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Add the following:

▲Mirtazapine Compounded Oral Suspension, Veterinary

DEFINITION

Mirtazapine Compounded Oral Suspension, Veterinary contains NLT 90.0% and NMT 110.0% of the labeled amount of mirtazapine ($C_{17}H_{19}N_3$).

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

Mirtazapine tablet(s),[a] equivalent to	1.2 g of mirtazapine
Vehicle: 1:1 mixture of Ora-Plus[b] and Ora-Sweet,[b] a sufficient quantity to make	120 mL

[a] Mirtazapine 30-mg tablets, Mylan Pharmaceuticals, Inc., Morgantown, WV.

[b] Perrigo, Allegan, MI.

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

ASSAY

• **Procedure**

Mobile phase: Add 23.5 mL of 25% tetramethylammonium hydroxide solution to 626.5 mL of water. Adjust with phosphoric acid to a pH of 7.4. Add 150 mL of acetonitrile, 125 mL of methanol, and 75 mL of tetrahydrofuran.

Diluent: Acetonitrile and water (50:50)

Standard solution: 0.5 mg/mL of USP Mirtazapine RS in *Diluent*

Sample solution: Transfer 0.5 mL of Oral Suspension, Veterinary to a 10-mL volumetric flask, and add *Diluent* to volume. Pass through a filter of 0.22-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 295 nm

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

Column temperature: 60°

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for mirtazapine is about 25.4 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 mirtazapine ($C_{17}H_{19}N_3$) 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 mirtazapine from the *Sample solution*

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

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

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 5.6–6.6

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 after the date on which it was compounded when stored at controlled room temperature or in a refrigerator.

• **Labeling:** Label it to state 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 Mirtazapine RS

▲2S *(USP41)*

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

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

Chromatographic Database Information: Chromatographic Database

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