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Draft Guidance on Desloratadine

October 2024

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Active Ingredient: Desloratadine

Dosage Form; Tablet, orally disintegrating

Route: Oral

Strengths: 2.5 mg, 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: The orally disintegrating tablet should be placed on the tongue, allowed to disintegrate, and swallowed without water. 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 active metabolite, 3-hydroxydesloratadine, in plasma

Submit the metabolite data as supportive evidence of the 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 area under the curve and maximum concentration.

Bioequivalence based on (90% CI): Desloratadine

Waiver request of in vivo testing: 2.5 mg strength based on (i) acceptable bioequivalence study on the 5 mg strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both strengths

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 reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

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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.*