

*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**Draft Guidance on Cetirizine Hydrochloride**

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

**Recommended studies:** 2 studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover *in-vivo*  
Strength: 10 mg  
Subjects: Healthy males and females, general population.
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2. Type of study: Fed  
Design: Single-dose, two-way crossover *in-vivo*  
Strength: 10 mg  
Subjects: Healthy males and females, general population.
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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:** 5 mg based on (i) acceptable bioequivalence studies on the 10 mg strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations across both strengths.

Please note that OTC Cetirizine hydrochloride capsules, 5 and 10 mg, are available in two presentations as: "Allergy" and "Hives Relief", under the same reference drug application. Please conduct the bioequivalence studies comparing to either one of the reference product presentations. You may submit the appropriate labeling and packaging information for one or both presentations under the same abbreviated new drug application. Both generic presentations of this product must be qualitatively and quantitatively the same.

**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.