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Cisapride Compounded Injection, Veterinary

DEFINITION

Cisapride Compounded Injection, 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 Injection, Veterinary 3 mg/mL as follows (see *Pharmaceutical Compounding—Sterile Preparations ⟨797⟩*).

Cisapride (as cisapride monohydrate) powder	30 mg (31.2 mg)
Tartaric acid 10% solution	0.75 mL
Sterile Water for Injection, a sufficient amount to make	10 mL

Dissolve the *Cisapride monohydrate powder* in 9 mL of *Sterile Water for Injection*. Add the *Tartaric acid 10% solution*. Add sufficient *Sterile Water for Injection* to bring to final volume, and mix well. Pass through a sterile filter of 0.22-µm pore size into a sterile single-dose container. [NOTE—Tartaric acid is added to aid in solubility.]

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 0.67 mL of Injection, Veterinary to a 10-mL volumetric flask, dilute with methanol to volume, and sonicate to mix.

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 Injection, 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⟩:** 2.1–3.1
- **Sterility Tests ⟨71⟩:** It meets the requirements when tested as directed in *Test for Sterility of the Product to Be Examined, Membrane Filtration*.
- **Bacterial Endotoxins Test ⟨85⟩:** NMT 5.0 USP Endotoxin Units/mg
- **Particulate Matter in Injections ⟨788⟩:** It meets the requirements.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Package in single-dose sterile glass containers and store in a refrigerator (2°–8°).
- **Labeling:** Label it to indicate that it is for veterinary use only and to state the *Beyond-Use Date*.

Change to read:

Beyond-Use Date:

▲In the absence of performing and completing a sterility and endotoxins test, the storage conditions for *High-Risk Level CSPs* in *Pharmaceutical Compounding—Sterile Preparations ⟨797⟩* apply. After successful completion of sterility and endotoxin testing, NMT 90 days after the date on which it was compounded when stored in a refrigerator.▲ (CN 1-May-2020)

- **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 INJECTION, VETERINARY	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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