Active ingredient: Sotalol Hydrochloride

Form/Route: Tablet/Oral

Recommended studies: 2 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:

2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: 160 mg
   Additional Comments: Please refer to the Amantadine Hydrochloride Tablet Draft Guidance for additional information regarding fed studies.

Analyte to measure: Sotalol in plasma

Bioequivalence based on (90% CI): Sotalol

Waiver request of in-vivo testing: 80 mg, 120 mg and 240 mg based on (i) acceptable bioequivalence studies on the 160 mg strength, (ii) proportional similarity of the 80 mg, 120 mg, 160 mg and 240 mg strengths, and (iii) acceptable in vitro dissolution testing of all strengths. Please refer to the Mirtazapine Tablet Draft Guidance for additional information regarding waivers of in-vivo testing.

Dissolution test method and sampling times: Please note that a Dissolution Methods Database is available to the public at the OGD website at http://www.accessdata.fda.gov/scripts/cder/dissolution/. Please find the dissolution information for this product at this website. Please 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 application.

Recommended Dec 2010