

*Contains Nonbinding Recommendations*

**Draft Guidance on Acetaminophen**

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

**Form/Route:** Extended Release Tablet/Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover in-vivo  
Strength: 650 mg  
Subjects: Healthy males and nonpregnant females, general population.  
Additional Comments:

2. Type of study: Fed  
Design: Single-dose, two-way crossover in-vivo  
Strength: 650 mg  
Subjects: Healthy males and nonpregnant females, general population.  
Additional Comments: Please refer to the Amantadine Hydrochloride Tablet Guidance for additional information regarding fed studies.

**Analytes to measure:** Acetaminophen in plasma

**Bioequivalence based on (90% CI):** Acetaminophen

**Waiver request of in-vivo testing:** Acetaminophen Extended Release Caplet or Gelcap, 650 mg based on (i) acceptable bioequivalence studies on the 650 mg strength Geltab or Caplet, (ii) acceptable in-vitro dissolution testing of both dosage forms, and (iii) proportional similarity of both formulations.

**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.accessdata.fda.gov/scripts/cder/dissolution/>. 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. Specifications will be determined upon review of the application.