



# ALVENTA PHARMA LIMITED

VILL. KISHANPURA, BADDI- NALAGARH ROAD, DISTT.- SOLAN-174101 (H.P.)

Quality Control Department

## CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Fuxorime 1.5 g	A.R. No.	FG/C/25A0001
Generic Name	Cefuroxime Sodium Injection IP	Sample Quantity	65 Vials
Batch No.:	ACD50202	Sample Received on	15/02/2025
Batch Size:	10000 Vials	Analysis Date	15/02/2025
Mfg. Date.	02/2025	Release Date	01/03/2025
Exp. Date	01/2027	Page No.:	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result
1.	Description	A White or almost white powder filled in a transparent 20 ml molded glass vial sealed with rubber stopper blue coloured flip off having aluminium seal.	A white powder filled in a transparent 20 ml molded glass vial sealed with rubber stopper blue coloured flip off having aluminium seal.
2.	Identification:		
	A. By HPLC	In the assay, the principal peak in the chromatogram obtained with the test solution should corresponds to the peak in the chromatogram obtained with the reference solution.	Complies
	B. By Chemically	It gives reaction of Sodium Salts: A dense white precipitate is formed.	Complies
3.	Average filled weight	$\pm 7.5\%$ of Target filled weight.	1582.48 mg
4.	Uniformity of filled weight	$\pm 10\%$ of its average filled weight	Min: 1550.27 mg ; Max: 1610.50 mg - 2.04% ; + 1.77%
5.	Clarity of Solution	Solid should dissolve completely when, leaving no visible residue as undissolved matter.	Solid dissolve completely when, leaving no visible residue as undissolved matter.
6.	pH	Between 6.0 to 8.5, determine in a 10 % w/v solution.	6.91
7.	Water	NMT 3.5%w/w	2.96 %w/w
8.	Particulate matter	The Sample Solution should be clear and free from any visible particles when examine visually against black background.	The Sample Solution is clear and free from any visible particles.
9.	Bacterial Endotoxins	NMT 0.1 EU/mg of Cefuroxime	Less than 0.1 EU/mg
10.	Sterility	Should be sterile	Sterile

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Amit Kumar Keni	Harjeet Kaur
Designation	Executive	Executive	Head Q.C.
Signature			
Date	01/03/2025	01/03/2025	01/03/2025



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11.	Assay:				
	Each Vial contains:	Claim	Limit	g	%
	Cefuroxime Sodium IP eq. to Cefuroxime	1.5 g	Between 90.00 % to 120.00 % of stated amount of Cefuroxime. (Between 1.35 g to 1.8 g)	1.4812 g	98.75%

Remarks: The above test parameters are complies/ not complies as per IP/BP/USP & In-House Specification.

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Amit Kumar Rai	Subjeet Kaur
Designation	Executive	Executive	Head QC
Signature			
Date	01/03/2025	01/03/2025	01/03/2025