Status: Currently Official on 16-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-0A43FDB5-B4A4-4178-BAB1-65B37F9FCD06_1_en-US
DOI: https://doi.org/10.31003/USPNF_M56278_01_01
DOI Ref: pes5u

Neomycin and Polymyxin B Sulfates and Hydrocortisone Ophthalmic Suspension

» Neomycin and Polymyxin B Sulfates and Hydrocortisone Ophthalmic Suspension is a sterile, aqueous suspension containing the equivalent of not less than 90.0 percent and not more than 130.0 percent of the labeled amounts of neomycin and of polymyxin B. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of hydrocortisone.

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 Hydrocortisone RS
USP Neomycin Sulfate RS
USP Polymyxin B Sulfate RS

Thin-layer chromatographic identification test ⟨201BNP⟩: meets the requirements.

Sterility Tests ⟨71⟩ : meets the requirements.

pH ⟨791⟩: between 4.1 and 7.0.

Assay for neomycin—Proceed as directed for neomycin under *Antibiotics—Microbial Assays ⟨81⟩*, using an accurately measured volume of Ophthalmic Suspension, freshly mixed and free from air bubbles, 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 Suspension, freshly mixed and free from air bubbles, 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 Neomycin Sulfate RS, dissolved in *Buffer B.6*, to yield the same concentration of neomycin as is present in the *Test Dilution*.

Assay for hydrocortisone—

Mobile phase, *Standard preparation*, and *Chromatographic system*—Prepare as directed in the *Assay for hydrocortisone* under *Neomycin and Polymyxin B Sulfates, Bacitracin Zinc and Hydrocortisone Ophthalmic Ointment*.

Assay preparation—Transfer an accurately measured volume of Ophthalmic Suspension, freshly mixed and free from air bubbles, equivalent to about 30 mg of hydrocortisone, to a 200-mL volumetric flask, dilute with a mixture of methanol and water (1:1) to volume, and mix. Filter the solution, rejecting the first 10 mL of the filtrate.

Procedure—Proceed as directed for *Procedure* in the *Assay for hydrocortisone* under *Neomycin and Polymyxin B Sulfates, Bacitracin Zinc and Hydrocortisone Ophthalmic Ointment*. Calculate the quantity, in mg, of $C_{21}H_{30}O_5$ in each mL of the Ophthalmic Suspension taken by the formula:

$$200(C/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Hydrocortisone RS in the *Standard preparation; V* is the volume, in mL, of Ophthalmic Suspension taken; and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE OPHTHALMIC SUSPENSION	Julie Zhang Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Topic/Question	Contact	Expert Committee
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. Information currently unavailable

Current DocID: GUID-0A43FDB5-B4A4-4178-BAB1-65B37F9FCD06_1_en-US
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