

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-Dec-2016
 Document Type: USP Monographs
 DocId: GUID-FE7CCE68-66B4-409C-9DD1-C04830A444DF_1_en-US
 DOI: https://doi.org/10.31003/USPNF_M75105_01_01
 DOI Ref: c2hrd

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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- μ m 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 $\times$ 25-cm; 5- μ m packing L10

Column temperature: 30°

Flow rate: 1.5 mL/min

Injection volume: 10 μ L

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

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*.

