Contains Nonbinding Recommendations

Guidance on Cetirizine Hydrochloride

This guidance represents the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Cetirizine hydrochloride

Dosage Form; Route: Capsule; oral

Recommended Studies: Two 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.

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: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. 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 abbreviated new drug application (ANDA).