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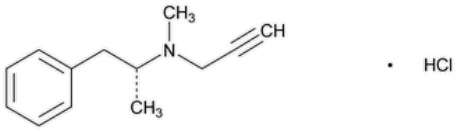
Selegiline Hydrochloride



· HCl

$C_{13}H_{17}N \cdot HCl$ 223.74

Benzeneethanamine, *N*,α-dimethyl-*N*-2-propynyl-, hydrochloride, (*R*)-.

(−)-(*R*)-*N*,α-Dimethyl-*N*-2-propynylphenethylamine hydrochloride CAS RN®: 14611-52-0; UNII: 6W731X367Q.

» Selegiline Hydrochloride contains not less than 98.0 percent and not more than 101.0 percent of $C_{13}H_{17}N \cdot HCl$, calculated on the dried basis.

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

USP Reference standards ⟨11⟩—
USP Selegiline Hydrochloride RS
USP Methamphetamine Hydrochloride RS

Identification—

Change to read:

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

Change to read:

B: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Ultraviolet-Visible Spectroscopy: 197U*▲ (CN 1-May-2020)

Solution: 0.5 mg per mL.

Medium: water.

C: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that of the *Standard preparation* obtained as directed in the *Assay*.

D: It responds to the tests for *Chloride* ⟨191⟩.

Melting range ⟨741⟩: not greater than 2°, within the limits of 141° and 145°.

Specific rotation ⟨781S⟩: between −10.0° and −12.0°.

Test solution: 100 mg per mL, in water.

Loss on drying ⟨731⟩—Dry it in vacuum at 60° for 3 hours: it loses not more than 1.0% of its weight.

Residue on ignition ⟨281⟩: not more than 0.2%.

Chromatographic purity—

Buffer solution, Mobile phase, and *System suitability solution*—Proceed as directed in the *Assay*.

Standard solution—Transfer 10.0 mL of the *System suitability solution* to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. Transfer 10.0 mL of this solution to a 50 mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Test solution—Transfer 50 mg of Selegiline Hydrochloride to a 50-mL volumetric flask, dissolve in and dilute with *Mobile phase* to volume, and mix.

Chromatographic system—Proceed as directed in the *Assay*. Inject about 20 µL of the *Standard solution*, and record the peak responses as directed in the *Procedure:* the resolution, *R,* between the methamphetamine and selegiline peaks is not less than 3, and the relative standard deviation for replicate injections is not more than 5.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard solution* and the *Test solution* into the chromatograph, and allow the *Test solution* to elute for not less than three times the retention time of selegiline. Record the chromatograms, and measure the peak responses. Calculate the percentage of each impurity in the portion of Selegiline Hydrochloride taken by the formula:

$$5000(C/W)(r_i/r_S)$$

in which *C* is the concentration, in mg per mL, of USP Selegiline Hydrochloride RS in the *Standard solution*, *W* is the weight, in mg, of Selegiline

Hydrochloride taken to prepare the *Test solution*, r_i is the peak response for each impurity in the chromatogram of the *Test solution*, and r_S is the peak response for selegiline in the chromatogram of the *Standard solution*. Not more than 0.2% of any individual impurity is found, and the sum of all impurities is not more than 1.0%.

Assay—

Buffer solution—Prepare a solution of 0.1 M monobasic ammonium phosphate, adjust with phosphoric acid to a pH of 3.1, and mix.

Mobile phase—Prepare a filtered and degassed mixture of *Buffer solution* and acetonitrile (80:20). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Dissolve an accurately weighed quantity of USP Selegiline Hydrochloride RS, and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 0.1 mg per mL.

System suitability solution—Dissolve accurately weighed quantities of USP Methamphetamine Hydrochloride RS and USP Selegiline Hydrochloride RS in *Mobile phase* to obtain a solution containing 0.1 mg per mL of each Reference Standard.

Assay preparation—Transfer an accurately weighed quantity, about 50 mg of Selegiline Hydrochloride, to a 50-mL volumetric flask, dissolve in and dilute with *Mobile phase* to volume, and mix. Transfer 10.0 mL of this solution to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 205-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 1 mL per minute. Chromatograph the *System suitability solution*, and record the peak responses as directed for *Procedure:* the resolution, *R,* between the methamphetamine and selegiline peaks is not less than 3, and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{13}H_{17}N \cdot HCl$ in the portion of Selegiline Hydrochloride taken by the formula:

$$500C(r_U/r_S)$$

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

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

Topic/Question	Contact	Expert Committee
SELEGILINE HYDROCHLORIDE	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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