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Prednisolone Oral Solution

» Prednisolone Oral Solution contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of prednisolone ($C_{21}H_{28}O_5$). It may contain alcohol.

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

USP Reference standards ⟨11⟩—

USP Prednisolone RS

Identification—The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.

pH ⟨791⟩: between 3.0 and 4.5.

Alcohol Determination, *Method II*⟨611⟩ (*if present*): not less than 90.0% and not more than 115.0% of the labeled amount.

Assay—

Citrate buffer—Prepare a 0.0033 M solution of citric acid in water, adjust with 1 N sodium hydroxide to a pH of 6.2, and mix.

Diluting solution: a mixture of methanol and water (1:1).

Mobile phase—Prepare a filtered and degassed mixture of *Citrate buffer* and methanol (31:19). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

System suitability solution—Dissolve suitable quantities of prednisolone and hydrocortisone in a mixture of methanol and water (1:1) to obtain a solution containing about 100 µg per mL and 90 µg per mL, respectively.

Standard preparation—Dissolve an accurately weighed quantity of USP Prednisolone RS in *Diluting solution*, and dilute quantitatively, and stepwise if necessary, with *Diluting solution* to obtain a solution having a known concentration of about 0.1 mg per mL.

Assay preparation—Transfer an accurately measured volume of Oral Solution, equivalent to about 5.0 mg of prednisolone, to a 50-mL volumetric flask, dissolve in *Diluting solution*, shake by mechanical means for 15 minutes, dilute with *Diluting solution* to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm × 15-cm column that contains packing L10. The flow rate is about 1 mL per minute. Chromatograph the *System suitability solution*, and record the peak responses as directed for *Procedure*: the relative retention times are about 0.8 for hydrocortisone and 1.0 for prednisolone; the resolution, *R,* between hydrocortisone and prednisolone is not less than 2.5; and the relative standard deviation for replicate injections is not more 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 prednisolone ($C_{21}H_{28}O_5$) in the volume of Oral Solution taken by the formula:

$$50C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Prednisolone 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.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
PREDNISOLONE ORAL 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

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