

## Draft Guidance on Diphenhydramine Hydrochloride

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

**Form/Route:** Capsule/Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover in vivo  
Strength: 50 mg  
Subjects: Healthy males and nonpregnant females, general population.

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2. Type of study: Fed  
Design: Single-dose, two-way crossover in vivo  
Strength: 50 mg  
Subjects: Healthy males and nonpregnant females, general population.  
Additional Comments: Please refer to the Amantadine Hydrochloride Tablet Draft Guidance for additional information regarding fed studies.

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**Analytes to measure (in appropriate biological fluid):** Diphenhydramine in plasma

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

**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.