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Ceftizoxime Injection

» Ceftizoxime Injection is a sterile solution of Ceftizoxime Sodium in a diluent containing one or more tonicity-adjusting agents in Water for Injection. It contains the equivalent of not less than 90.0 percent and not more than 115.0 percent of the labeled amount of ceftizoxime ($C_{13}H_{13}N_5O_5S_2$).

Packaging and storage—Preserve as described in [Packaging and Storage Requirements \(659\)](#), [Injection Packaging](#). Maintain in the frozen state.

Labeling—It meets the requirements for [Labeling \(7\)](#), [Labels and Labeling for Injectable Products](#). The label states that it is to be thawed just prior to use, describes conditions for proper storage of the resultant solution, and directs that the solution is not to be refrozen.

USP REFERENCE STANDARDS (11)—
[USP Ceftizoxime RS](#)

Identification—The chromatogram of the Assay preparation obtained as directed in the Assay exhibits a major peak for ceftizoxime, the retention time of which corresponds to that exhibited in the chromatogram of the Standard preparation obtained as directed in the Assay.

BACTERIAL ENDOTOXINS TEST (85)—It contains not more than 0.10 USP Endotoxin Unit per mg of ceftizoxime.

STERILITY TESTS (71)—It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

pH (791): between 5.5 and 8.0.

PARTICULATE MATTER IN INJECTIONS (788): meets the requirements for small-volume injections.

Assay—

pH 3.6 Buffer, pH 7.0 Buffer, Mobile phase, Internal standard solution, Standard preparation, and Chromatographic system—Prepare as directed in the [Assay](#) under [Ceftizoxime Sodium](#).

Assay preparation—Allow 1 container of Injection to thaw, and mix. Transfer an accurately measured volume of the Injection, equivalent to about 40 mg of ceftizoxime, to a 100-mL volumetric flask, dilute with *pH 7.0 Buffer* to volume, and mix. Transfer 5.0 mL of this solution to a 100-mL volumetric flask, add 5.0 mL of *Internal standard solution*, dilute with *pH 7.0 Buffer* to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the [Assay](#) under [Ceftizoxime Sodium](#). Calculate the quantity, in mg, of ceftizoxime ($C_{13}H_{13}N_5O_5S_2$) in each mL of the Injection taken by the formula:

$$2000(C/V)(R_U/R_S)$$

in which V is the volume, in mL, of Injection taken, and the other terms are as defined therein.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
CEFTIZOXIME INJECTION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

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