

*Contains Nonbinding Recommendations*  
**Draft Guidance on Cetirizine Hydrochloride**

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

**Form/Route:** Orally Disintegrating Tablet; Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover in vivo  
Strength: 10mg  
Subjects: Healthy males and healthy non-pregnant females, general population  
Additional Comments: The whole tablet should be placed in the mouth and allowed to disintegrate for 30 seconds. After 30 seconds, all subjects should consume 240 mL of water.

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2. Type of study: Fed  
Design: Single-dose, two-way crossover in vivo  
Strength: 10mg  
Subjects: Healthy males and healthy non-pregnant females, general population  
Additional Comments: Please refer to the Amantadine Hydrochloride Tablet Guidance for additional information regarding fed studies. Also see comments in the study above.

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

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

**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.accessdata.fda.gov/scripts/cder/dissolution/>. Please find the dissolution information for this product at this website. Please conduct comparative drug 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.