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Add the following:

▲Fludrocortisone Acetate Compounded Oral Suspension, Veterinary

DEFINITION

Fludrocortisone Acetate Compounded Oral Suspension, Veterinary contains NLT 90.0% and NMT 110.0% of the labeled amount of fludrocortisone acetate ($C_{23}H_{31}FO_6$).

Prepare Fludrocortisone Acetate Compounded Oral Suspension, Veterinary 1 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Fludrocortisone Acetate	100 mg
Ora-Blend,[a] a sufficient quantity to make	100 mL

[a] Perrigo, Allegan, MI.

Place the *Fludrocortisone Acetate* in a suitable container and triturate to a fine powder. Add a small amount of *Ora-Blend*, and mix well to form a smooth paste. Add a sufficient amount of *Ora-Blend* to make the contents pourable. Transfer the contents stepwise and quantitatively to a calibrated container using the remainder of the *Ora-Blend*. Add a sufficient amount of *Ora-Blend* to bring to final volume. Mix well.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and water (44:56)

Diluent: Acetonitrile, water, and 1 N hydrochloric acid (44:55:1)

Standard stock solution: Transfer 20 mg of USP Fludrocortisone Acetate RS into a 200-mL volumetric flask, add about 10 mL of acetonitrile, and sonicate for 5 min. Dilute with *Diluent* to volume.

Standard solution: Transfer 0.5 mL of *Standard stock solution* into a 25-mL volumetric flask, and dilute with *Diluent* to volume.

Sample solution: Transfer 1 mL of Oral Suspension, Veterinary into a 500-mL volumetric flask. Add approximately 400 mL of *Diluent*, sonicate for 10 min, and then dilute with *Diluent* to volume. Pass through a polyvinylidene difluoride filter of 0.22-µm pore size, discarding the first 10 drops.

Chromatographic system

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

Mode: LC

Detector: UV 240 nm

Column: 4.6-mm × 25-cm; 5-µm packing L96

Temperatures

Autosampler: 4°

Column: 25°

Flow rate: 2 mL/min

Injection volume: 100 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for fludrocortisone acetate is about 5.6 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 fludrocortisone acetate ($C_{23}H_{31}FO_6$) 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 fludrocortisone acetate from the *Sample solution*

r_S = peak response of fludrocortisone acetate from the *Standard solution*

C_S = concentration of USP Fludrocortisone Acetate RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.7–4.7

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at controlled room temperature or in a refrigerator.

• **Beyond-Use Date:** NMT 90 days from the date on which it was compounded when stored at controlled room temperature or in a refrigerator

• **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.

• **USP Reference Standards** ⟨11⟩

USP Fludrocortisone Acetate RS▲ (USP 1-Dec-2021)

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

Topic/Question	Contact	Expert Committee
FLUDROCORTISONE ACETATE COMPOUNDED ORAL SUSPENSION, VETERINARY	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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