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Draft Guidance on Cetirizine Hydrochloride

October 2024

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Active Ingredient: Cetirizine hydrochloride

Dosage Form: Tablet

Route: Oral

Strengths: 5 mg, 10 mg

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 10 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

Analyte to measure: Cetirizine in plasma

Bioequivalence based on (90% CI): Cetirizine

Waiver request of in vivo testing: 5 mg strength based on (i) acceptable bioequivalence study on the 10 mg strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both strengths.

Note that OTC cetirizine hydrochloride tablets, 5 mg and 10 mg, are available in two presentations as: "Allergy" and "Hives Relief", under the same reference drug application. Conduct the bioequivalence studies comparing the proposed test product to either one of the reference listed drug (RLDs) presentations. Applicants may submit the appropriate labeling and packaging information for one or both presentations under the same abbreviated new drug

application (ANDA). Both presentations of the generic product indicated for allergy and hives relief in the labeling and packaging should be the same as the RLD.

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units for each of both strengths of the test product and RLD.[1] Specifications will be determined upon review of the ANDA.

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[1] If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.