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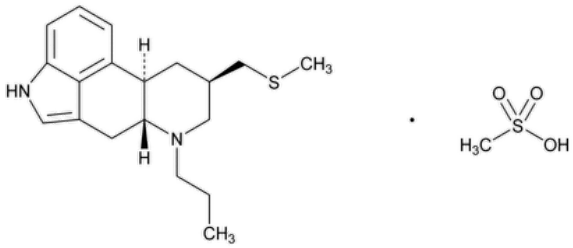
Pergolide Mesylate



$C_{19}H_{26}N_2S \cdot CH_4O_3S$ 410.59

Ergoline,8-[(methylthio)methyl]-6-propyl-,monomethanesul fonate, (8β)-.

8β-[(Methylthio)methyl]-6-propylergoline monomethanesul fonate CAS RN®: 66104-23-2; UNII: 55B9HQY616.

» Pergolide Mesylate contains not less than 97.5 percent and not more than 102.0 percent of $C_{19}H_{26}N_2S \cdot CH_4O_3S$, calculated on the dried basis.

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩—

USP Pergolide Mesylate RS
USP Pergolide Sulfoxide RS
(8β)-8-[(Methylsulfinyl)methyl]-6-propyl-D-ergoline.

Change to read:

Identification, ▲*Spectroscopic Identification Tests* ⟨197⟩*, Infrared Spectroscopy: 197K*▲ (CN 1-May-2020) ·

Specific rotation ⟨781S⟩**:** between −17° and −23° at 20°.

Test solution: 10 mg per mL, in dimethylformamide.

Loss on drying ⟨731⟩—Dry it in vacuum at 105° for 1 hour: it loses not more than 0.5% of its weight.

Residue on ignition ⟨281⟩**:** not more than 0.1%.

Chromatographic purity—

Solution A—Prepare a filtered and degassed mixture of 5.0 mL of morpholine with 995 mL of water, and adjust with phosphoric acid to a pH of 7.0.

Solution B—Prepare a filtered and degassed mixture of methanol, acetonitrile, and tetrahydrofuran (1:1:1). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Mobile phase—Use variable mixtures of *Solution A* and *Solution B* as directed for *Chromatographic system* (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard solution 1—Dissolve an accurately weighed quantity of USP Pergolide Mesylate RS in methanol, and dilute quantitatively, and stepwise if necessary, with methanol to obtain a solution having a known concentration of about 30 µg per mL.

Standard solution 2—Dilute 10.0 mL of *Standard solution 1* to 50 mL with methanol.

Test solution—Transfer about 60 mg of Pergolide Mesylate, accurately weighed, to a 10-mL volumetric flask, dissolve in and dilute with methanol to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 280-nm detector and a 4.6-mm × 25-cm column that contains base-deactivated packing L1. The flow rate is about 1 mL per minute. The column temperature is maintained at 40°. The

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chromatograph is programmed as follows.

Time (minutes)	*Solution A* (%)	*Solution B* (%)	Elution
0	70	30	equilibration
0–35	70→0	30→100	linear gradient

Chromatograph *Standard solution 1*, and record the peak responses as directed for *Procedure:* the column efficiency is not less than 10,000 theoretical plates; the tailing factor is not more than 1.5; and the relative standard deviation for replicate injections is not more than 2.0%.
Procedure—Separately inject equal volumes (about 10 µL) of *Standard solution 1, Standard solution 2,* the *Test solution*, and a methanol blank into the chromatograph, record the chromatograms, and measure all of the peak responses. Disregard the contributions due to any peaks found in the methanol blank. The sum of the peak responses, excluding that of pergolide, from the *Test solution* is not more than the pergolide peak response obtained from *Standard solution 1* (0.5%), and no single peak response is more than the pergolide peak response obtained from *Standard solution 2* (0.1%).

Assay—

Diluent—Dissolve 5 mg of methionine in 500 mL of 0.01 N hydrochloric acid. Add 500 mL of methanol, and mix.
Mobile phase—Prepare a solution of 0.009 M sodium 1-octanesulfonate containing 1.0 mL of glacial acetic acid per L. Prepare a filtered and degassed mixture of this solution, methanol, and acetonitrile (2:1:1). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).
Resolution solution—Dissolve about 4 mg of USP Pergolide Sulfoxide RS and 8 mg of USP Pergolide Mesylate RS in 50 mL of *Diluent.*
Standard preparation—Dissolve an accurately weighed quantity of USP Pergolide Mesylate RS in *Diluent*, and dilute quantitatively, and stepwise if necessary, with *Diluent* to obtain a solution having a known concentration of about 0.13 mg per mL.
Assay preparation—Transfer about 6.5 mg of Pergolide Mesylate, accurately weighed, to a 50-mL volumetric flask, dissolve in and dilute with *Diluent* to volume, and mix.
Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 280-nm detector and a 4.6-mm × 25-cm column that contains base-deactivated packing L7. The flow rate is about 1 mL per minute. The column temperature is maintained at 40°. Chromatograph the *Resolution solution*, and record the peak responses as directed for *Procedure:* the resolution, *R*, between pergolide sulfoxide and pergolide is not less than 12.0. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the tailing factor is not more than 1.5; and the relative standard deviation for replicate injections is not more than 2.0%.
Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the pergolide peaks. Calculate the quantity, in mg, of $C_{19}H_{26}N_2S \cdot CH_4O_3S$ in the portion of Pergolide Mesylate taken by the formula:

$$50C(r_U/r_S)$$

in which *C* is the concentration, in mg per mL, of USP Pergolide Mesylate RS in the *Standard preparation;* and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
PERGOLIDE MESYLATE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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