Contains Nonbinding Recommendations

Draft Guidance on Levocetirizine Dihydrochloride

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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: Levocetirizine dihydrochloride

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way, crossover in-vivo
   Strength: 5 mg
   Subjects: Males and females, general population
   Additional comments: None

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2. Type of study: Fed
   Design: Single-dose, two-way, crossover in-vivo
   Strength: 5 mg
   Subjects: Males and females, general population
   Additional comments: None

Analytes to measure (in appropriate biological fluid): Levocetirizine in plasma using an achiral assay.

Bioequivalence based on (90% CI): Levocetirizine

Waiver request of in-vivo testing: If the Over-the-Counter (OTC) Referenced List Drug (RLD) Levocetirizine Dihydrochloride Tablet is sufficiently similar to the previous prescription (Rx) version of RLD (NDA 022064) at the same strength of 5 mg, the FDA may deem the bioequivalence between the OTC test and OTC RLD Levocetirizine Dihydrochloride Tablets at the same strength of 5 mg by cross-referencing the acceptable in vivo bioequivalence studies conducted on the Rx test product and the Rx RLD (NDA 022064) at the same strength of 5 mg. The deemed bioequivalence may be based on (i) approval of Levocetirizine Dihydrochloride Tablet for Rx use (5 mg), (ii) both Rx and OTC products have the same formulation composition, are manufactured with the same manufacturing process and process controls, and conform to the same quality standards, and (iii) comparable in vitro dissolution testing of the Rx and OTC tablets. A separate Abbreviated New Drug Applications (ANDAs) must be submitted for the Generic OTC product.

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the USP monograph of the drug product as well as on the FDA-Recommended Dissolution Methods website 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).