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# Sertraline Hydrochloride Tablets

**DEFINITION**

Sertraline Hydrochloride Tablets contain an amount of sertraline hydrochloride equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of sertraline free base ($C_{17}H_{17}Cl_2N$).

**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**

**Mobile phase:** Methanol and 0.1% (v/v) phosphoric acid (1:1)

**Standard solution:** 0.05 mg/mL of USP Sertraline Hydrochloride RS in *Mobile phase*

**Sample stock solution:** 0.5 mg/mL of sertraline free base prepared as follows. Transfer NLT 10 Tablets to a suitable volumetric flask. Dissolve in 0.1% phosphoric acid equivalent to 50% of the flask volume. Sonicate for 15 min with intermittent shaking to disperse the Tablets. Add an amount of methanol equivalent to 40% of the flask volume, and continue to sonicate for an additional 10 min. Cool the solution, and dilute with methanol to volume.

**Sample solution:** Nominally 0.05 mg/mL of sertraline free base in *Mobile phase* from the *Sample stock solution*. Pass a portion of this solution through a nylon filter of 0.45-µm or finer pore size, discard the first few mL, and collect the rest of the filtrate.

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 210 nm

**Column:** 4.6-mm × 25-cm; 5-µm packing L10

**Column temperature:** 30°

**Flow rate:** 1.5 mL/min

**Injection volume:** 10 µL

**Run time:** Twice the retention time of sertraline

**System suitability**

**Sample:** *Standard solution*

**Suitability requirements**

**Tailing factor:** NMT 2.0

**Relative standard deviation:** NMT 1.0%

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

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

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

$r_U$ = peak response from the *Sample solution*

$r_S$ = peak response from the *Standard solution*

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

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

$M_{r1}$ = molecular weight of sertraline, 306.23

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

**Acceptance criteria:** 90.0%–110.0% of sertraline free base

**PERFORMANCE TESTS**

• **Dissolution ⟨711⟩**

**Test 1**

**Medium:** Acetate buffer (3.0 g/L of sodium acetate trihydrate and 1.6 mL/L of glacial acetic acid; adjust with glacial acetic acid to a pH of 4.5); 900 mL

**Apparatus 2:** 75 rpm

**Time:** 30 min

**Standard stock solution:** 0.56 mg/mL of USP Sertraline Hydrochloride RS in *Medium*. A small volume of methanol, not exceeding 5% of the final volume, may be used to help solubilize sertraline.

**Standard solution**

**For Tablets labeled to contain 50, 100, 150, or 200 mg:** 0.056 mg/mL of USP Sertraline Hydrochloride RS in *Medium* from the *Standard stock solution*

**For Tablets labeled to contain 25 mg:** 0.028 mg/mL of USP Sertraline Hydrochloride 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. Dilute with *Medium*, if necessary.

**Mobile phase:** Acetonitrile and 0.1% (v/v) phosphoric acid (1:3)

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 210 nm

**Column:** 4.6-mm × 25-cm; 5-µm packing L10

**Column temperature:** 40°

**Flow rate:** 1.5 mL/min

**Injection volume**

**For Tablets labeled to contain 50, 100, 150, or 200 mg:** 10 µL

**For Tablets labeled to contain 25 mg:** 20 µL

**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 sertraline free base ($C_{17}H_{17}Cl_2N$) dissolved:

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

$r_U$ = peak response from the *Sample solution*

$r_S$ = peak response from the *Standard solution*

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

$L$ = label claim (mg/Tablet)

$M_{r1}$ = molecular weight of sertraline, 306.23

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

$D$ = dilution factor for the *Sample solution*

$V$ = volume of *Medium*, 900 mL

**Tolerances:** NLT 80% ($Q$) of the labeled amount of sertraline free base ($C_{17}H_{17}Cl_2N$) is dissolved.

**Test 2:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

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**Medium:** pH 4.5 acetate buffer (6.8 g/L of sodium acetate trihydrate and 32 mL/L of 2 N acetic acid; adjust with 2 N acetic acid to a pH of 4.5); 900 mL

**Apparatus 2:** 75 rpm

**Time:** 45 min

**Buffer:** 3 mL/L of glacial acetic acid and 7 mL/L of triethylamine in water

**Mobile phase:** Acetonitrile, methanol, and *Buffer* (10:4:8)

**Standard solution:** (*L*/800) mg/mL of USP Sertraline Hydrochloride RS in *Medium*, where *L* is the label claim in mg/Tablet

**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 273 nm

**Column:** 3.9-mm × 15-cm; 4-µm packing L1

**Column temperature:** 30°

**Flow rate:** 1.0 mL/min

**Injection volume:** 20 µL

**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 sertraline free base ($C_{17}H_{17}Cl_2N$) dissolved:

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

$r_U$ = peak response from the *Sample solution*

$r_S$ = peak response from the *Standard solution*

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

$L$ = label claim (mg/Tablet)

$M_{r1}$ = molecular weight of sertraline, 306.23

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

$D$ = dilution factor for the *Sample solution*

$V$ = volume of *Medium*, 900 mL

**Tolerances:** NLT 80% (*Q*) of the labeled amount of sertraline free base ($C_{17}H_{17}Cl_2N$) is dissolved.

**Test 3:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 3*.

**Medium:** pH 4.5 acetate buffer (6.8 g/L of sodium acetate trihydrate; adjust with 2 N acetic acid to a pH of 4.5); 900 mL

**Apparatus 2:** 75 rpm

**Time:** 30 min

**Buffer:** Dissolve 0.8 g/L of ammonium acetate in water and add 10 mL of triethylamine. Adjust with phosphoric acid to a pH of 5.0 ± 0.05.

**Mobile phase:** Acetonitrile and *Buffer* (35:65)

**Standard stock solution:** 0.6 mg/mL of USP Sertraline Hydrochloride RS in *Medium*, prepared as follows. Place an appropriate amount of USP Sertraline Hydrochloride RS into a suitable volumetric flask and add 70% of the final flask volume of *Medium*. Sonicate to dissolve and dilute with *Medium* to volume. Pass through a suitable filter of 0.45-µm pore size.

**Standard solution:** (*L*/800) mg/mL of USP Sertraline Hydrochloride RS in *Medium* from *Standard stock solution*, where *L* is the label claim in mg/Tablet

**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

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**Detector:** UV 220 nm

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

**Column temperature:** 50°

**Flow rate:** 2.0 mL/min

**Injection volume:** 20 µL

**System suitability**

**Sample:** *Standard solution*

**Suitability requirements**

**Tailing factor:** NMT 2.0

**Relative standard deviation:** NMT 1.0%

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of sertraline free base ($C_{17}H_{17}Cl_2N$) dissolved:

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

$r_U$ = peak response from the *Sample solution*

$r_S$ = peak response from the *Standard solution*

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

$L$ = label claim (mg/Tablet)

$M_{r1}$ = molecular weight of sertraline, 306.23

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

$V$ = volume of *Medium*, 900 mL

**Tolerances:** NLT 80% ($Q$) of the labeled amount of sertraline free base ($C_{17}H_{17}Cl_2N$) is dissolved.

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

**IMPURITIES**

• **Organic Impurities**

[Note—Use freshly prepared samples.]

**Buffer:** 2.72 g/L of monobasic potassium phosphate. Adjust with triethylamine to a pH of 7.0.

**Mobile phase:** Methanol, acetonitrile, and *Buffer* (6:3:11). Adjust with triethylamine to a pH of 8.0.

**System suitability solution:** 5 µg/mL of USP Sertraline Hydrochloride Racemic Mixture RS and 0.5 mg/mL of USP Sertraline Hydrochloride RS in *Mobile phase*

**Standard solution:** 2.5 µg/mL of USP Sertraline Hydrochloride RS in *Mobile phase*

**Sample solution:** [Note—Sonicate for about 10 min with shaking to disperse the Tablets.] Prepare a solution of 0.5 mg/mL of sertraline in *Mobile phase* from NLT 20 powdered Tablets. Pass a portion of this solution through a nylon filter of 0.45-µm or finer pore size, discard the first few mL, and use the filtrate.

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 210 nm

**Column:** 4.0-mm × 25-cm; 5-µm packing L45

**Flow rate:** 0.7 mL/min

**Injection volume:** 20 µL

**System suitability**

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

[Note—The relative retention times for the 1*R*,4*R*-*cis*-isomer of sertraline and sertraline are 0.9 and 1.0, respectively.]

**Suitability requirements**

**Resolution:** NLT 1.5 between sertraline and the 1*R*,4*R*-*cis*-isomer of sertraline, *System suitability solution*

**Relative standard deviation:** NMT 5%, *Standard solution*

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

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Calculate the percentage of each individual degradation product in the portion of Tablets 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 degradation product 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, 306.23

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

**Acceptance criteria**

Disregard any peak below 0.1%. Disregard the peak due to the process impurity 1*R*,4*R*-*cis*-isomer of sertraline.

**Individual degradation product:** NMT 0.2%

**Total degradation products:** NMT 2.0%, excluding the 1*R*,4*R*-*cis*-isomer of sertraline

## ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers, and store at controlled room temperature.
- **Labeling:** When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.
- **USP Reference Standards** ⟨11⟩

USP Sertraline Hydrochloride RS

USP Sertraline Hydrochloride Racemic Mixture RS

(1*RS*,4*RS*)-4-(3,4-Dichlorophenyl)-*N*-methyl-1,2,3,4-tetrahydro-1-naphthylamine hydrochloride.

$C_{17}H_{17}Cl_2N \cdot HCl$ 342.69

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

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| SERTRALINE HYDROCHLORIDE TABLETS | Documentary Standards Support | SM42020 Small Molecules 4 |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br>RSTECH@usp.org | SM42020 Small Molecules 4 |

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