

Status: Currently Official on 16-Feb-2025

Official Date: Official Prior to 2013

Document Type: USP Monographs

DocID: GUID-83CBBF53-6812-4694-9E49-951CDE7D53DA_1_en-US

DOI: https://doi.org/10.31003/USPNF_M56240_01_01

DOI Ref: t090v

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Do not distribute

Neomycin and Polymyxin B Sulfates and Gramicidin Ophthalmic Solution

» Neomycin and Polymyxin B Sulfates and Gramicidin Ophthalmic Solution is a sterile, isotonic aqueous solution of Neomycin Sulfate, Polymyxin B Sulfate, and Gramicidin. It contains the equivalent of not less than 90.0 percent and not more than 130.0 percent of the labeled amounts of neomycin, polymyxin B, and gramicidin.

Packaging and storage—Preserve in tight containers. The containers or individual cartons are sealed and tamper-proof so that sterility is assured at time of first use.

USP REFERENCE STANDARDS (11)—

[USP Gramicidin RS](#)

[USP Neomycin Sulfate RS](#)

[USP Polymyxin B Sulfate RS](#)

THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST (201BNP): meets the requirements.

STERILITY TESTS (71)—It meets the requirements when tested as directed for *Membrane Filtration under Test for Sterility of the Product to be Examined*.

pH (791): between 4.7 and 6.0.

Assay for neomycin—Proceed as directed for neomycin under [Antibiotics—Microbial Assays \(81\)](#), using an accurately measured volume of Ophthalmic Solution diluted quantitatively and stepwise with *Buffer B.3* to yield a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard.

Assay for polymyxin B—Proceed as directed for polymyxin B under [Antibiotics—Microbial Assays \(81\)](#), using an accurately measured volume of Ophthalmic Solution diluted quantitatively and stepwise with *Buffer B.6* to yield a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard. 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 is present in the *Test Dilution*.

Assay for gramicidin—Proceed as directed for gramicidin under [Antibiotics—Microbial Assays \(81\)](#), using an accurately measured volume of Ophthalmic Solution diluted quantitatively and stepwise with alcohol to yield a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard.

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

Topic/Question	Contact	Expert Committee
NEOMYCIN AND POLYMYXIN B SULFATES AND GRAMICIDIN OPHTHALMIC SOLUTION	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 28(4)

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