Contains Nonbinding Recommendations

Guidance on Diflunisal

This guidance represents the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Diflunisal

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way, crossover *in-vivo*
   Strength: 500 mg
   Subjects: Healthy males and nonpregnant females, general population
   Additional Comments: The subjects should have no history of any cardiovascular and gastrointestinal diseases and have no known allergy to aspirin or any other anti-inflammatory drugs.

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2. Type of study: Fed
   Design: Single-dose, two-way, crossover *in-vivo*
   Strength: 500 mg
   Subjects: Healthy males and nonpregnant females, general population
   Additional comments: See comment above.

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

Bioequivalence based on (90% CI): Diflunisal

Waiver request of in-vivo testing: Not applicable.

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).