

## Draft Guidance on Diflunisal

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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:** Diflunisal

**Form/Route:** Tablets/Oral

**Recommended studies:** 1 study

Type of study: Fasting

Design: Single-dose, two-way, crossover *in-vivo*

Strength: 500 mg

Subjects: Normal healthy males and females, general population

Additional Comments: Subjects should not have a history of cardiovascular and gastrointestinal disease, allergy to aspirin or other anti-inflammatory drugs.

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**Analytes to measure:** Diflunisal in plasma

**Bioequivalence based on (90% CI):** Diflunisal

**Waiver request of in-vivo testing:** 250 mg based on (i) acceptable bioequivalence studies on the 500 mg strength, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity in the formulations across 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.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.