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Prednisolone Sodium Phosphate Ophthalmic Solution

» Prednisolone Sodium Phosphate Ophthalmic Solution is a sterile solution of Prednisolone Sodium Phosphate in a buffered, aqueous medium. It contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of prednisolone phosphate ($C_{21}H_{29}O_8P$), present as the disodium salt.

Packaging and storage—Preserve in tight, light-resistant containers.

USP REFERENCE STANDARDS (11).—
[USP Prednisolone RS](#)

Identification—

Change to read:

A: [▲][SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Infrared Spectroscopy: 197K* [▲] (CN 1-May-2020)

Test specimen: Place 5 mL of the *Assay preparation* obtained as directed in the *Assay*, in a glass-stoppered, 100-mL volumetric flask, mix with 5 mL of *Alkaline phosphatase solution* prepared as directed in the *Assay*, and add 50 mL of methylene chloride. Insert the stopper, and allow to stand, with occasional gentle inversion (about once every 15 minutes), for 2 hours. Filter the methylene chloride layer through a dry paper, and evaporate 25 mL of the filtrate to dryness.

Standard specimen: Prepare as directed in [▲][Spectroscopic Identification Tests \(197\)](#), *Infrared Spectroscopy: 197K* [▲] (CN 1-May-2020), using [USP Prednisolone RS](#).

B: Dissolve 65 mg of phenylhydrazine hydrochloride in 100 mL of dilute sulfuric acid (3 in 5), add 5 mL of isopropyl alcohol, and mix. Heat 5 mL of this solution with 1 mL of *Assay preparation* (obtained as directed in the *Assay*) at 70° for 2 hours: a yellow color develops.

STERILITY TESTS (71): meets the requirements.

pH (791): between 6.2 and 8.2.

Assay—Proceed with Ophthalmic Solution as directed in the *Assay* under [Prednisolone Sodium Phosphate Injection](#).

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
PREDNISOLONE SODIUM PHOSPHATE OPTHALMIC SOLUTION	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](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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