

Contains Nonbinding Recommendations

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Draft Guidance on Desloratadine

October 2024

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Active Ingredient: Desloratadine

Dosage Form: Tablets

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: Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of desloratadine. Alternatively, a parallel study design may be considered.

Analytes to measure: Desloratadine and its metabolite, 3-hydroxydesloratadine, in plasma

Submit the metabolite data as supportive evidence of comparable therapeutic outcome. For the metabolite, the following data should be submitted: individual and mean concentrations, individual and mean pharmacokinetic parameters, and geometric means and ratios of means for AUC and C_{max} .

Bioequivalence based on (90% CI): Desloratadine

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 May 2007; Finalized May 2008; Revised October 2024

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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*.