



VELLINTON HEALTHCARE

Village Rampur Jattan, Trilokpur Road, Kala Amb, Dist. Sirmour.

QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

Product Name : Fazolin Cefazolin for Injection USP 1gm	
Batch No. : C25J-11	Mfg. Date : 10/2025
Batch Size : 10000 Vials	Exp. Date : 09/2027
Sample Qty. : 50 Vials	Analytical Report No.: CFP20250447
Date of Receiving : 17/10/2025	Date of Completion : 31/10/2025
Mfg.Lic.No. : HP/DRUGS/18-201-1585	

S. No.	Tests	Specifications	Observations		
1.	Description	A White to off- white crystalline powder filled in clear glass vial.	White crystalline powder filled in clear glass vial.		
2.	Identification				
	A. By UV	Should be complies	Complies		
	B. By HPLC	The retention time of the major peak from the sample solution corresponds to that of the standard solution, as obtained in the Assay.	Complies		
	C. By Sodium test	A dense white precipitate is formed.	Complies		
3.	Average filled Weight	1106.85 mg \pm 2%	1106.24 mg		
4.	Uniformity of filled weight	\pm 10% of the average fill weight	Complies		
5.	Uniformity of Dosage Unit	NMT 15	Complies		
6.	pH	Between (4.0 to 6.0)	4.78		
7.	Constituted solution	The solid dissolves completely leaving no visible residue as undissolved matter.	Complies		
8.	Particulate Matter	The solution is essentially free from particles of foreign matter that can be seen on visual inspection.	Complies		
9.	Optical Rotation	- 10 ⁰ to - 24 ⁰	-19.06 ⁰		
10.	Water	NMT 6.0 %w/w	1.16 %		
11.	Bacterial Endotoxins	NMT 0.15 USP EU/mg of Cefazolin.	Less than 0.15 USP EU/mg of Cefazolin.		
12.	Sterility	Should be sterile	Sterile		
13.	Assay : Each vial contains:-				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Cefazolin Sodium (Sterile) USP Eq. to Cefazolin		1000 mg	1007.91 mg	100.79 %	90.0% to 115.0%

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

Name	Prepared By Manisha	Checked By Anuj Kumar	Approved By Vikas Gupta
Designation	Sr. Officer (QC)	Asst. Manager (QC)	Manager (QC)
Sign/ Date	<i>Manisha</i> 31/10/2025	<i>Anuj Kumar</i> 31/10/2025	<i>Vikas Gupta</i> 31/10/2025

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