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Polymyxin B Sulfate and Bacitracin Zinc Topical Aerosol

» Polymyxin B Sulfate and Bacitracin Zinc Topical Aerosol contains the equivalent of not less than 90.0 percent and not more than 130.0 percent of the labeled amounts of polymyxin B and bacitracin.

Packaging and storage—Preserve in pressurized containers, and avoid exposure to excessive heat.

Identification—Collect in a suitable container the expelled contents of 1 Aerosol container, shake with a volume of 0.1 N hydrochloric acid sufficient to obtain a solution containing about 500 USP Bacitracin Units per mL, centrifuge, and use the clear supernatant as the test solution. Proceed as directed under *Thin-Layer Chromatographic Identification Test* ⟨201BNP⟩. The specified result is observed.

Microbial enumeration tests ⟨61⟩ **and Tests for specified microorganisms** ⟨62⟩—Collect aseptically in a suitable container half the contents expelled from 5 containers, dissolve in 500 mL of *Fluid A* containing 0.25 g of sodium thioglycollate and adjusted with sodium hydroxide to a pH of 6.6 ± 0.6, pass through a membrane filter as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined* under *Sterility Tests* ⟨71⟩, except to place the filter on the surface of Soybean–Casein Digest Agar Medium in a Petri dish, incubate for 7 days at 30° to 35°, and count the number of colonies on the filter. Similarly prepare a second specimen, except to incubate at 20° to 25°. Not more than 20 colonies are observed from the two specimens. It meets also the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa* under *Microbial Enumeration Tests* ⟨61⟩ and *Tests for Specified Microorganisms* ⟨62⟩.

Water Determination, *Method I* ⟨921⟩—Store 1 container of Topical Aerosol in a freezer for not less than 2 hours, open the container, and transfer 10.0 mL of the freshly mixed specimen to a titration vessel containing 20 mL of a mixture of toluene and methanol (7:3) instead of methanol. In titrating the specimen, determine the endpoint at a temperature of 10° or higher: not more than 0.5% of water is found.

Other requirements—It meets the requirements for *Pressure Test*, *Minimum Fill*, and *Leakage Test* under *Topical Aerosols* ⟨603⟩.

Assay for polymyxin B—Proceed as directed for polymyxin B under *Antibiotics—Microbial Assays* ⟨81⟩, expelling the entire contents of 1 container of Topical Aerosol, according to the directions in the labeling, into a 2000-mL conical flask held in a horizontal position. Add 500.0 mL of 0.01 N hydrochloric acid, and shake to dissolve. Immediately dilute an accurately measured volume of this acidic solution quantitatively and stepwise with *Buffer B.6* to obtain a *Test Dilution* having a concentration of polymyxin B assumed to be equal to the median dose level of the Standard.

Assay for bacitracin—Proceed as directed for bacitracin under *Antibiotics—Microbial Assays* ⟨81⟩, using an accurately measured volume of the acidic solution obtained in the *Assay for polymyxin B* immediately diluted quantitatively and stepwise with *Buffer B.1* to yield a *Test Dilution* having a bacitracin concentration assumed to be equal to the median dose level of the Standard. [Note—Add additional hydrochloric acid to each test dilution of the Standard to obtain the same concentration of hydrochloric acid as in the *Test Dilution*.]

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

Topic/Question	Contact	Expert Committee
POLYMYXIN B SULFATE AND BACITRACIN ZINC TOPICAL AEROSOL	Ying Han Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

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