



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Fuxorime 750 mg	A.R. No.	FG/C/24A0031
Generic Name	Cefuroxime Sodium Injection IP	Sample Quantity	65 Vials
Batch No.:	ACD40803	Sample Received on	29/08/2024
Batch Size:	7200 Vials	Analysis Date	29/08/2024
Mfg. Date.	08/2024	Release Date	18/09/2024
Exp. Date	07/2026	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 10 ml molded glass vial sealed with rubber stopper blue coloured flip off having aluminium seal.	A white powder filled in a transparent 10 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	807.60 mg
4.	Uniformity of filled weight	$\pm 10\%$ of its average filled weight.	Min: 801.38 mg ; Max: 823.61 mg - 0.77% ; + 1.98%
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.	6.73
7.	Water	NMT 3.5%w/w	2.90 %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	Braveen Kumar	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head- QA
Signature			
Date	18/09/2024	18/09/2024	18/09/2024



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11.	Assay:				
	Each Vial contains:	Claim	Limit	mg	%
	Cefuroxime Sodium IP eq. to Cefuroxime	750 mg	Between 90.00 % to 120.00 % of stated amount of Cefuroxime. (Between 675.0 mg to 900.0 mg)	759.78 mg	101.30%

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	Harveen Kumar	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head-QA
Signature			
Date	18/09/2024	18/09/2024	18/09/2024