

Draft Guidance on Desmopressin Acetate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Desmopressin acetate

Dosage Form; Route: Tablet; sublingual

Recommended Studies: One study

1. Type of study: Fasting
Design: Single-dose, two-way crossover in-vivo
Strength: 0.0553 mg
Subjects: Males and non-pregnant, non-lactating females, general population
Additional Comments: (1) The dose should be administered sublingually without water; (2) Fluids should be restricted for 2 hours prior to dosing and a minimum of 8 hours post-dose. Monitor serum electrolytes regularly to identify any trend toward worsening hyponatremia prior to discharge from the study site.

Analytes to measure (in appropriate biological fluid): Desmopressin in plasma

Bioequivalence based on (90% CI): Desmopressin

Waiver request of in-vivo testing: 0.0277 mg strength based on (i) acceptable bioequivalence study on the 0.0553 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website, available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).