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Cefuroxime for Injection

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

USP Reference standards ⟨11⟩—
USP Cefuroxime Sodium RS

Constituted solution—At the time of use, the constituted solution for intravenous administration prepared from Cefuroxime for Injection 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 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*.

Uniformity of dosage units ⟨905⟩: meets the requirements.

Procedure for content uniformity—Perform the *Assay* on individual containers using *Assay preparation 1* or *Assay preparation 2*, or both, as appropriate.

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

Other requirements—It meets the requirements of the tests for *Identification*, *pH*, and *Water* under *Cefuroxime Sodium*. It meets also the requirements for *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*.

Assay—

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

Assay preparation 1 (where it is represented as being in a single-dose container)—Constitute Cefuroxime 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 water to obtain a solution containing about 1 mg of cefuroxime per mL. Immediately transfer 5.0 mL of the resulting solution to a 100-mL volumetric flask, add 20.0 mL of *Internal standard solution*, dilute with water to volume, and mix.

Assay preparation 2 (where the label states the quantity of cefuroxime in a given volume of constituted solution or suspension)—Constitute Cefuroxime 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 or suspension quantitatively with water to obtain a solution containing about 1 mg of cefuroxime per mL. Immediately transfer 5.0 mL of the resulting solution to a 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 ($C_{16}H_{16}N_4O_8S$) withdrawn from the container, or in the portion of constituted solution or suspension taken by the formula:

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

in which L is the labeled quantity, in mg of cefuroxime ($C_{16}H_{16}N_4O_8S$), in the container, or in the volume of constituted solution or suspension taken; D is the concentration, in mg of cefuroxime ($C_{16}H_{16}N_4O_8S$) 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 or suspension taken, respectively, and the extent of dilution; C is the concentration, in mg of cefuroxime ($C_{16}H_{16}N_4O_8S$) per mL, of the *Standard preparation;* and R_U and R_S are the peak response ratios of cefuroxime to the internal standard obtained from the *Assay preparation* and the *Standard preparation,* respectively. Where the test for *Uniformity of dosage units* has been performed using the *Procedure for content uniformity*, use the average of these determinations as the *Assay* value.

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

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

Chromatographic Database Information: Chromatographic Database

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