

Draft Guidance on Diflunisal

October 2024

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Active Ingredient: Diflunisal

Dosage Form: Tablet

Route: Oral

Strength: 500 mg

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 500 mg
Subjects: Healthy males and non-pregnant non-lactating females
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.

Analyte to measure: 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 in the FDA's Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each of the test product and reference listed drug (RLD).¹ Specifications will be determined upon review of the abbreviated new drug application.

Document History: Recommended July 2008; Revised December 2012; Finalized August 2017; Revised October 2024

Unique Agency Identifier: PSG_018445

¹ If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.