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Bacitracin Ophthalmic Ointment

DEFINITION

Bacitracin Ophthalmic Ointment is a sterile preparation of Bacitracin 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 \(81\)](#).)

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 *Buffer B.1* (see the chapter). Combine the buffer extracts, and dilute with *Buffer B.1* to a suitable volume.

Analysis: Proceed as directed in the chapter. Add sufficient [0.01 N hydrochloric acid](#) to a suitable aliquot of the *Sample 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%–140.0%

SPECIFIC TESTS

- **[STERILITY TESTS \(71\)](#):** Meets the requirements
- **OTHER REQUIREMENTS:** It meets the requirements for *Particulate and Foreign Matter* in [Ophthalmic Products—Quality Tests \(771\)](#), [Drug Product Quality, Universal Tests, Particulate and Foreign Matter](#).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in collapsible ophthalmic ointment tubes. Store 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 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

Chromatographic Database Information: [Chromatographic Database](#)

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