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Spironolactone Compounded Oral Suspension, Veterinary

DEFINITION

Spironolactone Compounded Oral Suspension, Veterinary contains NLT 90.0% and NMT 110.0% of the labeled amount of spironolactone ($C_{24}H_{32}O_4S$).

Prepare Spironolactone Compounded Oral Suspension, Veterinary 25 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Spironolactone tablets[a] equivalent to	2.5 g
Vehicle: a 1:1 mixture of Ora-Sweet[b] and Ora-Plus[b], a sufficient quantity to make	100 mL

[a] Spironolactone 25-mg tablets, Mylan, Morgantown, WV.

[b] Paddock Laboratories, Minneapolis, MN.

Calculate the required quantity of each ingredient for the total amount to be prepared. Place the required number of tablets in a suitable mortar, and comminute to a fine powder with a pestle. Add the *Vehicle* in small portions, and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a spironolactone liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough of the *Vehicle* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and 20 mM dibasic ammonium phosphate (55:45). Filter and degas.

Diluent: Acetonitrile and water (50:50)

Standard stock solution: 1.0 mg/mL of USP Spironolactone RS in *Diluent*

Standard solution: Pipet 2.5 mL of the *Standard stock solution* to a 10-mL volumetric flask, and dilute with *Diluent* to volume to obtain a solution with a nominal concentration of 0.25 mg/mL.

Sample solution: Shake each bottle of Oral Suspension, Veterinary thoroughly by hand. Pipet 1.0 mL of the Oral Suspension, Veterinary into a 100-mL volumetric flask, and dilute with *Diluent* to volume to obtain a solution with a nominal concentration of 0.25 mg/mL.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

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

Flow rate: 1.0 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for spironolactone is about 10.4 min.]

Suitability requirements

Column efficiency: NLT 9000 theoretical plates

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 spironolactone ($C_{24}H_{32}O_4S$) in the portion of Oral Suspension, Veterinary taken:

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 spironolactone in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.7–4.9

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 to indicate that it is for veterinary use only.

• **Beyond-Use Date:** NMT 60 days after the date on which it was compounded, when stored at 2°–8° or controlled room temperature

• **USP Reference Standards** ⟨11⟩

USP Spironolactone RS

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

Topic/Question	Contact	Expert Committee
SPIRONOLACTONE 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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