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Ampicillin for Injection

DEFINITION

Ampicillin for Injection contains an amount of Ampicillin Sodium equivalent to NLT 90.0% and NMT 115.0% of the labeled amount of ampicillin ($C_{16}H_{19}N_3O_4S$).

ASSAY

• **Procedure**

Mobile phase: Acetonitrile, water, 1 M monobasic potassium phosphate, and 1 N acetic acid (80:909:10:1)

Diluent: Water, 1 M monobasic potassium phosphate, and 1 N acetic acid (989:10:1)

Standard solution: 1 mg/mL of USP Ampicillin RS in *Diluent*. Shake and sonicate, if necessary, to dissolve. Use this solution promptly after preparation.

System suitability solution: 0.12 mg/mL of caffeine in the *Standard solution*

Sample solution 1 (where it is represented as being in a single-dose container)**:** 1 mg/mL of ampicillin in *Diluent*. Constitute Ampicillin for Injection in a volume of *Diluent*, corresponding to the volume of solvent specified in the labeling. Withdraw all of the withdrawable contents, using a suitable hypodermic needle and syringe, and dilute with *Diluent*. Use this solution promptly after preparation.

Sample solution 2 (where the label states the quantity of ampicillin in a given volume of constituted solution)**:** 1 mg/mL of ampicillin in *Diluent*. Constitute 1 container of Ampicillin for Injection in a volume of *Diluent*, corresponding to the volume of solvent specified in the labeling. Dilute a suitable aliquot of the constituted solution with *Diluent*. Use this solution promptly after preparation.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Columns

Precolumn: 4-mm × 5-cm; 5- to 10-µm packing L1

Analytical: 4-mm × 30-cm; 5- to 10-µm packing L1

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

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

[Note—The relative retention times for ampicillin and caffeine are 0.5 and 1.0, respectively, *System suitabilty solution*.]

Suitability requirements

Resolution: NLT 2.0 between caffeine and ampicillin, *System suitability solution*

Tailing factor: NMT 1.4, *Standard solution*

Capacity factor: NMT 2.5, *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 ampicillin ($C_{16}H_{19}N_3O_4S$) in the container or in the volume of constituted solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times P \times (1/F) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

P = potency of ampicillin in USP Ampicillin RS (µg/mg)

F = conversion factor, 0.001 mg/µg

Where the test for *Uniformity of Dosage Units* has been performed using the *Procedure for content uniformity*, use the average of these determinations as the *Assay* value.

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

Change to read:

• **Uniformity of Dosage Units ⟨905⟩:** ▲Meets the requirements▲ (CN 1-Aug-2023)

Procedure for content uniformity

Analysis: Perform the *Assay* on individual containers using *Sample solution 1* or *Sample solution 2*, or both, as appropriate.

▲▲ (CN 1-Aug-2023)

SPECIFIC TESTS

• **Crystallinity ⟨695⟩:** Meets the requirements. Freeze-dried products are exempt from this requirement.

• **pH ⟨791⟩**

Sample solution: 10.0 mg/mL of ampicillin

Acceptance criteria: 8.0–10.0

• **Water Determination, *Method I*⟨921⟩:** NMT 2.0%

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

• **Sterility Tests ⟨71⟩:** Meets the requirements

• **Bacterial Endotoxins Test ⟨85⟩:** NMT 0.15 USP Endotoxin Units/mg of ampicillin

• **Constituted Solution:** At the time of use, it meets the requirements for *Injections and Implanted Drug Products ⟨1⟩, Specific Tests, Completeness and clarity of solutions.*

• **Other Requirements:** It meets the requirements of the tests for *Identification* in *Ampicillin Sodium*. It also 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*. Protect the constituted solution from freezing.

• **USP Reference Standards ⟨11⟩**

USP Ampicillin RS

USP Ampicillin Sodium RS

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

Topic/Question	Contact	Expert Committee
AMPICILLIN 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:
Pharmacopeial Forum: Volume No. Information currently unavailable

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