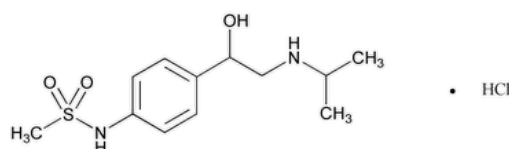


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Sotalol Hydrochloride

Change to read:



$C_{12}H_{20}N_2O_3S \cdot HCl$ ▲308.82▲ (CN 1-Aug-2024)

Methanesulfonamide, *N*-[4-[1-hydroxy-2-[(1-methylethyl)amino]ethyl]phenyl]-, monohydrochloride;

4'-[1-Hydroxy-2-(isopropylamino)ethyl]methanesulfonanilide monohydrochloride CAS RN®: 959-24-0; UNII: HEC37C70XX.

DEFINITION

Sotalol Hydrochloride contains NLT 98.5% and NMT 101.5% of sotalol hydrochloride ($C_{12}H_{20}N_2O_3S \cdot HCl$).

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy: 197K**
- **B.** The retention time of the sotalol peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Mobile phase: Transfer about 1.08 g of [sodium 1-octanesulfonate](#) to a 1000-mL volumetric flask. Dissolve in 10 mL of [glacial acetic acid](#) and about 70 mL of [water](#). Add 720 mL of [water](#) and dilute with [acetonitrile](#) to volume.

Diluent: [Acetonitrile](#) and [water](#) (1:4)

Internal standard solution: 4.5 mg/mL of caffeine in *Diluent*

Standard stock solution: 2 mg/mL of [USP Sotalol Hydrochloride RS](#) in *Diluent*

Standard solution: 0.2 mg/mL of [USP Sotalol Hydrochloride RS](#) prepared as follows. Transfer 10.0 mL of *Standard stock solution* and 5.0 mL of *Internal standard solution* to a 100-mL volumetric flask. Dilute with *Diluent* to volume.

Sample stock solution: 2 mg/mL of Sotalol Hydrochloride in *Diluent*

Sample solution: 0.2 mg/mL of Sotalol Hydrochloride prepared as follows. Transfer 10 mL of *Sample stock solution* and 5.0 mL of *Internal standard solution* to a 100-mL volumetric flask. Dilute with *Diluent* to volume.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 238 nm

Column: 3.9-mm × 30-cm; 10-μm packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 25 μL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for caffeine and sotalol are 0.39 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 8.5 between caffeine and sotalol

Relative standard deviation: NMT 0.55%

Analysis

Samples: *Standard solution* and *Sample solution*

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

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak area ratio of sotalol to caffeine from the *Sample solution*

R_S = peak area ratio of sotalol to caffeine from the *Standard solution*

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

C_U = concentration of Sotalol Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 98.5%–101.5%

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.5%

• ORGANIC IMPURITIES

Mobile phase and Chromatographic system: Proceed as directed in the Assay.

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*

Sample solution: 2 mg/mL of Sotalol Hydrochloride in *Mobile phase*

System suitability

Sample: *Standard solution*

[NOTE—See [Table 1](#) for relative retention times.]

Suitability requirements

Resolution: NLT 2.0 between sotalol related compound A and sotalol

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each sotalol related compound in the portion of Sotalol Hydrochloride taken:

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

r_U = peak response of the corresponding sotalol related compound from the *Sample solution*

r_S = peak response of the corresponding sotalol related compound from the *Standard solution*

C_S = concentration of the corresponding Reference Standard in the *Standard solution* (µg/mL)

C_U = concentration of Sotalol Hydrochloride in the *Sample solution* (µg/mL)

Calculate the percentage of any unspecified impurity in the portion of Sotalol Hydrochloride taken:

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

r_U = peak response of each unspecified impurity 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* (µg/mL)

C_U = concentration of Sotalol Hydrochloride in the *Sample solution* (µg/mL)

Acceptance criteria: See [Table 1](#).

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Sotalol related compound B	0.65	0.3

