

Draft Guidance on Levocetirizine Dihydrochloride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: Not applicable

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 the test product and reference listed drug (RLD).¹ Specifications will be determined upon review of the abbreviated new drug application.

Document History: Recommended October 2008; Revised October 2024

Unique Agency Identifier: PSG_022064

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*.