	25 Vials
Date of Analysis	04/12/2023	Date of Release	18/12/2023
Stage	Finished	A.R.No.	QC/FP/CG/23408

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	7.26
5.	Average fill weight	1205.0 mg $\pm$ 3 %	1194.97 mg
6.	Uniformity of weight	$\pm$ 10.0 %w /w of Average weight	Mini: 1170.4 mg & Maxi: 1212.7 mg
7.	Related Substance Any secondary impurity The sum of all impurities	NMT 1.0 % NMT 5.0 %	0.08 % 0.08 %
8.	Water	NMT 11.0 %	9.23 %
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.	Less Than 0.2 EU /mg
11.	Sterility	Complies with the test of sterility.	Complies
12.	Assay Each Vial Contains Ceftriaxone Sodium IP eq. to Ceftriaxone 1000 mg	900.0 mg to 1150.0 mg (NLT 90.0 % & NMT 115.0 %)	997.47 mg 99.75 % of C <sub>18</sub> H <sub>18</sub> N <sub>8</sub> O <sub>7</sub> S <sub>3</sub>

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

	Analysis By	Checked By	Approved By
Name	VINEET KUMAR	AWNEESH KUMAR	SANDEEP KUMAR
Signature			
Date	18/12/2023	18/12/2023	18/12/2023

F/QC-017-03