Active ingredient: Amlodipine Besylate; Olmesartan Medoxomil

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way, crossover in-vivo
   Strength: 10 mg base/40 mg
   Subjects: Normal healthy males and females, general population
   Additional Comments: Females should not be pregnant, and if applicable, should practice abstention or contraception during the study.

2. Type of study: Fed
   Design: Single-dose, two-way, crossover in-vivo
   Strength: 10 mg base/40 mg
   Subjects: Normal healthy males and females, general population
   Additional comments: Please see comment above.

Analytes to measure: Amlodipine and olmesartan in plasma

Bioequivalence based on (90% CI): Amlodipine and olmesartan

Waiver request of in-vivo testing: 5 mg base/20 mg, 5 mg base/40 mg and 10 mg base/20 mg based on (i) acceptable bioequivalence studies on the 10 mg base/40 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.fda.gov/cder/ogd/index.htm. 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 Oct 2008