



VELLINTON HEALTHCARE
(Earlier Known as Texus Meditech)
Village Rampur Jattan, Trilokpur Road, Kala Amb, Dist. Sirmour-173030.
HP

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS

Product Name	: AONE 1g Ceftriaxone for Injection USP 1G		
Batch No.	: C24K-06	Mfg. Date	: 11/2024
Batch Size	: 20000 Vials	Exp. Date	: 10/2027
Sample Qty.	: 50 Vials	Analytical Report No.:	CFP20240438
Date of Receiving	: 10/11/2024	Date of Completion	: 25/11/2024
Neutral Code No.	: HP/DRUGS/18-201-1585		

S. No.	Tests		Specifications	Observations
1.	Description		A white or almost white powder filled in transparent glass vial.	An almost powder filled in transparent glass vial.
2.	Identification			
	A (By IR)		The Infrared absorption spectrum obtained from the sample corresponds with the infrared absorption spectrum obtained from the Ceftriaxone sodium working standard.	Complies
	B (By HPLC)		The retention time of the major peak in the test chromatogram corresponds to the major peak in the chromatogram of standard solution as obtained in the assay.	
3.	pH(10% w/v solution)		Between (6.0 to 8.0)	7.39
4.	Average fill Weight		1225.48 mg $\pm$ 2%	1228.10 mg
5.	Uniformity of filled weight		$\pm$ 10% of the average fill weight.	Complies
6.	Uniformity of dosage unit		NMT 15 %	Complies
7.	Clarity of solution	A.	The solid dissolves completely leaving no visible residue as undissolved matter.	Complies
		B.	The constituted solution shall not be significantly less clear than an equal volume of the diluents or of water for injection contained in a similar vessel or examined similarly.	Complies
8.	Organic impurities			
	Deacetylcefotaxime lactone ^a		NMT 0.50%	Not Detected
	Ceftriaxone triazine analog ^c		NMT 1.0%	Not Detected
	Ceftriaxone benzothiazolyl oxime ^d		NMT 0.20%	Not Detected
	Deacyl ceftriaxone ^e		NMT 1.0%	Not Detected
	Ceftriaxone-3-ene-isomer ^f		NMT 0.30%	Not Detected
	Ceftriaxone E-isomer ^g		NMT 1.0%	Not Detected

	Prepared By	Checked By	
Name	Punam Kumari	Anuj Kumar	
Designation	Executive	Sr. Executive	
Sign/ Date	25/11/2024	25/11/2024	

Format No.: VH/SOP/QC-062/FT01-01

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	Any individual unspecified impurity	NMT 0.20%	Not Detected		
	Total impurities	NMT 5.0%	Not Detected		
9.	Particulate Matter	Constitute the injection as directed on the label; the solution is essentially free from particles of foreign matter that can be seen on visual inspection.	Complies		
10.	Water (Determine by 0.1g)	8.0% to 11.0%	9.52 %		
11.	Bacterial Endotoxins	NMT 0.20 EU/mg of Ceftriaxone.	Less than 0.20 EU/mg of Ceftriaxone		
12.	Sterility	Should be Sterile	Sterile		
13.	Assay : Each vial contains:-				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Ceftriaxone Sodium (Sterile) USP Eq. to Ceftriaxone		1000 mg	1023.60 mg	102.36 %	90.0% to 115.0 %

Remarks: In the opinion of the undersigned the sample submitted complies/does not comply with the prescribed standard/net standard of quality, as according to USP with respect to the above test only.

Name	Prepared By Punam Kumari	Checked By Anuj Kumar	Approved By Vikas Gupta
Designation	Executive	Sr. Executive	Manager (QC)
Sign/ Date	 25/11/2024	 25/11/2024	 25/11/2024

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