Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-0111DA94-EAAF-4FAE-905E-0C25EE2DDB16_3_en-US
DOI: https://doi.org/10.31003/USPNF_M14147_03_01
DOI Ref: 5t069

Ceftriaxone Injection

» Ceftriaxone Injection is a sterile solution of Ceftriaxone 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 ceftriaxone ($C_{18}H_{18}N_8O_7S_3$).

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 Ceftriaxone Sodium RS
USP Ceftriaxone Sodium E-Isomer RS

Identification—The chromatogram of the *Assay preparation* obtained as directed in the *Assay* exhibits a major peak for ceftriaxone, 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 0.20 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*.

pH ⟨791⟩: between 6.0 and 8.0.

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

Assay—

pH 7.0 Buffer—Dissolve 13.6 g of dibasic potassium phosphate and 4.0 g of monobasic potassium phosphate in water to obtain 1000 mL of solution. Adjust this solution with phosphoric acid or 10 N potassium hydroxide to a pH of 7.0 ± 0.1.

pH 5.0 Buffer—Dissolve 25.8 g of sodium citrate in 500 mL of water, adjust with citric acid solution (1 in 5) to a pH of 5.0 ± 0.1, and dilute with water to a volume of 1000 mL.

Mobile phase—Dissolve 3.2 g of tetraheptylammonium bromide in 400 mL of acetonitrile, add 44 mL of *pH 7.0 Buffer* and 4 mL of *pH 5.0 Buffer*, and add water to make 1000 mL. Pass through a membrane filter of 0.5-µm or finer porosity, and degas. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Ceftriaxone Sodium RS in *Mobile phase* to obtain a solution having a known concentration of about 0.2 mg per mL. Use this solution promptly after preparation.

Resolution solution—Dissolve a suitable quantity of USP Ceftriaxone Sodium E-Isomer RS in *Standard preparation*, and dilute with *Mobile phase* to obtain a solution containing about 160 µg of USP Ceftriaxone Sodium E-Isomer RS per mL and 160 µg of USP Ceftriaxone Sodium RS per mL. Use this solution promptly after preparation.

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 ceftriaxone, to a 200-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. Use this solution promptly after preparation.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 270-nm detector and a 4.0-mm × 15-cm column that contains 5-µm packing L1. The flow rate is about 2 mL per minute. Chromatograph the *Resolution solution*, and record the peak responses as directed for *Procedure*. The resolution, *R*, between the ceftriaxone *E*-isomer and ceftriaxone peaks is not less than 3. Chromatograph the *Standard preparation*, and record the peak responses as directed under *Procedure*. The column efficiency determined from the analyte peak is not less than 1500 theoretical plates, the tailing factor for the analyte is not more than 2, and the relative standard deviation for replicate injections is not more than 2%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of ceftriaxone ($C_{18}H_{18}N_8O_7S_3$) in each mL of Injection taken by the formula:

$$200(C/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Ceftriaxone Sodium RS in the *Standard preparation*; V is the volume, in mL, of Injection taken; and r_U and r_S are the ceftriaxone peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Topic/Question	Contact	Expert Committee
CEFTRIAXONE IN DEXTROSE INJECTION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-0111DA94-EAAF-4FAE-905E-0C25EE2DDB16_3_en-US
Previous DocID: GUID-0111DA94-EAAF-4FAE-905E-0C25EE2DDB16_1_en-US
DOI: https://doi.org/10.31003/USPNF_M14147_03_01
DOI ref: 5t069