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Bacitracin Zinc and Polymyxin B Sulfate Ointment

DEFINITION

Bacitracin Zinc and Polymyxin B Sulfate Ointment contains the equivalent of NLT 90.0% and NMT 130.0% of the labeled amounts of bacitracin and polymyxin B. It may contain a suitable local anesthetic.

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 Ointment.

Sample solution: Shake a portion of Ointment with about 50 mL of ether in a separator, and extract 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. Add sufficient hydrochloric acid to each *Test Dilution* of the standard to obtain the same concentration of hydrochloric acid as in the *Test Dilution* of the sample.

Acceptance criteria: 90.0%–130.0%

• POLYMYXIN B

(See [Antibiotics—Microbial Assays \(81\)](#)).

Sample solution: Shake a portion of 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

- **[WATER DETERMINATION, Method I \(921\)](#):**

Analysis: Use 20 mL of a mixture of toluene and methanol (7:3) in place of methanol in the titration vessel.

Acceptance criteria: NMT 0.5%

- **[MINIMUM FILL \(755\)](#):** Meets the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed, light-resistant containers.

- **[USP REFERENCE STANDARDS \(11\)](#):**

[USP Bacitracin Zinc RS](#)

[USP Polymyxin B Sulfate RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

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

Chromatographic Database Information: [Chromatographic Database](#)

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