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Cefoxitin for Injection

DEFINITION
Cefoxitin for Injection contains Cefoxitin Sodium equivalent to NLT 90.0% and NMT 120.0% of the labeled amount of cefoxitin ($C_{16}H_{17}N_3O_7S_2$).

ASSAY

• **Procedure**

Buffer: Dissolve 1.0 g of monobasic potassium phosphate and 1.8 g of dibasic sodium phosphate in 900 mL of water. Adjust with phosphoric acid or 10 N sodium hydroxide to a pH of 7.1 ± 0.1, and dilute with water to 1 L. Pass through a membrane filter of 1-µm or finer pore size.

Mobile phase: Acetonitrile, water, and glacial acetic acid (160:840:10). Pass through a membrane filter of 1-µm or finer pore size.

Standard solution: 0.3 mg/mL of USP Cefoxitin RS in *Buffer*. Sonicate, if necessary, to dissolve. Use this solution within 5 h.

Sample solution 1 (where it is represented as being in a single-dose container)**:** Nominally 0.3 mg/mL of cefoxitin prepared as follows. Constitute Cefoxitin for Injection in a volume of water corresponding to the volume of solvent specified in the labeling. Withdraw all of the withdrawable contents, using a suitable hypodermic needle and syringe, transfer to a suitable volumetric flask, and dilute with water to volume. Use this solution within 5 h.

Sample solution 2 (where the label states the quantity of cefoxitin in a given volume of constituted solution)**:** Nominally 0.3 mg/mL of cefoxitin prepared as follows. Constitute Cefoxitin for Injection in a volume of water corresponding to the volume of solvent specified in the labeling. Transfer a suitable aliquot of the constituted solution to a suitable volumetric flask, and dilute with water to volume. Use this solution within 5 h.

Chromatographic system
(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; 5- to 10-µm packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 2800 theoretical plates

Tailing factor: NMT 1.5

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Sample solution 1* or *Sample solution 2* and *Standard solution*

Calculate the percentage of the labeled amount of cefoxitin ($C_{16}H_{17}N_3O_7S_2$) in the portion of Cefoxitin for Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times P \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

C_U = nominal concentration of cefoxitin in *Sample solution 1* or *Sample solution 2* (mg/mL)

P = potency of cefoxitin in USP Cefoxitin RS (mg/mg)

Acceptance criteria: 90.0%–120.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements

SPECIFIC TESTS

• **Constituted Solution:** At the time of use, it meets the requirements in *Injections and Implanted Drug Products ⟨1⟩, Specific Tests, Completeness and clarity of solutions*.

• **Bacterial Endotoxins Test ⟨85⟩:** NMT 0.13 USP Endotoxin Unit/mg of cefoxitin

• **Sterility Tests ⟨71⟩:** It meets the requirements when tested as directed in *Test for Sterility of the Product to Be Examined, Membrane Filtration*.

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

• **pH ⟨791⟩**

Sample solution: 100 mg/mL

Acceptance criteria: 4.2–7.0

• **Water Determination, *Method I*⟨921⟩**

Analysis: Use a mixture of ethylene glycol and pyridine (3:1) in the titration vessel in place of methanol.

Acceptance criteria: NMT 1.0%

• **Other Requirements:** It meets the requirements of the *Identification* tests in *Cefoxitin Sodium*. It meets the requirements in *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for constitution*.

• **USP Reference Standards ⟨11⟩**

USP Cefoxitin RS

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

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

Chromatographic Database Information: Chromatographic Database

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