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Cefotetan for Injection

DEFINITION

Cefotetan for Injection contains an amount of Cefotetan Disodium equivalent to 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 appropriate *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

• **B.** **Identification Tests—General, *Sodium*⟨191⟩:** Meets the requirements

ASSAY

• **Procedure**

[Note—Protect the *Standard solution*, the *System suitability solution*, *Sample solution A*, and *Sample solution B* from light, and use within 2 h.]

Solution A: Acetonitrile, methanol, and water (1:1:18)

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

Standard solution: 20 mg of USP Cefotetan RS in a 100-mL volumetric flask. Add 5 mL of methanol, swirl for several min, add 5 mL of acetonitrile, and swirl until dissolved. Dilute with water to volume.

System suitability solution: 10 mL of *Standard solution* in 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. Filter the turbid solution through a filter of 0.5-µm or finer pore size. Use the clear filtrate.

Sample solution A (where the package is represented as being in a single-dose container)**:** Constitute Cefotetan for Injection as directed in the labeling. Withdraw all of the withdrawable contents, and quantitatively dilute with *Solution A* to obtain a solution containing the equivalent of 200 µg/mL of cefotetan.

Sample solution B (where the label states the quantity of cefotetan in a given volume of constituted solution)**:** Constitute Cefotetan for Injection as directed in the labeling. Dilute an aliquot of the constituted solution with *Solution A* to obtain a solution containing the equivalent of 200 µg/mL of cefotetan.

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 size: 20 µL

System suitability

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

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

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 A* or *Sample solution B*

Calculate the percentage of $C_{17}H_{17}N_7O_8S_4$ withdrawn from the container, or in the portion of solution taken:

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

r_U = peak response from *Sample solution A* or *Sample solution B*

r_S = peak response from the *Standard solution*

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

C_U = nominal concentration of cefotetan in *Sample solution A* or *Sample solution B* (µg/mL)

Acceptance criteria: 90.0%–120.0%

PERFORMANCE TESTS

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

SPECIFIC TESTS

• **Injections and Implanted Drug Products ⟨1⟩, *Specific Tests, Completeness and clarity of solutions*:** Meets the requirements at the time of use

• **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*

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

• **pH ⟨791⟩:** 4.0–6.5, in a solution 100 mg/mL

• **Water Determination, *Method Ic*⟨921⟩:** NMT 2.8%

• **Other Requirements:** It meets the requirements under *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*.

ADDITIONAL REQUIREMENTS

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

• **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 FOR INJECTION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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