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Cefotetan Injection

DEFINITION

Cefotetan Injection is a sterile isoosmotic solution of Cefotetan and Sodium Bicarbonate in Water for Injection. It contains one or more buffer substances and a tonicity-adjusting agent. It contains NLT 90.0% and NMT 120.0% of the labeled amount of cefotetan ($C_{17}H_{17}N_7O_8S_4$).

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**

Protect the *Standard solution*, the *System suitability solution*, and the *Sample solution* from light. Use the *Standard solution* and the *System suitability solution* within 2 h. Use the *Sample solution* within 10 min.

Mobile phase: Methanol, acetonitrile, glacial acetic acid, and 0.1 M phosphoric acid (105:105:100:1700)

Standard solution: 0.2 mg/mL of USP Cefotetan RS in methanol, acetonitrile, and water (5:5:90), prepared as follows. Place a suitable quantity of USP Cefotetan RS in a suitable volumetric flask, and add methanol, using 5% of the final volume. Swirl for several min, and add acetonitrile, using 5% of the final volume. Swirl until dissolved, and dilute with water to volume.

System suitability solution: Transfer 10 mL of *Standard solution* to a glass-stoppered flask containing a few mg of magnesium carbonate. Sonicate for 10 min. If the solution is not turbid, add a few more mg of magnesium carbonate, and repeat the sonication. Pass the turbid solution through a filter of 0.5-µm or finer pore size. Use the clear filtrate.

Sample solution: 0.2 mg/mL of cefotetan in methanol, acetonitrile, and water (5:5:90) from Injection, prepared as follows. Allow the contents of a container of Injection to thaw, and mix the resultant solution. Transfer a suitable aliquot of this solution to a suitable volumetric flask, and dilute with *Mobile phase* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—The relative retention times for cefotetan and cefotetan tautomer are 0.75 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between cefotetan and cefotetan tautomer, *System suitability solution*

Column efficiency: NLT 1500 theoretical plates, *Standard solution*

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of cefotetan ($C_{17}H_{17}N_7O_8S_4$) in the portion of Injection taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Cefotetan RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of cefotetan in the *Sample solution* (mg/mL)

P = potency of cefotetan in USP Cefotetan RS (µg/mg)

F = conversion factor, 0.001 mg/µg

Acceptance criteria: 90.0%–120.0%

SPECIFIC TESTS

- **Bacterial Endotoxins Test ⟨85⟩:** NMT 0.17 USP Endotoxin Unit/mg of cefotetan
- **Sterility Tests ⟨71⟩:** Meets the requirements when tested as directed for *Test for Sterility of the Product to Be Examined, Membrane Filtration*.
- **pH ⟨791⟩:** 4.0–6.5
- **Particulate Matter in Injections ⟨788⟩:** 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:** 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 the conditions for proper storage of the resultant solution, and directs that the solution is not to be refrozen.
- **USP Reference Standards ⟨11⟩**
  USP Cefotetan RS

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

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

Chromatographic Database Information: Chromatographic Database

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