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Ceftriaxone for Injection

» Ceftriaxone for Injection contains an amount of Ceftriaxone Sodium equivalent to not less than 90.0 percent and not more than 115.0 percent of the labeled amount of ceftriaxone ($C_{13}H_{13}N_5O_5S_2$).

Packaging and storage—Preserve as described in [Packaging and Storage Requirements \(659\)](#), [Injection Packaging](#), [Packaging for constitution](#).

USP REFERENCE STANDARDS (11)—

[USP Ceftriaxone 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 ceftriaxone.

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 [Ceftriaxone 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 [Ceftriaxone Sodium](#).

Standard preparation—Dissolve a suitable quantity of [USP Ceftriaxone RS](#), accurately weighed, in *pH 7.0 Buffer* to obtain a solution having a known concentration of about 1 mg of ceftriaxone ($C_{13}H_{13}N_5O_5S_2$) 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 ceftriaxone per mL.

Assay preparation 1 (where it is represented as being in a single-dose container)—Constitute Ceftriaxone 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 ceftriaxone 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 ceftriaxone in a given volume of constituted solution)—Constitute Ceftriaxone 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 ceftriaxone 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 Ceftriaxone for Injection as directed for *Procedure* in the [Assay](#) under [Ceftriaxone Sodium](#). Calculate the quantity, in mg, of ceftriaxone ($C_{13}H_{13}N_5O_5S_2$) 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 ceftriaxone ($C_{13}H_{13}N_5O_5S_2$), in the container, or in the volume of constituted solution taken, and *D* is the concentration, in mg of ceftriaxone ($C_{13}H_{13}N_5O_5S_2$) 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 ceftriaxone ($C_{13}H_{13}N_5O_5S_2$) per mL, of the *Standard preparation*; and *R_U* and *R_S* are the peak response ratios of the ceftriaxone 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
CEFTRIAZONE FOR INJECTION	Documentary Standards Support	SM12020 Small Molecules 1

Most Recently Appeared In:

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