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Draft Guidance on Levocetirizine Dihydrochloride

October 2024

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Active Ingredient: Levocetirizine dihydrochloride

Dosage Form: Tablet

Route: Oral

Strength: 5 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: 5 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

Analyte to measure: 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) reference listed drug (RLD) levocetirizine dihydrochloride tablet is same as the 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 tablet at the same strength of 5 mg by cross-referencing the acceptable in vivo bioequivalence study 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 application (ANDA) 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 FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution. Conduct comparative dissolution testing on 12 dosage units each 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.*