Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-2BFA0D04-F004-42FA-8C0F-0B314C91C0D7_3_en-US
DOI: https://doi.org/10.31003/USPNF_M14156_03_01
DOI Ref: x0uug

Cefuroxime Injection

» Cefuroxime Injection is a sterile isoosmotic solution of Cefuroxime Sodium in Water for Injection. It contains one or more suitable buffers and a tonicity-adjusting agent. It contains not less than 90.0 percent and not more than 120.0 percent of the labeled amount of cefuroxime ($C_{16}H_{16}N_4O_8S$).

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 Cefuroxime Sodium RS

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

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 5.0 and 7.5.

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

Other requirements—It meets the requirements for *Uniformity of Dosage Units* ⟨905⟩.

Assay—

pH 3.4 Acetate buffer, Mobile phase, Internal standard solution, Standard preparation, and *Chromatographic system*—Prepare as directed in the *Assay* under *Cefuroxime Sodium.*

Assay preparation—Allow a container of Injection to thaw, and mix the solution. Transfer an accurately measured volume of the Injection, equivalent to about 50 mg of cefuroxime, to a 50-mL volumetric flask, dilute with water to volume, and mix. Immediately transfer 5.0 mL of this solution to a second 100-mL volumetric flask, add 20.0 mL of *Internal standard solution*, dilute with water to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Cefuroxime Sodium.* Calculate the quantity, in mg, of cefuroxime ($C_{16}H_{16}N_4O_8S$) in each mL of the Injection taken by the formula:

$$1000(C/V)(R_U/R_S)$$

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
CEFUROXIME INJECTION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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Current DocID: GUID-2BFA0D04-F004-42FA-8C0F-0B314C91C0D7_3_en-US
Previous DocID: GUID-2BFA0D04-F004-42FA-8C0F-0B314C91C0D7_1_en-US
DOI: https://doi.org/10.31003/USPNF_M14156_03_01
DOI ref: x0uug