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Prednisolone Sodium Phosphate Injection

» Prednisolone Sodium Phosphate Injection is a sterile solution of Prednisolone Sodium Phosphate in Water for Injection. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of prednisolone phosphate ($C_{21}H_{29}O_8P$), present as the disodium salt.

Packaging and storage—Preserve in single-dose or in multiple-dose containers, preferably of Type I glass, protected from light.

USP Reference standards ⟨11⟩—
USP Prednisolone RS

Identification—

A: 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.

Change to read:

B: ▲*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.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 5.0 USP Endotoxin Units per mg of prednisolone phosphate.

pH ⟨791⟩: between 7.0 and 8.0.

Particulate Matter in Injections ⟨788⟩: meets the requirements under small-volume injections.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*.

Assay—

pH 9 Buffer with magnesium—Mix 3.1 g of boric acid and 500 mL of water in a 1-L volumetric flask, add 21 mL of 1 N sodium hydroxide and 10 mL of 0.1 M magnesium chloride, dilute with water to volume, and mix.

Alkaline phosphatase solution—Transfer 250 mg of alkaline phosphate enzyme to a 25-mL volumetric flask, dissolve by adding *pH 9 Buffer with magnesium* to volume, and mix. Prepare this solution fresh daily.

Standard preparation—Dissolve a suitable, accurately weighed quantity of USP Prednisolone RS in methylene chloride, and dilute quantitatively and stepwise with methylene chloride to obtain a solution having a known concentration of about 16 µg per mL. Pipet 100 mL of the solution into a glass-stoppered, 100-mL cylinder, and add 1.0 mL of *Alkaline phosphatase solution* and 1.0 mL of water. Allow to stand, with occasional gentle inversion, for 2 hours.

Assay preparation—Pipet a volume of Injection, equivalent to about 100 mg of prednisolone phosphate, into a separator containing 20 mL of water. Wash the solution with two 10-mL portions of methylene chloride, and discard the washings. Transfer the aqueous layer to a 50-mL volumetric flask, dilute with water to volume, and mix.

Procedure—Pipet 1 mL of the *Assay preparation* into a glass-stoppered, 100-mL cylinder, add 1.0 mL of *Alkaline phosphatase solution* and about 50 mL of methylene chloride, insert the stopper, and allow to stand, with occasional gentle inversion (about once every 15 minutes), for 2 hours. Add methylene chloride to volume, mix, and allow to stand until the methylene chloride layer is clear (about 20 minutes). Concomitantly and without delay, determine the absorbances of the methylene chloride solution obtained from the *Assay preparation* and the *Standard preparation* at 241 nm, with a suitable spectrophotometer, using methylene chloride as the blank. Calculate the quantity, in mg, of $C_{21}H_{29}O_8P$ in each mL of the Injection taken by the formula:

$$6.11(C/V)(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Prednisolone RS in the *Standard preparation*, V is the volume, in mL, of Injection taken, and A_U and A_S are the absorbances of the solution 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
PREDNISOLONE SODIUM PHOSPHATE INJECTION	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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