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Selegiline Hydrochloride Compounded Topical Gel

DEFINITION

Selegiline Hydrochloride Compounded Topical Gel contains NLT 90.0% and NMT 110.0% of the labeled amount of selegiline hydrochloride ($C_{13}H_{17}N \cdot HCl$).

Prepare Selegiline Hydrochloride Compounded Topical Gel 10 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*). For this preparation, a soy lecithin–isopropyl palmitate mixture and a poloxamer gel need to be separately prepared.

Sorbic Acid	0.2 g
Soy lecithin	50 g
Isopropyl Palmitate	50 g

Prepare a soy lecithin–isopropyl palmitate mixture by mixing 0.2 g of *Sorbic Acid*, 50 g of *Soy lecithin*, and 50 g of *Isopropyl Palmitate* together. Allow the mixture to set overnight, and mix again.

Sorbic Acid	0.2 g
Poloxamer 407	30 g
Purified Water, a sufficient quantity to make	100 mL

Separately, prepare a 30% poloxamer gel by mixing 0.2 g of *Sorbic Acid*, 30 g of *Poloxamer 407,* and a sufficient amount of *Purified Water* to bring to a final volume of 100 mL. Place the gel in the refrigerator overnight, and mix again.

Selegiline hydrochloride powder	1 g
Purified Water	5 mL
Soy lecithin–isopropyl palmitate mixture	22 mL
Poloxamer gel (30%), a sufficient quantity to make	100 mL

Dissolve 1 g of *Selegiline hydrochloride powder* in 5 mL of *Purified Water* in a suitable mortar. Add 22 mL of the previously prepared soy lecithin–isopropyl palmitate mixture to the mortar, and mix well. Add a sufficient amount of the previously prepared 30% poloxamer gel to bring to final volume, and mix using high-shear methods.

ASSAY

• **Procedure**

Solution A: 0.1 M monobasic ammonium phosphate adjusted with phosphoric acid to a pH of 3.1

Mobile phase: Acetonitrile and *Solution A* (20:80). Filter, and degas.

System suitability solution: 0.4 mg/mL each of USP Selegiline Hydrochloride RS and USP Methamphetamine Hydrochloride RS in *Mobile phase*

Standard solution: 0.4 mg/mL of USP Selegiline Hydrochloride RS in *Mobile phase*

Sample solution: Shake thoroughly each container of Topical Gel. Transfer 0.4 mL of Topical Gel into a 10-mL volumetric flask, dilute with *Mobile phase* to volume, and mix well.

Chromatographic system

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

Mode: LC

Detector: UV 205 nm

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

Flow rate: 1.0 mL/min

Injection volume: 8 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for methamphetamine hydrochloride and selegiline hydrochloride are about 0.63 and 1.0, respectively.]

Suitability requirements

Tailing factor: NMT 2.0, *Standard solution*

Resolution: NLT 8.0 between selegiline and methamphetamine, *System suitability solution*

Relative standard deviation: NMT 2.0% for replicate injections, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of selegiline hydrochloride ($C_{13}H_{17}N \cdot HCl$) in the portion of Topical Gel taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of selegiline hydrochloride from the *Sample solution*

r_S = peak response of selegiline hydrochloride from the *Standard solution*

C_S = concentration of selegiline hydrochloride in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH ⟨791⟩:** 4.6–5.6

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Package in a tight, light-resistant suitable calibrated dispenser. Store at 2°–8° or at controlled room temperature.

• **BEYOND-USE DATE:** NMT 90 days after the date on which it was compounded when stored at 2°–8° or at controlled room temperature

• **LABELING:** Label it to indicate that it is for external use only, keep out of the reach of children, use only as directed, and to state the *Beyond-Use Date*.

• **USP REFERENCE STANDARDS ⟨11⟩**

USP Methamphetamine Hydrochloride RS

USP Selegiline Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
SELEGILINE HYDROCHLORIDE COMPOUNDED TOPICAL GEL	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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