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Ticarcillin for Injection

DEFINITION

Ticarcillin for Injection contains an amount of Ticarcillin Disodium equivalent to NLT 90.0% and NMT 115.0% of the labeled amount of ticarcillin ($C_{15}H_{16}N_2O_6S_2$).

ASSAY

• **Procedure**

Buffer A: 13.8 g/L of monobasic sodium phosphate in water adjusted with phosphoric acid or 10 N sodium hydroxide to a pH of 4.3 ± 0.1 before final dilution

Buffer B: 6.9 g/L of monobasic sodium phosphate adjusted with 10 N sodium hydroxide to a pH of 6.4 ± 0.1 before final dilution

Mobile phase: Acetonitrile and *Buffer A* (5:95)

System suitability stock solution: 0.15 mg/mL of clavulanic acid from USP Clavulanate Lithium RS in *Buffer B*

System suitability solution: 30 µg/mL of clavulanic acid from *System suitability stock solution* and 1 mg/mL of USP Ticarcillin Monosodium Monohydrate RS in *Buffer B*. Use this solution on the day prepared.

Standard solution: 1 mg/mL of USP Ticarcillin Monosodium Monohydrate RS in *Buffer B*

Sample solution 1 (where the article is represented as being in a single-dose container)**:** Nominally 0.9 mg/mL of ticarcillin prepared as follows. Constitute Ticarcillin for Injection as directed in the labeling. Withdraw all of the withdrawable contents, and dilute with *Buffer B*.

Sample solution 2 (where the label states the quantity of ticarcillin in a given volume of constituted solution)**:** Nominally 0.9 mg/mL of ticarcillin prepared as follows. Constitute Ticarcillin for Injection as directed in the labeling. Dilute a suitable aliquot of the constituted solution with *Buffer B*.

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4-mm × 30-cm; 3- to 10-µm 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 clavulanic acid and ticarcillin are 0.2 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 5.0 between clavulanic acid and ticarcillin, *System suitability solution*

Column efficiency: NLT 1000 theoretical plates, *Standard solution*

Tailing factor: NMT 2.0, *Standard solution*

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

Analysis

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

Calculate the percentage of the labeled amount of ticarcillin ($C_{15}H_{16}N_2O_6S_2$) in the portion of Ticarcillin for Injection taken:

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

r_U = peak response of ticarcillin from *Sample solution 1* or *Sample solution 2*

r_S = peak response of ticarcillin from the *Standard solution*

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

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

P = potency of ticarcillin in USP Ticarcillin Monosodium Monohydrate RS (µg/mg)

F = conversion factor, 0.001 mg/µg

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

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

IMPURITIES

• **Dimethylaniline ⟨223⟩:** Meets the requirements

SPECIFIC TESTS

• **Content of Ticarcillin**

This test is to be performed on Ticarcillin for Injection that contains no added substances.

Solution A: 0.1 N methanolic hydrochloric acid prepared by diluting 4 mL of hydrochloric acid with methanol to 500 mL

Standard stock solution: 0.4 mg/mL of USP Ticarcillin Monosodium Monohydrate RS in water

Standard solution: 20 µg/mL of USP Ticarcillin Monosodium Monohydrate RS from *Standard stock solution* in *Solution A*

Sample stock solution: 0.4 mg/mL of ticarcillin from Ticarcillin for Injection in water

Sample solution: 20 µg/mL of ticarcillin from *Sample stock solution* in *Solution A*

Blank: Dilute 5.0 mL of water with *Solution A* to 100 mL.

Instrumental conditions

Analytical wavelength: 230 nm

Cell: 1 cm

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Calculate the percentage of ticarcillin ($C_{15}H_{16}N_2O_6S_2$) in the portion of Ticarcillin for Injection taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times P \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

C_U = nominal concentration of ticarcillin in the *Sample solution* (µg/mL)

P = potency of ticarcillin in USP Ticarcillin Monosodium Monohydrate RS (µg/mg)

Acceptance criteria: 80.0%–94.0% on the anhydrous basis

• **Bacterial Endotoxins Test ⟨85⟩:** It contains NMT 0.05 USP Endotoxin Unit/mg of ticarcillin.

• **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⟩**

Sample solution: Constitute as directed in the labeling.

Acceptance criteria: 6.0–8.0

• **Labeling ⟨7⟩, *Labels and Labeling for Injectable Products*:** Meets the requirements

• **Water Determination, *Method I*⟨921⟩:** NMT 6.0%

• **Optical Rotation, *Specific Rotation* ⟨781S⟩**

This test is to be performed on Ticarcillin for Injection that contains no added substances.

Sample solution: 10 mg/mL of Ticarcillin for Injection in water

Acceptance criteria: +172° to +187°

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

• **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*.

• **Other Requirements:** It meets the requirements of the *Identification* tests in *Ticarcillin Disodium*. 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 Clavulanate Lithium RS

  USP Ticarcillin Monosodium Monohydrate RS

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

Topic/Question	Contact	Expert Committee
TICARCILLIN FOR 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:
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