

Draft Guidance on Ibuprofen

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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: Ibuprofen

Dosage Form; Route: Suspension; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way, crossover *in-vivo*
Strength: 100 mg/5 mL
Subjects: Healthy males and non-pregnant females, general population.
Additional comments: None

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2. Type of study: Fed
Design: Single-dose, two-way, crossover *in-vivo*
Strength: 100 mg/5 mL
Subjects: Healthy males and non-pregnant females, general population.
Additional comments: None
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Analytes to measure (in appropriate biological fluid): Ibuprofen in plasma

Bioequivalence based on (90% CI): Ibuprofen.

Waiver request of in-vivo testing: N/A

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. A dosage unit for a suspension is the labeled strength (5 mL). Twelve (12) units from 12 different bottles should be used. Specifications will be determined upon review of the abbreviated new drug application (ANDA).