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Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension

» Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension contains the equivalent of not less than 90.0 percent and not more than 130.0 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 dexamethasone. It may contain one or more suitable buffers, stabilizers, preservatives, and suspending agents.

Packaging and storage—Preserve in tight, light-resistant containers in a cool place or at controlled room temperature. 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 Dexamethasone RS
- USP Neomycin Sulfate RS
- USP Polymyxin B Sulfate RS

Identification—Transfer a quantity of Ophthalmic Suspension, equivalent to about 2.5 mg of dexamethasone, to a suitable test tube, add 5 mL of chloroform, mix, and centrifuge. Apply 25 µL of the lower chloroform layer and 25 µL of a Standard solution of USP Dexamethasone RS in chloroform containing 500 µg per mL to a suitable thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel. Allow the spots to dry, and develop the chromatogram in a solvent system consisting of a mixture of chloroform and diethylamine (2:1) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate. Locate the spots on the plate by examination under short-wavelength UV light: the R_F value of the principal spot obtained from the test solution corresponds to that obtained from the Standard solution.

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 3.5 and 6.0.

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 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 dexamethasone—

Mobile phase and *Chromatographic system*—Proceed as directed in the *Assay for dexamethasone* under *Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment*.

Standard preparation—Dissolve an accurately weighed quantity of USP Dexamethasone RS in *Mobile phase* to obtain a solution having a known concentration of about 0.12 mg per mL.

Assay preparation—Dilute an accurately measured volume of freshly mixed Ophthalmic Suspension quantitatively with *Mobile phase* to obtain a solution containing about 0.12 mg of dexamethasone per mL.

Procedure—Proceed as directed for *Procedure* in the *Assay for dexamethasone* under *Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment*. Calculate the quantity, in mg per mL, of $C_{22}H_{29}FO_5$ in the Ophthalmic Suspension taken by the formula:

$$(CL/D)(r_U/r_S)$$

in which L is the labeled quantity, in mg per mL, of dexamethasone in the Ophthalmic Suspension, D is the concentration, in mg per mL, of dexamethasone in the *Assay preparation* based on the labeled quantity in the Ophthalmic Suspension and the extent of dilution, and the other terms are as defined therein.

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

Topic/Question	Contact	Expert Committee
NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE 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

Chromatographic Database Information: Chromatographic Database

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