

Sotalol Hydrochloride Compounded Oral Suspension

DEFINITION
Sotalol Hydrochloride Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of sotalol hydrochloride ($C_{12}H_{20}N_2O_3S \cdot HCl$).
Prepare Sotalol Hydrochloride Compounded Oral Suspension 5 mg/mL as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Sotalol Hydrochloride tablets ^a equivalent to	600 mg of sotalol hydrochloride
Vehicle: a 1:1 mixture of Ora-Sweet ^b and Ora-Plus, ^b a sufficient quantity to make	120 mL

- ^a Betapace 120-mg tablets, Berlex Laboratories, Wayne, NJ.
^b Paddock Laboratories, Minneapolis, MN.

Calculate the required quantity of each ingredient for the total amount to be prepared. Place the required number of *Sotalol Hydrochloride tablets* in a suitable mortar, and comminute to a fine powder with a pestle. Add the *Vehicle* in small portions, and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a sotalol hydrochloride liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough of the *Vehicle* to bring to final volume, and mix well.

ASSAY
PROCEDURE
Mobile phase: Acetonitrile and 5 mM octanesulfonic acid (25:75), adjusted to a pH of 3.2. Pass through a nylon 66 filter of 0.45-µm pore size, and degas.
Standard solution: 20 µg/mL of [USP Sotalol Hydrochloride RS](#) in *Mobile phase*
Sample solution: Shake thoroughly by hand each bottle of Oral Suspension. Prepare 20 µg/mL of sotalol hydrochloride from Oral Suspension and *Mobile phase*. Centrifuge.
Chromatographic system
(See [Chromatography \(621\), System Suitability](#).)
Mode: LC
Detector: UV 235 nm
Column: 3.0-mm × 15-cm; 5-µm packing L1
Flow rate: 0.4 mL/min
Injection volume: 10 µL
System suitability
Sample: *Standard solution*
[NOTE—The retention time for sotalol hydrochloride is about 5.1 min.]
Suitability requirements
Relative standard deviation: NMT 2.0% for replicate injections
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 Oral Suspension taken:

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

r_U = peak response from the *Sample solution*

r_s = peak response from the *Standard solution*

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

C_u = nominal concentration of sotalol hydrochloride in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **pH** (791): 3.8–4.8

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store in a refrigerator or at controlled room temperature.
- **BEYOND-USE DATE:** NMT 90 days after the date on which it was compounded when stored in a refrigerator or at controlled room temperature
- **LABELING:** Label it to indicate that it is to be well shaken before use, and to state the *Beyond-Use Date*.
- **USP REFERENCE STANDARDS** (11).
[USP Sotalol Hydrochloride RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
SOTALOL HYDROCHLORIDE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: [Chromatographic Database](#)

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