Active ingredient: Labetalol Hydrochloride

Form/Route: Tablet/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: 200 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: 200 mg
   Subjects: Healthy males and nonpregnant females, general population
   Additional Comments:

Analytes to measure (in appropriate biological fluid): Labetalol in plasma

Bioequivalence based on (90% CI): Labetalol

Waiver request of in-vivo testing: 100 mg and 300 mg based on (i) acceptable bioequivalence studies on the 200 mg strength, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity in the formulations across all strengths.

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 Jun 2009, Revised Apr 2010