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Ampicillin for Oral Suspension

DEFINITION

Ampicillin for Oral Suspension contains an amount of Ampicillin (anhydrous or as the trihydrate) equivalent to NLT 90.0% and NMT 120.0% of the labeled amount of ampicillin ($C_{16}H_{19}N_3O_4S$), when constituted as directed. It contains one or more suitable buffers, colors, flavors, preservatives, and sweetening ingredients.

IDENTIFICATION

• **A. Thin-Layer Chromatography**

Diluent: Acetone and 0.1 N hydrochloric acid (4:1)

Standard solution: 5 mg/mL of USP Ampicillin RS in *Diluent*

Sample solution: Nominally 5 mg/mL of ampicillin in *Diluent*

Chromatographic system

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 2 µL

Developing solvent system: Acetone, toluene, glacial acetic acid, and water (650:100:25:100)

Spray reagent: 3 mg/mL of ninhydrin in alcohol

Analysis

Samples: *Standard solution* and *Sample solution*

Apply the *Standard solution* and the *Sample solution* to the plate, and develop the chromatogram in the *Developing solvent system*. When the solvent front has moved about three-fourths of the length of the plate, remove the plate from the chamber, mark the solvent front, and allow to air-dry. Locate the spots on the plate by spraying lightly with *Spray reagent*, and dry at 90° for 15 min.

Acceptance criteria: The R_F value of the principal spot of the *Sample solution* corresponds to that of the *Standard solution*.

ASSAY

• **Procedure**

Standard solution: Prepare as directed for *Standard preparation* in *Iodometric Assay—Antibiotics ⟨425⟩*, using USP Ampicillin RS.

Sample solution: Nominally 1.25 mg/mL of ampicillin prepared as follows. Dilute a suitable aliquot of Ampicillin for Oral Suspension, constituted as directed in the labeling, freshly mixed and free from air bubbles, with water.

Analysis: Proceed as directed for *Iodometric Assay—Antibiotics ⟨425⟩, Procedure*.

Calculate the percentage of the labeled amount of ampicillin ($C_{16}H_{19}N_3O_4S$) in the portion of Ampicillin for Oral Suspension taken:

$$\text{Result} = (B - I) \times F \times (1/C_U) \times 100$$

B = volume of 0.01 N sodium thiosulfate consumed in the *Blank Determination* (mL)

I = volume of 0.01 N sodium thiosulfate consumed in the *Inactivation and Titration* (mL)

F = factor as calculated in *Iodometric Assay—Antibiotics ⟨425⟩*

C_U = nominal concentration of ampicillin in the *Sample solution* (mg/ml)

Acceptance criteria: 90.0%–120.0%

PERFORMANCE TESTS

• **Deliverable Volume ⟨698⟩:** Meets the requirements

• **Uniformity of Dosage Units ⟨905⟩**

For single-unit containers

Acceptance criteria: Meets the requirements

SPECIFIC TESTS

• **pH ⟨791⟩**

Sample solution: Constitute as directed in the labeling.

Acceptance criteria: 5.0–7.5

• **Water Determination, *Method I*⟨921⟩:** NMT 2.5% where the solid for Oral Suspension contains anhydrous ampicillin or NMT 5.0% if it contains ampicillin trihydrate and the equivalent of 100 mg/mL of ampicillin when constituted as directed in the labeling

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **Labeling:** Label to indicate whether the ampicillin therein is in the anhydrous form or is the trihydrate.

• **USP Reference Standards ⟨11⟩**

USP Ampicillin RS

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

Topic/Question	Contact	Expert Committee
AMPICILLIN FOR ORAL SUSPENSION	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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