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Draft Guidance on Celecoxib

May 2025

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Active Ingredient: Celecoxib

Dosage Form: Capsule

Route: Oral

Strengths: 50 mg, 100 mg, 200 mg, 400 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: 400 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Exclude geriatric subjects and subjects with a prior history of gastric ulcer and bleeding as well as allergic reaction from nonsteroidal anti-inflammatory drugs and sulfonamides. Exclude CYP2C9 poor metabolizers (i.e., CYP2C9*3/*3).

Analyte to measure: Celecoxib in plasma

Bioequivalence based on (90% CI): Celecoxib

Waiver request of in vivo testing: 50 mg, 100 mg, and 200 mg strengths based on (i) an acceptable bioequivalence study on the 400 mg strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths

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 all strengths of the test product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

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[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*.