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Draft Guidance on Desmopressin Acetate

October 2024

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Active Ingredient: Desmopressin acetate

Dosage Form: Tablet

Route: Oral

Strengths: 0.1 mg, 0.2 mg

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
Design: Single-dose, two-way, two-period crossover in vivo
Strength: 0.2 mg at a maximum dose of 0.6 mg (0.2 mg x 3 tablets)
Subjects: Healthy males and non-pregnant non-lactating females
Additional comments: Fluids should be restricted for 2 hours prior to dosing and a minimum of 8 hours post-dose. Monitor electrolytes pre-dose and every 2-4 hours post-dose until discharge from study site to identify any trending toward worsening hyponatremia prior to discharge from the study site. 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.

Analyte to measure: Desmopressin in plasma

Bioequivalence based on (90% CI): Desmopressin

Waiver request of in vivo testing: 0.1 mg strength based on (i) acceptable bioequivalence study on the 0.2 mg strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of 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*.