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Prednisolone Acetate Ophthalmic Suspension

» Prednisolone Acetate Ophthalmic Suspension is a sterile, aqueous suspension of prednisolone acetate containing a suitable antimicrobial preservative. It may contain suitable buffers, stabilizers, and suspending and viscosity agents. It contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of $C_{23}H_{30}O_6$.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—
USP Prednisolone Acetate RS

Identification—Transfer a volume of Ophthalmic Suspension, equivalent to about 7.5 mg of Prednisolone Acetate, to a test tube, add 5 mL of chloroform, and shake. Centrifuge, and apply 20 µL of the chloroform layer and 20 µL of a Standard solution of USP Prednisolone Acetate RS in chloroform containing 1.5 mg per mL on a thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel mixture. Develop the chromatogram in a mixture of chloroform and acetone (4:1) until the solvent front has moved about three-fourths the length of the plate. Mark the solvent front, and locate the spots on the plate by examining under UV light: the R_F value of the principal spot obtained from the solution under test corresponds to that obtained from the Standard solution.

Sterility Tests ⟨71⟩: meets the requirements.

pH ⟨791⟩: between 5.0 and 6.0.

Assay—

Mobile phase—Prepare a suitably filtered and degassed solution of water and acetonitrile (3:2). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Prednisolone Acetate RS in a mixture of acetonitrile and water (1:1) to obtain a solution having a known concentration of about 0.1 mg per mL.

System suitability preparation—Prepare a solution of prednisolone in a mixture of acetonitrile and methanol (1:1) having a concentration of about 0.1 mg per mL. Mix equal volumes of this solution and the *Standard preparation*.

Assay preparation—Transfer an accurately measured volume of Ophthalmic Suspension, equivalent to about 5 mg of prednisolone acetate, to a 50-mL volumetric flask. Dilute with a mixture of acetonitrile and water (1:1) to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a column that contains packing L1. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation* and the *System suitability preparation*, and record the peak responses as directed for *Procedure:* the relative retention times are 0.5 for prednisolone and 1.0 for prednisolone acetate, the column efficiency is not less than 7000 theoretical plates, the tailing factor is not more than 2.0, and the resolution, *R,* between prednisolone and prednisolone acetate is not less 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. Calculate the quantity, in mg, of $C_{23}H_{30}O_6$ in each mL of the Ophthalmic Suspension taken by the formula:

$$50(C/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Prednisolone Acetate RS in the *Standard preparation*, V is the volume, in mL, of Ophthalmic Suspension taken, and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Topic/Question	Contact	Expert Committee
PREDNISOLONE ACETATE OPHTHALMIC SUSPENSION	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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