Contains Nonbinding Recommendations

Draft Guidance on Diclofenac

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

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

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

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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).