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	**: Fazolin** Cefazolin for Injection USP		
Batch No.	: C24J-29	**Mfg. Date**	: 10/2024
Batch Size	: 8124 Vials	**Exp. Date**	: 09/2027
Sample Qty.	: 50 Vials	**Analytical Report No.:**	CFP20240421
Date of Receiving	: 15/10/2024	**Date of Completion**	: 29/10/2024
Mfg. License No.	: N-MB/18/201		

S. No.	Tests	Specifications	Observations
1.	Description	A White to off- white crystalline powder filled in clear glass vial.	A 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	1064.48 mg ± 2%	1065.70 mg
4.	Uniformity of filled weight	± 10% of the average fill weight	Complies
5.	Uniformity of Dosage Unit	NMT 15	Complies
6.	pH	Between (4.0 to 6.0)	5.14
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}	-18.18 ^{0}
10.	Water	NMT 6.0 %w/w	4.56 %
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	975.28 mg	97.53 %	90.0% to 115.0%

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

Analyzed By QC Officer	Checked By QC Executive	Approved By QC Manager/ In-charge
Signature:-	Signature:-	Signature:-
Date:- 29/10/2024	Date:- 29/10/2024	Date:- 29/10/2024

Format No.: VH/SOP/QC-062/FT01-00