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Neomycin Sulfate and Hydrocortisone Acetate Ophthalmic Suspension

» Neomycin Sulfate and Hydrocortisone Acetate 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 amount of neomycin, and not less than 90.0 percent and not more than 110.0 percent of the labeled amount of hydrocortisone acetate ($C_{23}H_{32}O_6$).

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 Hydrocortisone Acetate RS
USP Neomycin Sulfate RS

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

Sterility Tests ⟨71⟩ : meets the requirements.

pH ⟨791⟩ : between 5.5 and 7.5.

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 hydrocortisone 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 fluoxymesterone in chloroform containing 0.8 mg per mL.

Standard preparation—Dissolve about 10 mg of USP Hydrocortisone Acetate RS, accurately weighed, in 10.0 mL of *Internal standard solution*, dilute with about 40 mL of chloroform, and mix.

Assay preparation—Transfer an accurately measured volume of Ophthalmic Suspension, freshly mixed and free from air bubbles, equivalent to about 10 mg of hydrocortisone acetate, to a suitable container. Add 10.0 mL of *Internal standard solution* and about 40 mL of chloroform, shake vigorously for about 5 minutes, and allow the phases to separate. 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 15 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 0.7 and 1.0 for hydrocortisone acetate and fluoxymesterone, respectively. Calculate the quantity, in mg, of hydrocortisone acetate ($C_{23}H_{32}O_6$) in each mL of the Ophthalmic Suspension taken by the formula:

$$(W/V)(R_U/R_S)$$

in which W is the quantity, in mg, of USP Hydrocortisone Acetate RS taken to prepare 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 the hydrocortisone acetate peak to the internal standard peak obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

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Topic/Question	Contact	Expert Committee
NEOMYCIN SULFATE AND HYDROCORTISONE ACETATE OPHTHALMIC SUSPENSION	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

Chromatographic Database Information: Chromatographic Database

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