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Prednisolone Compounded Oral Suspension, Veterinary

DEFINITION

Prednisolone Compounded Oral Suspension, Veterinary contains NLT 90.0% and NMT 110.0% of the labeled amount of prednisolone ($C_{21}H_{28}O_5$).

Prepare Prednisolone Compounded Oral Suspension, Veterinary, 20 mg/mL, as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Prednisolone powder	2 g
Purified Water	a small amount
Syrup, NF, a sufficient quantity to make	100 mL

Pour the weighed *Prednisolone powder* into a suitable mortar. Wet the powder with a small amount of *Purified Water*, and triturate to make a smooth paste. Add the *Syrup* in small portions almost to volume, and mix thoroughly after each addition. Transfer the contents of the mortar stepwise and quantitatively to a calibrated container. Add sufficient *Syrup* to bring the preparation to final volume. Shake to mix well.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and water (30:70). Filter, and degas.

System suitability solution: 1 mg/mL of USP Prednisolone RS and 0.06 mg/mL of USP Hydrocortisone RS in *Mobile phase*

Standard solution: 0.2 mg/mL of prednisolone prepared from USP Prednisolone RS in *Mobile phase*

Sample solution: Shake thoroughly each bottle of Oral Suspension, Veterinary. Transfer 1.0 mL of the Oral Suspension, Veterinary into a 100-mL volumetric flask, and dilute with *Mobile phase* to volume to obtain a solution having a nominal concentration of 0.2 mg/mL of prednisolone.

Chromatographic system

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

Mode: LC

Detector: UV 246 nm

Column: 4.6-mm × 15-cm; 3-µm packing L1

Column temperature: 40°

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—The relative retention times for prednisolone and hydrocortisone are about 1.0 and 1.06, respectively.]

Suitability requirements

Resolution: NLT 2.0 between prednisolone and hydrocortisone, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Peak-to-valley ratio: The ratio of the height of the smallest peak to the height of the valley between the prednisolone and hydrocortisone peak is NLT 2, *System suitability solution*

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 Suspension, Veterinary taken:

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

r_U = peak response of prednisolone from the *Sample solution*

r_S = peak response of prednisolone from the *Standard solution*

C_S = concentration of prednisolone in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 2.6–3.6

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at 2°–8° 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.* Label it to state that it is for veterinary use only.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored at 2°–8° or at controlled room temperature

• **USP Reference Standards** ⟨11⟩

USP Hydrocortisone RS

USP Prednisolone RS

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

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

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