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

Ampicillin Tablets

DEFINITION
Ampicillin Tablets contain an amount of Ampicillin (anhydrous form or trihydrate form) equivalent to NLT 90.0% and NMT 120.0% of the labeled amount of ampicillin ($C_{16}H_{19}N_3O_4S$).

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: 5 mg/mL of ampicillin from powdered Tablets in *Diluent*
  Chromatographic system
  (See *Chromatography* ⟨621⟩, *Thin-Layer Chromatography*.)
  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 using 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 the *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: Place NLT 5 Tablets in a high-speed glass blender jar containing an accurately measured volume of water, and blend for 4 ± 1 min. Dilute a suitable aliquot with water to obtain a concentration of 1.25 mg/mL of ampicillin.
  Analysis
  Samples: *Standard solution* and *Sample solution*
  Proceed as directed for *Procedure* in *Iodometric Assay—Antibiotics* ⟨425⟩.
  Calculate the percentage of the labeled amount of ampicillin ($C_{16}H_{19}N_3O_4S$) in the portion of Tablets taken:

$$\text{Result} = (B - I) \times (F_1/2) \times (1/C_U) \times F_2 \times 100$$

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* of the *Sample solution* (mL)
F_1 = factor as calculated in *Iodometric Assay—Antibiotics* ⟨425⟩
C_U = nominal concentration of ampicillin in the *Sample solution* (mg/mL)
F_2 = conversion factor, 0.001 mg/µg
Acceptance criteria: 90.0%–120.0%

PERFORMANCE TESTS
- **DISSOLUTION,** *Procedure for a Pooled Sample* ⟨711⟩
  Medium: Water; 900 mL
  Apparatus 1: 100 rpm
  Time: 45 min
  Standard solution: L/900 mg/mL of USP Ampicillin RS in water, where L is the labeled amount of ampicillin in mg/Tablet
  Sample solution: Use a filtered portion of the solution under test.
  Solution A: 1 in 1000 solution of polyoxyethylene (23) lauryl ether in water
  Solution B: Dissolve 20 g of hydroxylamine hydrochloride in 5 mL of *Solution A*, and add water to make 1000 mL.
  Buffer: 26 mg/mL of sodium hydroxide and 3.1 mg/mL of sodium acetate in water
  Ferric nitrate solution: Suspend 233 g of ferric nitrate in about 600 mL of water, add 2.8 mL of sulfuric acid, stir until the ferric nitrate is dissolved, add 1 mL of polyoxyethylene (23) lauryl ether, dilute with water to 1000 mL, and mix.
  Apparatus: Automatic analyzer consisting of (1) a liquid sampler, (2) a proportioning pump, (3) suitable spectrophotometers equipped with matched flow cells and analysis capability at 480 nm, (4) a means of recording spectrophotometric readings, and/or computer for data retrieval and calculation, and (5) a manifold consisting of the components illustrated in *Figure 1*.