

Draft Guidance on Ibuprofen

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Dosage Form; Route: Capsule; oral

Recommended Studies: Two studies

1. **Type of study:** Fasting
Design: Single-dose, two-way crossover in vivo
Strength: EQ 200 mg free acid and potassium salt
Subjects: Healthy males, nonpregnant females, general population
Additional comments: None

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2. **Type of study:** Fed
Design: Single-dose, two-way crossover in vivo
Strength: EQ 200 mg free acid and potassium salt
Subjects: Healthy males, nonpregnant females, general population
Additional comments: None

Analytes to measure: Ibuprofen in plasma

Bioequivalence based on (90% CI): Ibuprofen

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 the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).