Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Aug-2024
Document Type: USP Monographs
DocId: GUID-AD59E2B6-99AF-4FB0-A957-6DAA9FC08E18_4_en-US
DOI: https://doi.org/10.31003/USPNF_M77678_04_01
DOI Ref: vjytq

Sotalol Hydrochloride Tablets

DEFINITION
Sotalol Hydrochloride Tablets contain NLT 95.0% and NMT 105.0% of the labeled amount of sotalol hydrochloride ($C_{12}H_{20}N_2O_3S \cdot HCl$).

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*.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY
- **Procedure**

Mobile phase: 2 g/L of octanesulfonic acid sodium salt prepared as follows. Transfer a suitable quantity of octanesulfonic acid sodium salt to an appropriate container containing 79% of the container volume of water. Adjust with phosphoric acid to a pH of 3.0. Dilute with acetonitrile to volume.

System suitability solution: 0.2 mg/mL of USP Sotalol Hydrochloride RS and 0.6 µg/mL of USP Sotalol Related Compound A RS in *Mobile phase*. Sonicate to dissolve as needed.

Standard solution: 0.2 mg/mL of USP Sotalol Hydrochloride RS in *Mobile phase*. Sonicate to dissolve as needed.

Sample stock solution: Nominally 2 mg/mL of sotalol hydrochloride from Tablets in *Mobile phase* prepared as follows. Weigh Tablets (NLT 5) into a suitable volumetric flask. Add about 60% of the volume of *Mobile phase*. Sonicate for NLT 20 min to disintegrate the tablets. Then shake by mechanical means for NLT 20 min. Allow to cool to room temperature. Dilute with *Mobile phase* to volume. Centrifuge a portion of the resulting solution and use the supernatant.

Sample solution: Nominally 0.2 mg/mL of sotalol hydrochloride from *Sample stock solution* in *Mobile phase*

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

Mode: LC

Detector: UV 228 nm. For *Identification B*, use a diode array detector in the range of 190–400 nm.

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

Run time: NLT 2 times the retention time of sotalol

System suitability

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

[Note—See *Table 1* for relative retention times.]

Suitability requirements

Resolution: NLT 4.0 between sotalol and sotalol related compound A, *System suitability solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of sotalol hydrochloride ($C_{12}H_{20}N_2O_3S \cdot HCl$) in the portion of Tablets taken:

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

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

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

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

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

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard solution: (*L*/900) mg/mL of USP Sotalol Hydrochloride RS in *Medium*, where *L* is the label claim of sotalol hydrochloride in mg/Tablet

Sample solution: Pass a portion of the solution under test through a suitable filter.

Instrument conditions

(See *Ultraviolet-Visible Spectroscopy ⟨857⟩*.)

Mode: UV

Analytical wavelength: 230 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of sotalol hydrochloride ($C_{12}H_{20}N_2O_3S \cdot HCl$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

V = volume of *Medium*, 900 mL

L = label claim of sotalol hydrochloride (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of sotalol hydrochloride ($C_{12}H_{20}N_2O_3S \cdot HCl$) is dissolved.

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

IMPURITIES

• **Organic Impurities**

Mobile phase: Prepare as directed in the *Assay*.

Sensitivity solution: 2 µg/mL of USP Sotalol Hydrochloride RS in *Mobile phase*. Sonicate to dissolve as needed.

Standard solution: 6 µg/mL each of USP Sotalol Hydrochloride RS, USP Sotalol Related Compound A RS, USP Sotalol Related Compound B RS, and USP Sotalol Related Compound C RS in *Mobile phase*. Sonicate to dissolve as needed.

Sample solution: Nominally 2 mg/mL of sotalol hydrochloride from Tablets in *Mobile phase* prepared as follows. Weigh Tablets (NLT 5) into a suitable volumetric flask. Add about 60% of the volume of *Mobile phase*. Sonicate for NLT 20 min to disintegrate the tablets. Then shake by mechanical means for NLT 20 min. Allow to cool to room temperature. Dilute with *Mobile phase* to volume. Centrifuge a portion of the resulting solution and use the supernatant.

Chromatographic system

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

Mode: LC

Detector: UV 228 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

Run time: NLT 2.5 times the retention time of sotalol

System suitability

Samples: *Sensitivity solution* and *Standard solution*

[Note—See *Table 1* for relative retention times.]

Suitability requirements

Resolution: NLT 4.0 between sotalol and sotalol related compound A, *Standard solution*

Relative standard deviation: NMT 5.0% each for sotalol, sotalol related compound A, sotalol related compound B, and sotalol related compound C, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sotalol related compound A, sotalol related compound B, or sotalol related compound C in the portion of Tablets taken:

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

r_U = peak response of sotalol related compound A, sotalol related compound B, or sotalol related compound C from the *Sample solution*

r_S = peak response of sotalol related compound A, sotalol related compound B, or sotalol related compound C from the *Standard solution*

C_S = concentration of USP Sotalol Related Compound A RS, USP Sotalol Related Compound B RS, or USP Sotalol Related Compound C RS in the *Standard solution* (mg/mL)

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

Calculate the percentage of any unspecified degradation product in the portion of Tablets taken:

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

r_U = peak response of any unspecified degradation product from the *Sample solution*

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

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

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

Acceptance criteria: See *Table 1*. The reporting threshold is 0.1%.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Sotalol related compound B	0.5	0.3
Sotalol	1.0	—
Sotalol related compound A	1.2	0.3
Sotalol related compound C	1.4	0.4
Any unspecified degradation product	—	0.2
Total degradation products	—	0.5

ADDITIONAL REQUIREMENTS

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

Change to read:

• **USP Reference Standards** ⟨11⟩

USP Sotalol Hydrochloride RS

USP Sotalol Related Compound A RS

N-[4-(Isopropylglycyl)phenyl]methanesulfonamide hydrochloride.

$C_{12}H_{18}N_2O_3S \cdot HCl$ 306.81

USP Sotalol Related Compound B RS

N-(4-Formylphenyl)methanesulfonamide.

$C_8H_9NO_3S$ 199.22

USP Sotalol Related Compound C RS

▲*N*-{4-[2-(Isopropylamino)ethyl]phenyl}methanesulfonamide hydrochloride.

$C_{12}H_{20}N_2O_2S \cdot HCl$ 292.82▲ (CN 1-Aug-2024)

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

Topic/Question	Contact	Expert Committee
SOTALOL HYDROCHLORIDE TABLETS	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 47(2)

Current DocID: GUID-AD59E2B6-99AF-4FB0-A957-6DAA9FC08E18_4_en-US

DOI: https://doi.org/10.31003/USPNF_M77678_04_01

DOI ref: vjytq