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Selegiline Hydrochloride Tablets

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

IDENTIFICATION

Change to read:

• **▲A.▲** (USP 1-Aug-2020) The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

Add the following:

▲• B. The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-Aug-2020)

ASSAY

Change to read:

• **Procedure**

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

Mobile phase: Acetonitrile and *Solution A* (20:80)

System suitability solution: 0.1 mg/mL each of USP Methamphetamine Hydrochloride RS and USP Selegiline Hydrochloride RS in *Mobile phase*

Standard solution: 0.1 mg/mL of USP Selegiline Hydrochloride RS in *Mobile phase*

▲Sample stock solution:▲ (USP 1-Aug-2020) Nominally 1 mg/mL of selegiline hydrochloride from Tablets prepared as follows. Finely powder NLT 20 Tablets and transfer a suitable portion of the powder to a suitable volumetric flask. Add 80% of the flask volume of *Mobile phase*, sonicate for 10 min, dilute with *Mobile phase* to volume. Centrifuge a portion of this solution for 10 min and use the supernatant. [Note—The use of a centrifuge speed of NLT 3500 rpm may be suitable.]

Sample solution: Nominally 0.1 mg/mL of selegiline hydrochloride from *Sample stock solution* diluted with *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 205 nm. ▲For *Identification B*, use a diode array detector in the range of 190–400 nm.▲ (USP 1-Aug-2020)

Column: 3.9-mm × 30-cm; ▲10-µm▲ (USP 1-Aug-2020) packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

▲Run time: NLT 2.5 times the retention time of selegiline▲ (USP 1-Aug-2020)

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT ▲3.0▲ (USP 1-Aug-2020) between methamphetamine and selegiline

Relative standard deviation: ▲NMT 1.0%▲ (USP 1-Aug-2020)

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 Tablets taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Selegiline Hydrochloride RS 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%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Water; 500 mL

Apparatus 1: 50 rpm

Time: 20 min

Solution A and **Mobile phase:** Prepare as directed in the *Assay*.

Standard solution: 0.01 mg/mL of USP Selegiline Hydrochloride RS in water

Sample solution: Withdraw a 10-mL portion of the solution under test, and centrifuge. [Note—The use of a centrifugation speed of 3500 rpm for 10 min is recommended.]

Chromatographic system: Proceed as directed in the *Assay* except for the *Injection volume*.

Injection volume: 15 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of selegiline hydrochloride ($C_{13}H_{17}N \cdot HCl$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (1/L) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

V = volume of the *Medium*, 500 mL

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of selegiline hydrochloride ($C_{13}H_{17}N \cdot HCl$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

Change to read:

• **Organic Impurities, Procedure 1**

Solution A, Mobile phase, System suitability solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 0.005 mg/mL each of USP Methamphetamine Hydrochloride RS and USP Selegiline Hydrochloride RS from the *System suitability solution* diluted with *Mobile phase*

▲**Sample solution:** Nominally 1 mg/mL of selegiline hydrochloride from Tablets prepared as follows. Finely powder NLT 20 Tablets and transfer a suitable portion of the powder to a suitable volumetric flask. Add 80% of the flask volume of *Mobile phase*, sonicate for 10 min, and dilute with *Mobile phase* to volume. Centrifuge a portion of this solution for 10 min and use the supernatant. [Note—The use of a centrifuge speed of NLT 3500 rpm may be suitable.]▲ (USP 1-Aug-2020)

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT ▲3.0▲ (USP 1-Aug-2020) between methamphetamine and selegiline

Relative standard deviation: NMT 5.0% for selegiline

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity, excluding methamphetamine hydrochloride, in the portion of Tablets taken:

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

r_U = peak response of each impurity from the *Sample solution*

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

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

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

Acceptance criteria

Individual impurities: NMT 0.5%

Total impurities: NMT 2.0% (excluding methamphetamine hydrochloride)

Change to read:

• **Organic Impurities, Procedure 2: Limit of Methamphetamine Hydrochloride**

Solution A, Mobile phase, System suitability solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: ▲0.02 mg/mL each of▲ (USP 1-Aug-2020) USP Methamphetamine Hydrochloride RS and ▲▲ (USP 1-Aug-2020) USP Selegiline Hydrochloride RS from the *System suitability solution* diluted with *Mobile phase*

▲**Sample solution:** Nominally 1 mg/mL of selegiline hydrochloride from Tablets prepared as follows. Finely powder NLT 20 Tablets and transfer a portion of the powder equivalent to 50 mg of selegiline hydrochloride to a suitable volumetric flask. Add 80% of the flask volume of *Mobile phase*, sonicate for 10 min, and dilute with *Mobile phase* to volume. Centrifuge a portion of this solution for 10 min and use the supernatant. [Note—The use of a centrifuge speed of NLT 3500 rpm may be suitable.]▲ (USP 1-Aug-2020)

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT ▲3.0▲ (USP 1-Aug-2020) between methamphetamine and selegiline

Relative standard deviation: NMT 5.0% for selegiline and methamphetamine

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of methamphetamine hydrochloride in the portion of Tablets taken:

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

r_U = peak response of methamphetamine from the *Sample solution*

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

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

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

Acceptance criteria: NMT 2.0% for methamphetamine hydrochloride

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **USP Reference Standards** ⟨11⟩

USP Methamphetamine Hydrochloride RS

USP Selegiline Hydrochloride RS

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

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