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Tranylcypromine Tablets

DEFINITION

Tranylcypromine Tablets contain an amount of tranylcypromine sulfate [$(C_9H_{11}N)_2 \cdot H_2SO_4$] equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of tranylcypromine ($C_9H_{11}N$).

IDENTIFICATION

Change to read:

• **▲A.▲1S** *(USP41)* 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*.▲1S *(USP41)*

ASSAY

Change to read:

• **Procedure**

Buffer: Transfer 3.4 g of monobasic ammonium phosphate into a 1-L volumetric flask containing about 900 mL of water. Adjust the solution with phosphoric acid to a pH of 2.2 ± 0.1. Dilute with water to volume, and mix well.

Mobile phase: Methanol and *Buffer* (30:70)

▲▲ (ERR 1-Oct-2018)

Diluent: Methanol, water, and 0.05 N sulfuric acid ▲VS▲1S *(USP41)* (20:60:20)

Standard stock solution: 0.4 mg/mL of USP Tranylcypromine Sulfate RS prepared as follows. Transfer a suitable quantity of USP Tranylcypromine Sulfate RS to a suitable volumetric flask. Add 60% of the flask volume of methanol and 0.05 N sulfuric acid ▲VS▲1S *(USP41)* (50:50), sonicate to dissolve, and dilute with *Diluent* to volume.

Standard solution: 0.04 mg/mL of USP Tranylcypromine Sulfate RS in *Diluent*, from the *Standard stock solution*

Sample stock solution: Nominally 0.5 mg/mL of tranylcypromine prepared as follows. Transfer a suitable number of Tablets to an appropriate volumetric flask, add 30% of the flask volume of 0.05 N sulfuric acid ▲VS▲1S *(USP41)* and sonicate for 10 min with intermittent shaking. Add 30% of the flask volume of methanol and sonicate for 10 min with intermittent shaking. Shake by mechanical means for 30 min, dilute with *Diluent* to volume, and mix. Centrifuge a portion of the solution and pass the supernatant through a filter of 0.45-µm pore size, discarding the first 2 mL.

Sample solution: Nominally 0.03 mg/mL of tranylcypromine in *Diluent*, from the *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 220 nm. ▲For *Identification B*, use a diode array detector in the range of 200–400 nm.▲1S *(USP41)*

Column: 4.6-mm × 25-cm; 4-µm packing L11

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 20 µL

▲Run time: NLT 2 times the retention time of tranylcypromine▲1S *(USP41)*

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of tranylcypromine ($C_9H_{11}N$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times [M \times (M_{r1}/M_{r2})] \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

M = number of moles of tranylcypromine per mole of tranylcypromine sulfate, 2

M_{r1} = molecular weight of tranylcypromine, 133.19

M_{r2} = molecular weight of tranylcypromine sulfate, 364.46

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• **Dissolution ⟨711⟩**

Medium: 0.1 N hydrochloric acid VS; 500 mL, deaerated

Apparatus 1: 100 rpm

Time: 45 min

Buffer: Transfer 6.94 g of sodium perchlorate monohydrate to a 1000-mL volumetric flask containing 900 mL of water and mix until dissolved. Adjust with perchloric acid to a pH of 2.50 and dilute with water to volume.

Mobile phase: Acetonitrile and *Buffer* (15:85)

Standard stock solution: 0.54 mg/mL of USP Tranylcypromine Sulfate RS in water. [Note—Sonicate as needed.]

Standard solution: 0.027 mg/mL of USP Tranylcypromine Sulfate RS in *Medium*, from the *Standard stock solution*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 3.9-mm × 15-cm; 5-µm packing *L1*

Column temperature: 35°

Flow rate: 1 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

▲▲▲1S *(USP41)* ▲ (ERR 1-Oct-2018)

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of tranylcypromine ($C_9H_{11}N$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times [M \times (M_{r1}/M_{r2})] \times (1/L) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

V = volume of *Medium*, 500 mL

M = number of moles of tranylcypromine per mole of tranylcypromine sulfate, 2

M_{r1} = molecular weight of tranylcypromine, 133.19

M_{r2} = molecular weight of tranylcypromine sulfate, 364.46

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of tranylcypromine ($C_9H_{11}N$) is dissolved.

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

IMPURITIES

Change to read:

• **Organic Impurities**

Buffer▲▲1S *(USP41)* and **Diluent:** Prepare as directed in the *Assay*.

Solution A: Methanol and *Buffer* (15:85)

Solution B: Methanol and *Buffer* (30:70)

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
20	100	0
25	0	100
37	0	100
39	100	0
45	100	0

Standard stock solution: 70 µg/mL of USP Tranylcypromine Sulfate RS and 280 µg/mL of USP Tranylcypromine Related Compound A RS in *Diluent*. [Note—Sonicate as needed.]

Standard solution: 0.7 µg/mL of USP Tranylcypromine Sulfate RS and 2.8 µg/mL of USP Tranylcypromine Related Compound A RS prepared as follows. Transfer a suitable volume of the *Standard stock solution* to a suitable volumetric flask, add 30% each of the flask volume of 0.05 N sulfuric acid ▲VS▲1S *(USP41)* and methanol, and dilute with *Diluent* to volume.

Sample solution: Use the *Sample stock solution* prepared as directed in the *Assay*.

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 15-cm; 3-µm packing *L1*

Column temperature: 35°

Flow rate: 1.2 mL/min

Injection volume: 25 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 2.0 between tranylcypromine and tranylcypromine related compound A

Tailing factor: NMT 2.0

Relative standard deviation: NMT 6.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each ▲degradation product▲1S *(USP41)* in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times [M \times (M_{r1}/M_{r2})] \times 100$$

r_U = peak response of the ▲degradation product▲1S *(USP41)* from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

M = number of moles of tranylcypromine per mole of tranylcypromine sulfate, 2

M_{r1} = molecular weight of tranylcypromine, 133.19

M_{r2} = molecular weight of tranylcypromine sulfate, 364.46

Acceptance criteria

Individual ▲degradation product:▲1S *(USP41)* NMT 0.2%

Total ▲degradation products:▲1S *(USP41)* NMT 1.2%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers, and store at controlled room temperature.
- **USP Reference Standards** ⟨11⟩

USP Tranylcypromine Sulfate RS

USP Tranylcypromine Related Compound A RS

(±)-*cis*-2-Phenylcyclopropanamine hydrochloride;
cis-Tranylcypromine hydrochloride.
$C_9H_{11}N \cdot HCl$ 169.65

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

Topic/Question	Contact	Expert Committee
TRANYLCYPROMINE 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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