

Guidance on Sotalol Hydrochloride

This guidance represents the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Sotalol hydrochloride

Dosage Form; Route: Tablet; oral

Recommended Studies: Two Options: BCS or *In-Vivo* Studies

I. BCS Waiver option:

It may be possible to request a waiver of *in-vivo* testing for all the strengths of this product provided that the appropriate documentation regarding high solubility, high permeability and rapid dissolution as detailed in the Guidance for Industry: *Waiver of In Vivo Bioavailability and Bioequivalence for Immediate – Release Solid Oral Dosage Forms Based on the Biopharmaceutics Classification System* is submitted in the application. You may use information contained in the approved labeling of the reference product. Peer reviewed articles may not contain the necessary details of the testing for the Agency to make a judgment regarding the quality of the studies. A decision regarding the acceptability of the waiver request can only be made upon review of the data submitted in the application.

II. *In-Vivo* option:

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: 160 mg
Subjects: Healthy males and nonpregnant females, general population
Additional Comments: None

2. Type of study: Fed
Design: Single-dose, two-way crossover *in-vivo*
Strength: 160 mg
Subjects: Healthy males and nonpregnant females, general population
Additional Comments: None

Analyte to measure: Sotalol in plasma

Bioequivalence based on (90% CI): Sotalol

Waiver request of in-vivo testing: 80 mg and 120 mg based on (i) acceptable bioequivalence studies on the 160 mg strength, (ii) proportional similarity of the 80 mg, 120 mg, and 160 mg strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).