Active Ingredient: Diclofenac

Dosage Form; Route: Capsule; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 35 mg
   Subjects: Healthy males and nonpregnant females, general population

2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 35 mg
   Subjects: Healthy males and nonpregnant females, general population

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

Bioequivalence based on (90% CI): Diclofenac

Waiver request of in vivo testing: 18 mg, based on (i) acceptable bioequivalence studies on the 35 mg strength, (ii) proportional similarity of the formulations between both strengths, and (iii) acceptable in vitro dissolution testing of both strengths.

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. 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 abbreviated new drug application (ANDA).