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Prednisolone Sodium Phosphate Compounded Oral Solution

Change to read:

DEFINITION

Prednisolone Sodium Phosphate Compounded Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of prednisolone ($C_{21}H_{28}O_5$). Prepare Prednisolone Sodium Phosphate Compounded Oral Solution ▲containing▲ (USP 1-May-2022) 10 mg/mL ▲of prednisolone▲ (USP 1-May-2022) as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Prednisolone (as ▲prednisolone sodium phosphate)▲ (USP 1-May-2022) powder	1 g (1.34 g of prednisolone sodium phosphate)
Purified Water	A small amount
Vehicle: a 1:1 mixture of Cherry Syrup[a] and Ora-Sweet,[b] a sufficient quantity to make	100 mL

[a] Humco, Texarkana, TX.

[b] Perrigo Pharmaceuticals, Allegan, MI.

Pour the weighed *prednisolone sodium phosphate powder* into a suitable container. Wet the powder with a small amount of *Purified Water*, and triturate to make a smooth paste. Add the *Vehicle* to make the contents pourable. Transfer the contents, stepwise and quantitatively, to a calibrated container. Add sufficient *Vehicle* to bring to final volume. Shake to mix well.

ASSAY

Change to read:

• **Procedure**

Solution A: Dissolve 2.0 g of 1-pentanesulfonic acid sodium in 1000 mL of water.

Solution B: Mix 980 mL of *Solution A* with 20 mL of tetrahydrofuran. Adjust with phosphoric acid to a pH of 2.0.

Mobile phase: Methanol and *Solution B* (45:55)

Standard solution: ▲0.54▲ (USP 1-May-2022) mg/mL of prednisolone ▲sodium phosphate,▲ (USP 1-May-2022) prepared from USP Prednisolone Sodium Phosphate RS in *Solution B*

Sample solution: Shake each bottle of Oral Solution thoroughly. Transfer 1.0 mL of Oral Solution to a 25-mL volumetric flask, dilute with *Solution B* to volume, and mix well.

Chromatographic system

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

Mode: LC

Detector: UV 246 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for prednisolone is about 11.3 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of prednisolone ($C_{21}H_{28}O_5$) in the portion of Oral Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times {}^{\blacktriangle}(M_{r1}/M_{r2})_{\blacktriangle\ (\text{USP 1-May-2022})} \times 100$$

r_U = peak response of prednisolone ▲sodium phosphate▲ (USP 1-May-2022) from the *Sample solution*

r_S = peak response of prednisolone ▲sodium phosphate▲ (USP 1-May-2022) from the *Standard solution*

C_S = concentration of ▲USP Prednisolone Sodium Phosphate RS▲ (USP 1-May-2022) in the *Standard solution* (mg/mL)

C_U = nominal concentration of prednisolone in the *Sample solution* (mg/mL)

$^{\blacktriangle}M_{r1}$ = molecular weight of prednisolone, 360.44

M_{r2} = molecular weight of prednisolone sodium phosphate, 484.39▲ (USP 1-May-2022)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.9–4.9

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Package in tight, light-resistant containers. Store ▲in a refrigerator▲ (USP 1-May-2022) or at controlled room temperature.

Change to read:

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored ▲in a refrigerator▲ (USP 1-May-2022) or at controlled room temperature

• **Labeling:** Label it to indicate that it is to be well shaken before use, and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Prednisolone Sodium Phosphate RS

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

Topic/Question	Contact	Expert Committee
PREDNISOLONE SODIUM PHOSPHATE COMPOUNDED ORAL SOLUTION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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