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Neomycin and Polymyxin B Sulfates and Prednisolone Acetate Ophthalmic Suspension

» Neomycin and Polymyxin B Sulfates and Prednisolone Acetate Ophthalmic Suspension is a sterile suspension of Prednisolone Acetate in an aqueous solution of Neomycin Sulfate and Polymyxin B Sulfate. It contains the equivalent of not less than 90.0 percent and not more than 125.0 percent of the labeled amounts of neomycin and polymyxin B, and not less than 90.0 percent and not more than 110.0 percent of the labeled amount of prednisolone acetate ($C_{23}H_{30}O_6$). It may contain suitable buffers, preservatives, and suspending agents.

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 Neomycin Sulfate RS
- USP Polymyxin B Sulfate RS
- USP Prednisolone Acetate RS

Identification—The chromatogram of the *Assay preparation* obtained as directed in the *Assay for prednisolone acetate* exhibits a major peak for prednisolone acetate, the retention time of which corresponds to that exhibited in the chromatogram of the *Standard preparation* obtained as directed in the *Assay for prednisolone acetate*.

Sterility Tests ⟨71⟩ **:** meets the requirements.

pH ⟨791⟩**:** between 5.0 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 obtain the same concentration of neomycin as is present in the *Test Dilution*.

Assay for prednisolone acetate—

Mobile phase, *Internal standard solution*, *Standard preparation,* and *Chromatographic system*—Prepare as directed in the *Assay for prednisolone acetate* under *Neomycin Sulfate and Prednisolone Acetate Ophthalmic Suspension*.

Assay preparation—Transfer an accurately measured volume of Ophthalmic Suspension, freshly mixed and free from air bubbles, equivalent to about 2.5 mg of prednisolone acetate, to a suitable container, add 5.0 mL of *Internal standard solution* and about 100 mL of water-saturated chloroform, and shake by mechanical means for about 15 minutes. Allow to separate for about 15 minutes, and use the clear chloroform layer as the *Assay preparation*.

Procedure—Proceed as directed in the *Assay for prednisolone acetate* under *Neomycin Sulfate and Prednisolone Acetate Ophthalmic Suspension*. Calculate the quantity, in mg, of prednisolone acetate ($C_{23}H_{30}O_6$) in each mL of the Ophthalmic Suspension taken by the formula:

$$0.1(C/V)(R_U/R_S)$$

in which C is the concentration, in µg per mL, of USP Prednisolone Acetate RS in the *Standard preparation,* V is the volume, in mL, of Ophthalmic Suspension taken, and R_U and R_S are the peak response ratios of prednisolone acetate to betamethasone obtained from the *Assay preparation* and the *Standard preparation,* respectively.

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

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Topic/Question	Contact	Expert Committee
NEOMYCIN AND POLYMYXIN B SULFATES AND PREDNISOLONE ACETATE OPHTHALMIC SUSPENSION	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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