Active ingredient: Ibuprofen
Form/Route: Tablets/Oral
Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: 800 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: 800 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments:

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

Bioequivalence based on (90% CI): Ibuprofen

Waiver request of in-vivo testing: 400 mg and 600 mg strengths, based on (i) acceptable bioequivalence studies on the 800 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of 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.