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Sertraline Hydrochloride Oral Solution

DEFINITION

Sertraline Hydrochloride Oral Solution contains an amount of sertraline hydrochloride equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of sertraline ($C_{17}H_{17}Cl_2N$).

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Buffer: 0.8 g/L of ammonium acetate in water. To each L of this solution add 10 mL of triethylamine, and adjust with phosphoric acid to a pH of 5.0.

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

Diluent: Methanol and water (50:50)

Standard solution: 0.1 mg/mL of USP Sertraline Hydrochloride RS in *Diluent*

Sample solution: Nominally, 0.1 mg/mL of sertraline in *Diluent*, from a portion of Oral Solution

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Column temperature: 50°

Flow rate: 2 mL/min

Injection volume: 20 µL

Run time: 1.3 times the retention time of sertraline

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.7

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of sertraline ($C_{17}H_{17}Cl_2N$) in the portion of Oral Solution taken:

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

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

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

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

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

M_{r1} = molecular weight of sertraline free base, 306.23

M_{r2} = molecular weight of sertraline hydrochloride, 342.69

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Deliverable Volume ⟨698⟩:** Meets the requirement

IMPURITIES

• **Organic Impurities**

Buffer: Dissolve 5.7 g of β-cyclodextrin hydrate and 8 mL of triethylamine in 1 L of water. Adjust with phosphoric acid to a pH of 6.5 ± 0.1.

Solvent mixture: Acetonitrile and methanol (55:45)

Mobile phase: *Solvent mixture* and *Buffer* (40:60)

Diluent: Acetonitrile and water (70:30)

Standard solution: 2.3 µg/mL of USP Sertraline Hydrochloride RS in *Diluent*

Sample solution: Nominally, 2 mg/mL of sertraline in *Diluent,* from a portion of Oral Solution

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; 5-µm packing L11

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 20 µL

Run time: 3 times the retention time of sertraline

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 5.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any individual degradation product in the portion of Oral Solution taken:

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

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

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

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

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

M_{r1} = molecular weight of sertraline free base, 306.23

M_{r2} = molecular weight of sertraline hydrochloride, 342.69

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Sertraline	1.0	—
Any individual unspecified degradation product	—	0.10
Total impurities	—	0.5

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.5–6.0

• **Microbial Enumeration Tests** ⟨61⟩and**Tests for Specified Microorganisms** ⟨62⟩**:** The total aerobic microbial count does not exceed 10^2 cfu/mL. The total molds and yeasts count does not exceed 10^1 cfu/mL. It meets the requirement of the test for absence of *Escherichia coli*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in light-resistant containers. Store at controlled room temperature.

• **USP Reference Standards** ⟨11⟩

USP Sertraline Hydrochloride RS

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

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

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