Status: Currently Official on 16-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-66775122-DA16-470D-98A0-5E48F210C4AF_2_en-US
DOI: https://doi.org/10.31003/USPNF_M56324_02_01
DOI Ref: 4kmn0

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Neomycin Sulfate and Prednisolone Acetate Ophthalmic Suspension

» Neomycin Sulfate and Prednisolone Acetate Ophthalmic Suspension contains the equivalent of not less than 90.0 percent and not more than 130.0 percent of the labeled amount of neomycin, and not less than 90.0 percent and not more than 110.0 percent of the labeled amount of prednisolone acetate ($C_{23}H_{30}O_6$).

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 Prednisolone Acetate RS

Identification—

A: Filter a portion of Ophthalmic Suspension, freshly mixed but free from air bubbles, equivalent to about 60 mg of prednisolone acetate, discarding the filtrate. Wash the filter with about 10 mL of water, and dry at 105° for 3 hours: the IR absorption spectrum of a potassium bromide dispersion of the dried residue on the filter so obtained exhibits maxima only at the same wavelengths as that of a similar preparation of USP Prednisolone Acetate RS.

B: 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⟩—It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

pH ⟨791⟩: between 5.5 and 7.5.

Assay for neomycin—Proceed with Ophthalmic Suspension as directed in the *Assay for neomycin* under *Neomycin and Polymyxin B Sulfates and Prednisolone Acetate Ophthalmic Suspension*.

Assay for prednisolone acetate—

Mobile phase—Prepare a solution containing *n*-butyl chloride, water-saturated *n*-butyl chloride, tetrahydrofuran, methanol, and glacial acetic acid (95:95:14:7:6).

Internal standard solution—Prepare a solution of betamethasone in tetrahydrofuran containing 10 mg per mL. Dilute this solution with water-saturated chloroform, and mix to obtain a solution having a concentration of about 1 mg per mL.

Standard preparation—Dissolve about 5 mg of USP Prednisolone Acetate RS, accurately weighed, in 10.0 mL of *Internal standard solution*. Use sonication, if necessary, dilute with water-saturated chloroform to 200.0 mL, and mix to obtain a solution having a known concentration of about 25 µg per mL.

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*.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 254-nm detector and a 4-mm × 30-cm column that contains packing L3. The flow rate is about 1 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the resolution, *R,* between the analyte and internal standard peaks is not less than 3.0, and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. The relative retention times are about 1.6 for betamethasone and 1.0 for prednisolone acetate. 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

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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.

Topic/Question	Contact	Expert Committee
NEOMYCIN SULFATE 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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-66775122-DA16-470D-98A0-5E48F210C4AF_2_en-US
Previous DocID: GUID-66775122-DA16-470D-98A0-5E48F210C4AF_1_en-US
DOI: https://doi.org/10.31003/USPNF_M56324_02_01
DOI ref: 4kmn0

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