Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-EAC9A49E-EA2D-46BC-9E32-8B5C2583EAE9_3_en-US
DOI: https://doi.org/10.31003/USPNF_M14106_03_01
DOI Ref: qsr1f

Cefoxitin Injection

DEFINITION

Cefoxitin Injection is a sterile solution of Cefoxitin Sodium and one or more suitable buffer substances in Water for Injection. It contains Dextrose or Sodium Chloride as a tonicity-adjusting agent. It contains the equivalent of NLT 90.0% and NMT 120.0% of the labeled amount of cefoxitin ($C_{16}H_{17}N_3O_7S_2$).

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

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: 0.3 mg/mL of cefoxitin prepared as follows. Allow one container of Injection to thaw, and mix. Dilute an aliquot of Injection with *Buffer* to a suitable 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: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of cefoxitin ($C_{16}H_{17}N_3O_7S_2$) in the portion of 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 the *Sample solution* (mg/mL)

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

Acceptance criteria: 90.0%–120.0%

SPECIFIC TESTS

• **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*.

• **pH ⟨791⟩:** 4.5–8.0

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

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging*. Maintain in the frozen state.

• **Labeling:** It meets the requirements in *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*. The label states that it is to be thawed just before 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 Cefoxitin RS

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

Topic/Question	Contact	Expert Committee
CEFOXITIN INJECTION	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 46(6)

Current DocID: GUID-EAC9A49E-EA2D-46BC-9E32-8B5C2583EAE9_3_en-US
Previous DocID: GUID-EAC9A49E-EA2D-46BC-9E32-8B5C2583EAE9_1_en-US
DOI: https://doi.org/10.31003/USPNF_M14106_03_01
DOI ref: qsr1f