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Ceftizoxime for Injection

» Ceftizoxime for Injection contains an amount of Ceftizoxime Sodium equivalent to 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, Packaging for constitution*.

USP Reference standards ⟨11⟩—
USP Ceftizoxime RS

Constituted solution—At the time of use, it meets the requirements for *Injections and Implanted Drug Products ⟨1⟩, Specific Tests, Completeness and clarity of solutions*.

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*.

Particulate Matter in Injections ⟨788⟩: meets the requirements for small-volume injections.

Other requirements—It responds to the *Identification* tests and meets the requirements for *Crystallinity*, *pH*, and *Water* under *Ceftizoxime Sodium*. It meets also the requirements for *Uniformity of Dosage Units ⟨905⟩* and for *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*.

Assay—

pH 3.6 Buffer, *pH 7.0 Buffer*, *Mobile phase*, *Internal standard solution*, and *Chromatographic system*—Prepare as directed in the *Assay* under *Ceftizoxime Sodium*.

Standard preparation—Dissolve a suitable quantity of USP Ceftizoxime RS, accurately weighed, in *pH 7.0 Buffer* to obtain a solution having a known concentration of about 1 mg of ceftizoxime ($C_{13}H_{13}N_5O_5S_2$) per mL. Transfer 2.0 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. This *Standard preparation* contains about 0.02 mg of ceftizoxime per mL.

Assay preparation 1 (where it is represented as being in a single-dose container)—Constitute Ceftizoxime for Injection in a volume of water, accurately measured, corresponding to the volume of solvent specified in the labeling. Withdraw all of the withdrawable contents, using a suitable hypodermic needle and syringe, and dilute quantitatively with *pH 7.0 Buffer* to obtain a solution containing about 1 mg of ceftizoxime per mL. Transfer 2.0 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.

Assay preparation 2 (where the label states the quantity of ceftizoxime in a given volume of constituted solution)—Constitute Ceftizoxime for Injection in a volume of water, accurately measured, corresponding to the volume of solvent specified in the labeling. Dilute an accurately measured volume of the constituted solution quantitatively with *pH 7.0 Buffer* to obtain a solution containing about 1 mg of ceftizoxime per mL. Transfer 2.0 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 with Ceftizoxime for Injection as directed for *Procedure* in the *Assay* under *Ceftizoxime Sodium*. Calculate the quantity, in mg, of ceftizoxime ($C_{13}H_{13}N_5O_5S_2$) withdrawn from the container, or in the portion of constituted solution taken by the formula:

$$(L/D)(C)(R_U/R_S)$$

in which L is the labeled quantity, in mg of ceftizoxime ($C_{13}H_{13}N_5O_5S_2$), in the container, or in the volume of constituted solution taken, and D is the concentration, in mg of ceftizoxime ($C_{13}H_{13}N_5O_5S_2$) per mL, of *Assay preparation 1* or *Assay preparation 2*, based on the labeled quantity in the container or in the portion of constituted solution taken, respectively; and the extent of dilution, C is the concentration, in mg of ceftizoxime ($C_{13}H_{13}N_5O_5S_2$) per mL, of the *Standard preparation*; and R_U and R_S are the peak response ratios of the ceftizoxime peak to the internal standard peak obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

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

Chromatographic Database Information: Chromatographic Database

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