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Oxytetracycline Hydrochloride and Hydrocortisone Acetate Ophthalmic Suspension

» Oxytetracycline Hydrochloride and Hydrocortisone Acetate Ophthalmic Suspension is a sterile suspension of Oxytetracycline Hydrochloride and Hydrocortisone Acetate in a suitable oil vehicle with one or more suitable suspending agents. It contains the equivalent of not less than 90.0 percent and not more than 115.0 percent of the labeled amount of oxytetracycline ($C_{22}H_{24}N_2O_9$) 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, light-resistant containers. The containers are sealed and tamper-proof so that sterility is assured at time of first use.

USP Reference standards ⟨11⟩—
USP Hydrocortisone Acetate RS
USP Oxytetracycline RS

Sterility Tests ⟨71⟩—It meets the requirements when tested as directed for *Direct Inoculation of the Culture Medium* under *Test for Sterility of the Product to be Examined* using 0.25 mL of specimen.

Water Determination, *Method I* ⟨921⟩**:** not more than 1.0%, 60 mL of a mixture of methanol and chloroform (2:1) being used instead of methanol in the titration vessel.

Assay for oxytetracycline—Transfer an accurately measured volume of Ophthalmic Suspension to a separator, add 50 mL of ether, and shake. Add 25 mL of 0.1 N hydrochloric acid, shake, and allow to separate. Collect the acid layer, and repeat the extraction with three additional 25-mL portions of 0.1 N hydrochloric acid. Combine the acid extracts in a 200-mL volumetric flask, dilute with 0.1 N hydrochloric acid to volume, and mix. Proceed as directed for oxytetracycline under *Antibiotics—Microbial Assays* ⟨81⟩, using an accurately measured volume of this solution diluted quantitatively and stepwise with water to obtain 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 degassed and filtered mixture of water and methanol (50:50).

Standard preparation—Dissolve an accurately weighed quantity of USP Hydrocortisone Acetate RS in a mixture of *Mobile phase* and alcohol (80:20) to obtain a solution having a known concentration of about 0.06 mg per mL.

Assay preparation—Transfer an accurately measured volume of Ophthalmic Suspension, equivalent to about 30 mg of hydrocortisone acetate, to a separator containing 25 mL of pH 9.0 alkaline borate buffer (see under *Buffer Solutions* in the section *Reagents, Indicators, and Solutions*). Extract with four 25-mL portions of chloroform, filtering each chloroform extract through a thin layer of chloroform-washed anhydrous sodium sulfate into a 250-mL volumetric flask. Rinse the sodium sulfate with chloroform, collecting the filtrate in the volumetric flask, dilute with chloroform to volume, and mix. Transfer 25.0 mL of the resulting solution to a 50-mL conical flask, and evaporate slowly with the aid of mild heat until about 5 mL remains. Add about 15 mL of alcohol, and evaporate slowly until about 5 mL remains. Transfer this solution to a 50-mL volumetric flask, dilute with a mixture of *Mobile phase* and alcohol (80:20) to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 1 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the column efficiency determined from the analyte peak is not less than 235 theoretical plates, the tailing factor for the analyte peak is not more than 1.7, and the relative standard deviation of replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 25 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{23}H_{32}O_6$ in each mL of the Ophthalmic Suspension taken by the formula:

$$500(C/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Hydrocortisone 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 responses 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
OXYTETRACYCLINE HYDROCHLORIDE AND HYDROCORTISONE ACETATE OPHTHALMIC SUSPENSION	Ying Han 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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