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/24A0023
Generic Name	Cefuroxime Sodium Injection IP	**Sample Quantity**	65 Vials
Batch No.:	ACD40602	**Sample Received on**	27/06/2024
Batch Size:	7200 Vials	**Analysis Date**	27/06/2024
Mfg. Date.	06/2024	**Release Date**	11/07/2024
Exp. Date	05/2026	**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**	834.00 mg ± 5.0%.	836.80 mg
4.	**Uniformity of filled weight**	± 10 % of its average filled weight	Min: 819.28 mg ; Max: 853.14 mg - 2.09% ; + 1.95%
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.	6.90
7.	**Water**	NMT 3.5%w/w	2.97 %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	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	11/07/2024	11/07/2024	11/07/2024

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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)	762.79 mg	101.71%

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	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	11/07/2024	11/07/2024	11/07/2024