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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

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