

Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-Aug-2017
Document Type: USP Monographs
DocId: GUID-55C3C65D-3D6F-4203-A3B3-2B5A15505B44_1_en-US
DOI: https://doi.org/10.31003/USPNF_M6927_01_01
DOI Ref: m1gk7

© 2025 USPC
Do not distribute

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](#)

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 39(5)

Current DocID: GUID-55C3C65D-3D6F-4203-A3B3-2B5A15505B44_1_en-US

DOI: https://doi.org/10.31003/USPNF_M6927_01_01

DOI ref: [m1gk7](#)

OFFICIAL