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Neomycin Sulfate Ophthalmic Ointment

DEFINITION
Neomycin Sulfate Ophthalmic Ointment is a sterile preparation of Neomycin Sulfate in a suitable ointment base. It contains the equivalent of NLT 90.0% and NMT 135.0% of the labeled amount of neomycin.

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

ASSAY
• **PROCEDURE**
(See [Antibiotics—Microbial Assays \(81\)](#).)
Sample solution: Shake a portion of the Ophthalmic Ointment containing nominally 3.5 mg of neomycin 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%–135.0%

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](#)

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

Topic/Question	Contact	Expert Committee
NEOMYCIN SULFATE 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](#)

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