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Pergolide Compounded Oral Suspension, Veterinary

DEFINITION

Pergolide Compounded Oral Suspension, Veterinary contains NLT 90.0% and NMT 110.0% of the labeled amount of pergolide ($C_{19}H_{26}N_2S$).

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

Pergolide (as Pergolide Mesylate, *USP*)	20 mg (26.11 mg)
Vehicle for Oral Suspension, *NF*	10 mL
Vehicle for Oral Solution, *NF*	10 mL

Connect an empty, calibrated, 35-mL Luer lock injection syringe to the port of a fluid-dispensing connector. Remove the plunger of another 35-mL Luer lock syringe, and set the plunger aside. Lock the barrel of this syringe onto the open port of the connector. Set this connected syringe apparatus in an upright, vertical position that is perpendicular to the work surface with the open syringe on top. Add the *Vehicle for Oral Suspension* and the *Pergolide Mesylate* into the open barrel. Replace the plunger on the open syringe, and invert the apparatus 180°. Apply 50 depressions to each syringe to mix. Consolidate the mixture into a single syringe. Disconnect the empty syringe. Add, via another 35-mL Luer lock injection syringe connected to the open port of the fluid-dispensing connector, a sufficient quantity of *Vehicle for Oral Solution* to bring the preparation to a final volume of 20 mL. Reattach the empty 35-mL syringe to the fluid-dispensing connector. Apply 50 depressions to each syringe to formulate a uniform suspension.

Alternatively, it may be prepared as follows. Add the *Pergolide Mesylate* to the mortar. Add the *Vehicle for Oral Suspension*, and mix to form a uniform paste. Add the *Vehicle for Oral Solution* in small portions almost to a final volume of 20 mL, and mix thoroughly after each addition. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add sufficient *Vehicle for Oral Solution* to bring the preparation to a final volume of 20 mL, and mix well.

IDENTIFICATION

• **A.** The retention time of the pergolide peak of the *Sample solution* corresponds to that of the *Standard solutions*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Solution A: 0.5 M sodium octanesulfonate solution and water (2:98), adjusted with glacial acetic acid to a pH of 2.2

Mobile phase: Acetonitrile and *Solution A* (50:50)

Diluent: Methanol and 0.01 N hydrochloric acid (50:50)

Standard stock solution: 1.0 mg/mL of USP Pergolide Mesylate RS in methanol prepared in low-actinic glassware

Standard solutions: Prepare five solutions of known concentrations of about 20, 10, 5, 2, and 1 µg/mL of pergolide mesylate by quantitatively diluting the *Standard stock solution* with *Mobile phase*. Use low-actinic glassware.

Sample solution: Transfer 500 µL of Oral Suspension, Veterinary to a 5-mL volumetric flask, and dilute with *Diluent* to volume. Further dilute an aliquot of the solution with *Mobile phase* to obtain a solution with a nominal concentration of 10 µg/mL of pergolide. Use low-actinic glassware.

Chromatographic system

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

Mode: LC

Detector: UV 223 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 25 µL

System suitability

Samples: *Standard solutions* and *Sample solution*

Suitability requirements

Tailing factor: NMT 2.0, *Standard solution* (20 µg/mL)

Relative standard deviation: NMT 2.0% for replicate injections, *Standard solution* (20 µg/mL)

Correlation coefficient: NLT 0.995, linear regression of the *Standard solutions*

Resolution: NLT 2.0, *Sample solution*

Analysis

Samples: *Standard solutions* and *Sample solution*

Generate a regression curve of peak height versus pergolide mesylate concentration, and calculate the equation for the linear regression line.

Calculate the percentage of the labeled amount of pergolide ($C_{19}H_{26}N_2S$) in the portion of Oral Suspension, Veterinary taken. Use the molecular weights of pergolide and pergolide mesylate, 314.50 and 410.60, respectively.

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.0–4.2

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers, and store in a refrigerator.

• **Beyond-Use Date:** NMT 14 days after the date on which it was compounded when stored in a refrigerator

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

• **USP Reference Standards** ⟨11⟩

USP Pergolide Mesylate RS

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

Topic/Question	Contact	Expert Committee
PERGOLIDE 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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