dose level of the Standard. [NOTE—The amount of hydrochloric acid in the *Test dilution* should be the same as that in the median dose level of the Standard.]
Analysis: Proceed as directed for Bacitracin in *Antibiotics—Microbial Assays* ⟨81⟩.
Acceptance criteria: NLT 8 Bacitracin Units/mg on the dried basis

SPECIFIC TESTS
- **pH** ⟨791⟩**:** 8.0–9.5, in a 25 mg/mL solution
- **Loss on Drying** ⟨731⟩**:** Dry 100 mg in a capillary-stoppered bottle in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 h: it loses NMT 8.5% of its weight.

ADDITIONAL REQUIREMENTS
- **Packaging and Storage:** Preserve in well-closed containers.
- **Labeling:** Label it to indicate that it is for veterinary use only.
- **USP Reference Standards** ⟨11⟩
  USP Bacitracin Zinc RS

Bacitracin Methylenedisalicylate Soluble Powder

DEFINITION
Bacitracin Methylenedisalicylate Soluble Powder contains NLT 90.0% and NMT 120.0% of the labeled amount of bacitracin.

ASSAY
- **Antibiotics—Microbial Assays** ⟨81⟩
  Diluent: 20 g/L of sodium bicarbonate
  Sample stock solution: Transfer a suitable amount of Bacitracin Methylenedisalicylate Soluble Powder to a high-speed glass blender jar, add 99.0 mL of *Diluent* and 1.0 mL of polysorbate 80, and blend for 3 min.
  Test dilution: To a suitable aliquot of the *Sample stock solution*, add a suitable volume of 0.01 N hydrochloric acid and dilute with *Buffer B.1* to obtain a concentration of bacitracin assumed to be equal to the median dose level of the Standard. [NOTE—The amount of hydrochloric acid in the *Test dilution* should be the same as that in the median dose level of the Standard.]
  Analysis: Proceed as directed for Bacitracin in *Antibiotics—Microbial Assays* ⟨81⟩.
  Acceptance criteria: 90.0%—120.0%

SPECIFIC TESTS
- **pH** ⟨791⟩**:** 8.0–9.5 in a 50 mg/mL solution
- **Loss on Drying** ⟨731⟩**:** Dry 100 mg in a capillary-stoppered bottle in a vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 h: it loses NMT 8.5% of its weight.

ADDITIONAL REQUIREMENTS
- **Packaging and Storage:** Preserve in tight containers.
- **Labeling:** Label it to indicate that it is for veterinary use only. Label it to state the content of bacitracin in terms of grams per pound, each gram of bacitracin being equivalent to 42,000 Bacitracin Units.
- **USP Reference Standards** ⟨11⟩
  USP Bacitracin Zinc RS

Bacitracin and Polymyxin B Sulfate Topical Aerosol

DEFINITION
Bacitracin and Polymyxin B Sulfate Topical Aerosol is a suspension of Bacitracin and Polymyxin B Sulfate in a suitable vehicle, packaged in a pressurized container with a suitable inert propellant. It contains NLT 90.0% and NMT 130.0% of the labeled amounts of bacitracin and polymyxin B. It may contain a suitable local anesthetic.
Prepare the specimen for the following tests and assays as follows. Maintain the container in the inverted position throughout this procedure. Store the container in a freezer at –70° for 16–24 h. Remove the container from the freezer, promptly puncture the container, and allow the propellant to volatilize. Open the container, and mix the contents.

IDENTIFICATION
- **A. Thin-Layer Chromatographic Identification Test** ⟨201BNP⟩
  Sample: Prepare as directed above.
  Analysis: Test as directed in the section *For Creams, Lotions, and Ointments* in the chapter.
  Acceptance criteria: Meets the requirements

ASSAY
- **Bacitracin**
  (See *Antibiotics—Microbial Assays* ⟨81⟩.)
  Sample solution: Use a portion of the contents of one container, containing nominally 500 USP Bacitracin Units, prepared as directed above. Transfer to a suitable separator containing 50 mL of ether, and extract with three 25-mL portions of *Buffer B.1* (see the chapter). Combine the buffer extracts in a 100-mL volumetric flask, dilute with *Buffer B.1* to volume, and mix.
  Analysis: Proceed as directed in the chapter. Add sufficient 0.01 N hydrochloric acid to this solution so that the amount of hydrochloric acid in the *Test Dilution* is the same as in the median level of the standard. Dilute with *Buffer B.1* to obtain a *Test Dilution* having a bacitracin concentration that is nominally equivalent to the median level of the standard.
  Acceptance criteria: 90.0%–130.0%
- **Polymyxin B**
  (See *Antibiotics—Microbial Assays* ⟨81⟩.)
  Sample solution: Use a portion of the contents of one container, containing nominally 5000 USP Polymyxin B Units, prepared as directed above. Transfer to a suitable separator containing 50 mL of ether, and extract with three 25-mL portions of *Buffer B.6* (see the chapter). Combine the buffer extracts in a 100-mL volumetric flask, dilute with *Buffer B.6* to volume, and mix.
  Analysis: Proceed as directed in the chapter. Dilute a suitable aliquot of the *Sample solution* with *Buffer B.6* to obtain a *Test Dilution* having a polymyxin B concentration that is nominally equivalent to the median level of the standard.
  Acceptance criteria: 90.0%–130.0%

SPECIFIC TESTS
- **Water Determination,** *Method I* ⟨921⟩
  Analysis: Use a portion of the contents of one container, prepared as directed above, and 20 mL of a mixture of toluene and methanol (7:3) in place of methanol in the titration vessel.