PERFORMANCE TESTS

**ASSAY**

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

**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 (C17H17Cl2N).

**IDENTIFICATION**

A. The retention time of the major peak in the **Sample solution** corresponds to that in 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**: 0.05 mg/mL prepared as follows. Pass a portion of this solution through a suitable filter of 0.45-µm pore size, discard the first few mL, and collect the rest of the filtrate.
  - **Sample solution**: 0.05 mg/mL 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**: 40°
- **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**
  - **Result** = (r0/rS) × (CJ/C0) × (Mi/L) × 100
  - **r0** = peak response from the **Sample solution**
  - **rS** = peak response from the **Standard solution**

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

**PERFORMANCE TESTS**

**Dissolution (711)**

- **Test 1**: Acceptance criteria (mg/Tablet) for Tablets labeled to contain 50 mg, 100 mg, 150 mg, or 200 mg:
  - **Standard stock solution**: 0.056 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.
  - **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**: 10 µL for Tablets labeled to contain 50 mg, 100 mg, 150 mg, or 200 mg; 20 µL for Tablets labeled to contain 25 mg

**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**
  - **Result** = (r0/rS) × (CJ/L) × (Mi/L) × V × 100

- **Tolerances**: NLT 80% (Q) of the labeled amount of sertraline (C17H17Cl2N) is dissolved.
Sertraline

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

**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

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

**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)

**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 1R,4R cis-isomer of sertraline and sertraline are 0.9 and 1.0, respectively.]

**Suitability requirements**

**Resolution:** NLT 1.5 between sertraline (cis isomer) and any other impurity

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

**Analysis**

**Samples:** Standard solution and Sample solution

Calculate the percentage of each individual impurity (other than process related) in the portion of Tablets taken:

\[
\text{Result} = \left( \frac{r_U}{r_S} \right) \times \left( \frac{C_S}{C_U} \right) \times \left( \frac{M_2}{M_1} \right) \times D \times V \times 100
\]

**r_0** = 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_2** = molecular weight of sertraline hydrochloride, 306.23

**M_1** = molecular weight of USP Sertraline Hydrochloride RS, 342.69

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

**V** = volume of Medium; 900 mL

**Acceptance criteria**

[NOTE—Disregard any peak below 0.1%]

**Individual impurities:** NMT 0.2% of any individual impurity

**Total impurities:** NMT 2.0%

**ADDITIONAL REQUIREMENTS**

**Packaging and Storage:** Preserve in well-closed containers, and store at controlled room temperature.

**Add the following:**

**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 (1R54R)-4-(3,4-Dichlorophenyl)-N-methyl-1,2,3,4-tetrahydro-1-naphthylamine hydrochloride. C_{17}H_{17}Cl_{2}N\cdot HCl 342.69\text{g/mol} 17-Dec-2014