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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.

Acceptance criteria: NMT 0.5%

• **Other Requirements:** It meets the requirements for *Topical Aerosols ⟨603⟩*, in the sections *Pressure Test, Minimum Fill,* and *Leakage Test*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in pressurized containers, and avoid exposure to excessive heat.

• **USP Reference Standards ⟨11⟩**

USP Bacitracin Zinc RS
USP Polymyxin B Sulfate RS

Topic/Question	Contact	Expert Committee
BACITRACIN AND POLYMYXIN B SULFATE TOPICAL AEROSOL	Ying Han Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

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