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Bacitracin Zinc Ointment

DEFINITION

Bacitracin Zinc Ointment is Bacitracin Zinc in an anhydrous ointment base. It contains NLT 90.0% and NMT 140.0% of the labeled amount of bacitracin.

IDENTIFICATION

- **A. [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST \(201BNP\)](#):** Meets the requirements

ASSAY

• **PROCEDURE**

(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: Use a portion of 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. 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%–140.0%

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 containers containing NMT 60 g, unless labeled solely for hospital use, preferably at controlled room temperature.

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

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

Topic/Question	Contact	Expert Committee
BACITRACIN ZINC 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

Chromatographic Database Information: [Chromatographic Database](#)

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