



# VELLINTON HEALTHCARE

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

## QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

|                                                       |                                    |
|-------------------------------------------------------|------------------------------------|
| Product Name : Fazolin<br>Cefazolin for Injection USP |                                    |
| Batch No. : C26I-11                                   | Mfg. Date : 09/2026                |
| Batch Size : 15000 Vials                              | Exp. Date : 08/2029                |
| Sample Qty. : 50 Vials                                | Analytical Report No.: CFP20260376 |
| Date of Receiving : 08/09/2026                        | Date of Completion : 22/09/2026    |
| Neutral Code No. : HP/DRUGS/18-201-1585               |                                    |

| S. No.                                          | Tests                        | Specifications                                                                                                                        | Observations                                                                                              |                     |                            |
|-------------------------------------------------|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|---------------------|----------------------------|
| 1.                                              | Description                  | A White to off- white crystalline powder filled in 10 ml clear glass vial with yellow colour flip-off seal.                           | White to off- white crystalline powder filled in 10 ml clear glass vial with yellow colour flip-off seal. |                     |                            |
| 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        | 1135.29 mg ± 2%                                                                                                                       | 1137.03 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)                                                                                                                  | 4.88                                                                                                      |                     |                            |
| 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 <sup>0</sup> to - 24 <sup>0</sup>                                                                                                | -17.07 <sup>0</sup>                                                                                       |                     |                            |
| 10.                                             | Water                        | NMT 6.0 %w/w                                                                                                                          | 2.31%                                                                                                     |                     |                            |
| 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                                                                                                                               | 1028.89 mg                                                                                                | 102.89 %            | 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.

|             |                        |                            |  |
|-------------|------------------------|----------------------------|--|
| Name        | Prepared By<br>Manisha | Checked By<br>Punam Kumari |  |
| Designation | Sr. Officer (QC)       | Executive (QC)             |  |
| Sign/ Date  |                        |                            |  |

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