

## Draft Guidance on Ibuprofen and Pseudoephedrine Hydrochloride

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

**Form/Route:** Suspension/Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover *in-vivo*  
Strength: 100 mg/5 mL and 15 mg/5 mL  
Subjects: Normal healthy males and females, general population.  
Additional Comments:

2. Type of study: Fed  
Design: Single-dose, two-way crossover *in-vivo*  
Strength: 100 mg/5 mL and 15 mg/5 mL  
Subjects: Normal healthy males and females, general population.  
Additional comments:

**Analytes to measure:** Ibuprofen and Pseudoephedrine in plasma

**Bioequivalence based on (90% CI):** Ibuprofen and Pseudoephedrine

**Waiver request of in-vivo testing:** Not Applicable

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