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Cisapride Compounded Oral Suspension, Veterinary

DEFINITION

Cisapride Compounded Oral Suspension, Veterinary contains NLT 90.0% and NMT 110.0% of the labeled amount of cisapride ($C_{23}H_{29}ClFN_3O_4$), calculated on the anhydrous basis.

Prepare Cisapride Compounded Oral Suspension, Veterinary 10 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Cisapride (as cisapride monohydrate) powder	1 g (1.04 g)
Vehicle: A 1:1 mixture of Ora-Plus[a] and Ora-Sweet,[a] a sufficient quantity to make	100 mL

[a] Perrigo Laboratories, Allegan, MI.

Pour the *Cisapride monohydrate powder* into a suitable container. Wet the powder with a small amount of *Vehicle* and triturate to make a smooth paste. Add the *Vehicle* to make the mortar contents pourable. Transfer contents stepwise and quantitatively to a calibrated container using the *Vehicle*. Add sufficient *Vehicle* to bring to final volume. Shake to mix well.

ASSAY

• **Procedure**

Solution A: Add 0.2 mL of triethylamine to 1000 mL of water.

Mobile phase: Acetonitrile and *Solution A* (65:35)

Standard solution: 0.2 mg/mL of cisapride prepared from USP Cisapride RS in methanol

Sample solution: Transfer 1.0 mL of Oral Suspension, Veterinary to a 50-mL volumetric flask, dilute with methanol to volume, and sonicate to mix. Filter into an HPLC vial.

Chromatographic system

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

Mode: LC

Detector: UV-Vis 308 nm

Column: 4.6-mm × 15-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 cisapride is about 2.0 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 cisapride ($C_{23}H_{29}ClFN_3O_4$) 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 cisapride from the *Sample solution*

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

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

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

Acceptance criteria: 90.0%–110.0% on the anhydrous basis

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.0–5.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant plastic containers. Store in a refrigerator (2°–8°) or at controlled room temperature.

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

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

• **USP Reference Standards** ⟨11⟩

USP Cisapride RS

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

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

Chromatographic Database Information: Chromatographic Database

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