

Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Aug-2017
Document Type: USP Monographs
DocId: GUID-1C3E9148-9AE3-4304-8F5B-A481881102ED_1_en-US
DOI: https://doi.org/10.31003/USPNF_M56077_01_01
DOI Ref: 5d4hz

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Neomycin and Polymyxin B Sulfates Ophthalmic Ointment

DEFINITION
Neomycin and Polymyxin B Sulfates Ophthalmic Ointment is a sterile ointment containing Neomycin Sulfate and Polymyxin B Sulfate. It contains the equivalent of NLT 90.0% and NMT 130.0% of the labeled amounts of neomycin and polymyxin B.

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

ASSAY
• **NEOMYCIN**
(See [Antibiotics—Microbial Assays \(81\)](#).)
Sample solution: Shake a portion of Ophthalmic Ointment in a separator with 50 mL of [ether](#). Extract with four 20-mL portions of *Buffer B.3*. Combine the aqueous extracts, and dilute with *Buffer B.3* to a suitable volume.
Analysis: Proceed as directed in the chapter. Dilute the *Sample solution* with *Buffer B.3* to obtain a *Test Dilution* having a neomycin 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 50 mL of [ether](#) in a separator. Extract with four 25-mL portions of *Buffer B.6*. Combine the aqueous 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 concentration that is nominally equivalent to the median level of the standard (10 Polymyxin B Units/mL). Add to each *Test Dilution* of the standard a quantity of [USP Neomycin Sulfate RS](#), dissolved in *Buffer B.6*, to obtain the same concentration of neomycin as in the *Test Dilution* of the sample.
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.
• **[USP REFERENCE STANDARDS \(11\)](#):**
[USP Neomycin Sulfate RS](#)
[USP Polymyxin B Sulfate RS](#)

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

Topic/Question	Contact	Expert Committee
NEOMYCIN AND POLYMYXIN B SULFATES OPHTHALMIC OINTMENT	Julie Zhang 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-1C3E9148-9AE3-4304-8F5B-A481881102ED_1_en-US

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