Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-3781EE03-6925-4713-B0B3-48CABB3B45A8_3_en-US
DOI: https://doi.org/10.31003/USPNF_M14084_03_01
DOI Ref: e0uxd

Cefotaxime Injection

DEFINITION

Cefotaxime Injection is a sterile solution of Cefotaxime Sodium in Water for Injection. It contains one or more suitable buffers, and it may contain Dextrose or Sodium Chloride as a tonicity-adjusting agent. It contains the equivalent of NLT 90.0% and NMT 110.0% of the labeled amount of cefotaxime ($C_{16}H_{17}N_5O_7S_2$).

IDENTIFICATION

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

ASSAY

• **Procedure**

Buffer: 7.1 g/L of anhydrous dibasic sodium phosphate in water, adjusted with phosphoric acid to a pH of 6.25

Solution A: Methanol and *Buffer* (14:86). Pass through a filter having a pore size of 0.5 µm or less, and degas before use.

Solution B: Methanol and *Buffer* (40:60). Pass through a filter having a pore size of 0.5 µm or less, and degas before use.

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
7	100	0
9	80	20
16	80	20
46	0	100
51	0	100
56	100	0

Standard solution: 0.8 mg/mL of USP Cefotaxime Sodium RS in *Solution A*. Use this solution promptly. It may be used within 24 h if stored in a refrigerator.

System suitability solution: Mix 1 mL of *Standard solution*, 7.0 mL of water, and 2.0 mL of methanol. Add 25 mg of sodium carbonate, mix, and allow to stand at room temperature for 10 min, with occasional swirling. Add 3 drops of glacial acetic acid and 1 mL of *Standard solution*.

Sensitivity solution: 1.6 µg/mL of USP Cefotaxime Sodium RS in *Solution A*

Sample solution: Nominally 0.8 mg/mL of cefotaxime,prepared as follows. Allow one container of Injection to thaw, and mix. Transfer an aliquot of the Injection to a suitable volumetric flask, and dilute with *Solution A* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 235 nm

Column: 3.9-mm × 15-cm; 5-µm packing L1

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Samples: *Standard solution, System suitability solution*, and *Sensitivity solution*. [NOTE—The retention times for desacetylcefotaxime and cefotaxime in the *System suitability solution* are 3.5 min and 14 min, respectively. The retention time for cefotaxime in the *Standard solution* is 12–15 min.]

Suitability requirements

Sensitivity: The response of the cefotaxime peak from the *Sensitivity solution* is between 0.18% and 0.22% of the response of the cefotaxime peak of the *Standard solution*.

Resolution: NLT 20 between desacetylcefotaxime and cefotaxime, *System suitability solution*

Tailing factor: NMT 2, *Standard solution*

Relative standard deviation: NMT 1.5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of cefotaxime ($C_{16}H_{17}N_5O_7S_2$) in the portion of Injection taken:

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

r_U = peak area of the *Sample solution*

r_S = peak area of the *Standard solution*

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

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

P = potency of cefotaxime in USP Cefotaxime Sodium RS (µg/mg)

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• **ORGANIC IMPURITIES**

Mobile phase, Standard solution, System suitability solution, Sensitivity solution, Sample solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Analysis

Calculate the percentage of each impurity in the portion of Injection taken:

$$\text{Result} = r_U/(r_T + r_C) \times 100$$

r_U = peak area of each individual impurity

r_T = sum of all of the impurity peak areas

r_C = peak area of cefotaxime

Acceptance criteria

Disregard any impurity peak that is less than 0.1%.

Individual impurities: NMT 6.0%

Total impurities: NMT 10.0%

SPECIFIC TESTS

• **BACTERIAL ENDOTOXINS TEST ⟨85⟩:** NMT 0.20 USP Endotoxin Unit/mg of cefotaxime

• **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⟩:** 5.0–7.5

• **PARTICULATE MATTER IN INJECTIONS ⟨788⟩:** It meets the requirements for small-volume injections.

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in single-dose containers, as described in *Packaging and Storage Requirements ⟨659⟩*. 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 Cefotaxime Sodium RS

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

Chromatographic Database Information: Chromatographic Database

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Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-3781EE03-6925-4713-B0B3-48CABB3B45A8_3_en-US
Previous DocID: GUID-3781EE03-6925-4713-B0B3-48CABB3B45A8_1_en-US
DOI: https://doi.org/10.31003/USPNF_M14084_03_01
DOI ref: e0uxd