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Sulfacetamide Sodium and Prednisolone Acetate Ophthalmic Suspension

» Sulfacetamide Sodium and Prednisolone Acetate Ophthalmic Suspension is a sterile, aqueous suspension containing not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of sulfacetamide sodium ($C_8H_9N_2NaO_3S.H_2O$) and prednisolone acetate ($C_{23}H_{30}O_6$). It may contain suitable preservatives, buffers, stabilizers, and suspending agents.

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 Prednisolone Acetate RS
USP Sulfacetamide Sodium RS

Identification—

A: Pass about 25 mL of the well-mixed Ophthalmic Suspension through a fine, sintered-glass filter, saving the filtrate. Wash the crystals in the funnel with a small amount of water. Dry the crystals at 105° for 3 hours: the IR absorption spectrum of a potassium bromide dispersion of the crystals exhibits maxima only at the same wavelengths as that of a similar preparation of USP Prednisolone Acetate RS.

B: To the filtrate saved from *Identification* test *A*, add 6 N acetic acid dropwise until the pH is between 4 and 5. Allow crystals of sulfacetamide to develop. Filter the crystals, wash with a small amount of water, and dry at 105° for 2 hours: the IR absorption spectrum of a potassium bromide dispersion of the crystals so obtained exhibits maxima only at the same wavelengths as a preparation of USP Sulfacetamide Sodium RS, similarly treated.

Sterility Tests ⟨71⟩: meets the requirements.

pH ⟨791⟩: between 6.0 and 7.4.

Assay for sulfacetamide sodium—

Mobile phase—Prepare a filtered and degassed mixture of water, methanol, and glacial acetic acid (890:100:10). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Dissolve an accurately weighed quantity of USP Sulfacetamide Sodium RS in a mixture of water and methanol (4:1), and dilute quantitatively, and stepwise if necessary, with the same solvent mixture to obtain a solution having a known concentration of about 30 µg per mL.

Assay preparation—Transfer an accurately measured volume of Ophthalmic Suspension, freshly mixed and free from air bubbles, equivalent to about 100 mg of sulfacetamide sodium, to a 100-mL volumetric flask, dilute with a mixture of water and methanol (4:1) to volume, and mix. Dilute 3.0 mL of this solution with the same solvent mixture to 100.0 mL, and mix.

System suitability preparation—Dissolve about 3 mg of sulfanilamide in 100 mL of the *Standard preparation*, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm × 25-cm column that contains packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation* and the *System suitability preparation*, and record the peak responses as directed for *Procedure:* the column efficiency determined for the analyte peak is not less than 1500 theoretical plates; the resolution, *R,* between the sulfacetamide and sulfanilamide peaks is not less than 3; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 90 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 sulfacetamide sodium ($C_8H_9N_2NaO_3S.H_2O$) in each mL of the Ophthalmic Suspension taken by the formula:

$$3.33(254.24/236.23)C(r_U/r_S)$$

in which 254.24 and 236.23 are the molecular weights of sulfacetamide sodium monohydrate and anhydrous sulfacetamide sodium, respectively; *C* is the concentration, in µg per mL, calculated on the anhydrous basis, of USP Sulfacetamide Sodium RS in the *Standard preparation;* and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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Assay for prednisolone acetate—

Mobile phase—Prepare a filtered and degassed mixture of water and acetonitrile (60:40). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Dissolve an accurately weighed quantity of USP Prednisolone Acetate RS in methanol to obtain a solution containing about 2 mg per mL. Transfer 2.0 mL of this solution to a 100-mL volumetric flask, and dilute with a solvent mixture prepared by dissolving 2.72 g of monobasic potassium phosphate in 300 mL of water and 700 mL of methanol. The *Standard preparation* has a known concentration of about 0.04 mg per mL.

Assay preparation—Using a "To contain" pipet, transfer an accurately measured volume of Ophthalmic Suspension, freshly mixed and free from air bubbles, equivalent to about 10 mg of prednisolone acetate, to a 250-mL volumetric flask. Rinse the pipet with the solvent mixture described under *Standard preparation*, collecting the rinsings in the flask, dilute with the same solvent mixture to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 254-nm detector and a 4.0-mm × 30-cm column that contains packing L1. The flow rate is about 1.5 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 3000 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:

$$250(C/V)(r_U/r_S)$$

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.

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Topic/Question	Contact	Expert Committee
SULFACETAMIDE SODIUM AND PREDNISOLONE ACETATE OPHTHALMIC SUSPENSION	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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