Active ingredient: Ketorolac Tromethamine

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way, crossover in-vivo
   Strength: 10 mg
   Subjects: Normal healthy males and females, general population
   Additional Comments: Females should not be pregnant or lactating, 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
   Subjects: Normal healthy males and females, general population
   Additional comments:

Analytes to measure: Ketorolac in plasma

Bioequivalence based on (90% CI): Ketorolac

Waiver request of in-vivo testing: Not Applicable

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 Jul 2008