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Gentamicin and Prednisolone Acetate Ophthalmic Suspension

» Gentamicin and Prednisolone Acetate Ophthalmic Suspension is a sterile aqueous suspension containing Gentamicin Sulfate and Prednisolone Acetate. It contains the equivalent of not less than 90.0 percent and not more than 130.0 percent of the labeled amount of gentamicin, 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.

USP Reference standards ⟨11⟩—
USP Gentamicin Sulfate RS
USP Prednisolone Acetate RS

Identification—

A: It meets the requirements of the *Identification* test in *Gentamicin Injection*.

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

Sterility Tests ⟨71⟩ —It meets the requirements when tested as directed for *Membrane Filtration* in *Test for Sterility of the Product To Be Examined*.

pH ⟨791⟩**:** between 5.4 and 6.6.

Assay for gentamicin—Proceed with Ophthalmic Suspension as directed in the *Assay* in *Gentamicin Sulfate Injection*.

Assay for prednisolone acetate—

Diluting solvent—Mix 700 mL of methanol and 300 mL of water.

Mobile phase—Prepare a suitable mixture of water and acetonitrile (60:40), and pass through a suitable filter having a porosity of 1 µm or less. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Transfer about 60 mg of USP Prednisolone Acetate RS, accurately weighed, to a 50-mL volumetric flask, dissolve in methanol, dilute with methanol to volume, and mix. Transfer 8.0 mL of this solution to a second 50-mL volumetric flask, dilute with *Diluting solvent* to volume, and mix. This solution contains about 0.2 mg of USP Prednisolone Acetate RS per mL.

Assay preparation—Transfer an accurately measured volume of well-mixed Ophthalmic Suspension, equivalent to about 10 mg of prednisolone acetate, to a 50-mL volumetric flask, dilute with *Diluting solvent* 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 2 mL per minute. Chromatograph the *Standard preparation*, and measure the peak responses as directed under *Procedure:* the tailing factor for the analyte peak is not more than 1.25, the column efficiency is not less than 2000 theoretical plates, and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 30 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 prednisolone acetate ($C_{23}H_{30}O_6$), 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 prednisolone acetate 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
GENTAMICIN AND PREDNISOLONE ACETATE OPHTHALMIC SUSPENSION	Ying Han Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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