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Prednisone Oral Solution

DEFINITION
Prednisone Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of prednisone ($C_{21}H_{26}O_5$).

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests** ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)

Sample: 50 mL of Oral Solution

Analysis: Shake the *Sample* with 25 mL of chloroform for 5 min. Filter the chloroform extract through a pledget of cotton and a layer of anhydrous sodium sulfate, and evaporate on a warm water bath with the aid of a current of air to 3 mL. Continue the evaporation to dryness at room temperature. Wash the residue with two 10-mL portions of hot solvent hexane, decanting the solvent and discarding it each time. Digest the residue with 25 mL of warm dehydrated alcohol for 15 min. Filter the mixture, and evaporate the filtrate to 3 mL. Add solvent hexane until the mixture becomes slightly cloudy, and chill in a freezer to promote the formation of crystals. Collect the crystals, and dry at 60° for 1 h.

Acceptance criteria: The crystals meet the requirements. If a difference appears, dissolve portions of both the crystals and the Reference Standard in methanol, evaporate the solutions to dryness, and repeat the tests.

ASSAY

• **Procedure**

Mobile phase: Dissolve 1.36 g of monobasic sodium phosphate in 600 mL of water. To this solution add 400 mL of methanol.

Standard stock solution: 1 mg/mL of USP Prednisone RS in alcohol

Standard solution: 40 µg/mL of USP Prednisone RS in water from the *Standard stock solution*

Sample solution: Nominally 40 µg/mL of prednisone in water from a measured volume of Oral Solution

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of prednisone ($C_{21}H_{26}O_5$) in the portion of Oral Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Prednisone RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of prednisone in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

OTHER COMPONENTS

• **Alcohol Determination, *Method II*⟨611⟩:** 2.0%–6.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩**

For single-unit containers

Acceptance critieria: Meets the requirements

• **Deliverable Volume ⟨698⟩**

For multiple-unit containers

Acceptance criteria: Meets the requirements

SPECIFIC TESTS

• **pH ⟨791⟩:** 2.6–4.5

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards ⟨11⟩**

USP Prednisone RS

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

Topic/Question	Contact	Expert Committee
PREDNISONE 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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