Active ingredient: Fenofibrate

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 120 mg
   Subjects: Normal healthy males and females, general population.
   Additional Comments: Females should not be pregnant or lactating, and if applicable, should practice abstinence or contraception during the study.

2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 120 mg
   Subjects: Normal healthy males and females, general population.
   Additional Comments: Please see comment above.

Analytes to measure: The active metabolite fenofibric acid in plasma

Bioequivalence based on (90% CI): Fenofibric acid

Waiver request of in-vivo testing: 40 mg based on (i) acceptable bioequivalence studies on the 120 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 Sept 2008