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Neomycin Sulfate and Prednisolone Acetate Ointment

» Neomycin Sulfate and Prednisolone Acetate Ointment contains the equivalent of not less than 90.0 percent and not more than 135.0 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 collapsible tubes or in tight containers, protected from light.

USP Reference Standards ⟨11⟩—
USP Neomycin Sulfate RS
USP Prednisolone Acetate RS

Identification—

A: It meets the requirements for neomycin under *Thin-Layer Chromatographic Identification Test ⟨201BNP⟩.*

B: The retention time of the major peak for prednisolone acetate in the chromatogram of the *Assay preparation* corresponds to that of the *Standard preparation,* as obtained in the *Assay for prednisolone acetate.*

Minimum fill ⟨755⟩: meets the requirements.

Water Determination, *Method I* ⟨921⟩: not more than 1.0%, 20 mL of a mixture of toluene and methanol (7:3) being used in place of methanol in the titration vessel.

Assay for neomycin—Proceed with Ointment as directed in the *Assay* under *Neomycin Sulfate Ointment*.

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 weighed portion of Ointment, equivalent to about 1 mg of prednisolone acetate, to a suitable container, add 2.0 mL of *Internal standard solution*, dilute with water-saturated chloroform to about 35 mL, and shake to dissolve the ointment. Transfer about 5 mL of this solution to a suitable container, and evaporate to dryness. Add about 5 mL of water-saturated chloroform, and sonicate for 5 minutes. Filter, and use the clear solution as the *Assay preparation*.

Procedure—Proceed as directed for *Procedure* 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 the portion of Ointment taken by the formula:

$$0.04C(R_U/R_S)$$

in which C is the concentration, in µg per mL, of USP Prednisolone Acetate RS in the *Standard preparation,* 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 OINTMENT	Rebecca C. Potts Associate Scientific Liaison	BIO42020 Biologics Monographs 4 - Antibiotics
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO42020 Biologics Monographs 4 - Antibiotics

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