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Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment

DEFINITION

Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment contains the equivalent of NLT 90.0% and NMT 130.0% of the labeled amounts of bacitracin and polymyxin B.

IDENTIFICATION

• **A. Thin-Layer Chromatographic Identification Test ⟨201BNP⟩:** Meets the requirements

ASSAY

• **Bacitracin**

(See *Antibiotics—Microbial Assays ⟨81⟩*.)

Standard solution: Proceed as directed in the chapter. To each *Test Dilution* of the standard add sufficient hydrochloric acid to obtain the same concentration of hydrochloric acid as in the *Test Dilution* of Ophthalmic Ointment.

Sample solution: Use a portion of Ophthalmic Ointment shaken with about 50 mL of ether in a separator and extracted with four 20-mL portions of 0.01 N hydrochloric acid. Combine the acid extracts, and dilute with 0.01 N hydrochloric acid to a suitable volume.

Analysis: Proceed as directed in the chapter. Dilute the *Sample solution* 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: Shake a portion of Ophthalmic Ointment with about 50 mL of ether in a separator, and extract with four 20-mL portions of *Buffer B.6* (see the chapter). Combine the buffer extracts, and dilute with *Buffer B.6* to a suitable volume.

Analysis: Proceed as directed in the chapter. Dilute 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

• **Sterility Tests ⟨71⟩:** Meets the requirements

• **Other Requirements:** It meets the requirements for *Particulate and Foreign Matter* and *Container Contents* in *Ophthalmic Products—Quality Tests ⟨771⟩, Drug Product Quality, Universal Tests, Particulate and Foreign Matter* and *Container Contents*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in collapsible ophthalmic ointment tubes. Store at controlled room temperature.

• **USP Reference Standards ⟨11⟩**

USP Bacitracin Zinc RS
USP Polymyxin B Sulfate RS

OFFICIAL

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

Topic/Question	Contact	Expert Committee
BACITRACIN ZINC AND POLYMYXIN B SULFATE OPHTHALMIC OINTMENT	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

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