

Draft Guidance on Desmopressin Acetate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Desmopressin Acetate

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period, crossover in vivo
Strength: 0.2 mg [Maximum Dose: 0.6 mg (0.2 mg x 3 tablets)]
Subjects: Healthy males and nonpregnant females, general population
Additional comments: 1) In both study periods, fluids should be restricted for 2 hours prior to dosing and a minimum of 8 hours post-dose, 2) In both study periods, monitor serum 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.

2. Type of study: Fed
Design: Single-dose, two-treatment, two-period, crossover in vivo
Strength: 0.2 mg [Maximum Dose: 0.6 mg (0.2 mg x 3 tablets)]
Subjects: Healthy males and nonpregnant females, general population
Additional comments: See additional comments for Study 1.

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

Bioequivalence based on (90% CI): Desmopressin

Waiver request of in-vivo testing: 0.1 mg based on (i) acceptable bioequivalence studies on the 0.2 mg strength, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity of all strengths.

Dissolution test method and sampling times:

Please note that a **Dissolution Method Database** is available to the public at the OGD website at <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Please find the dissolution information for this product at this website. Please find the dissolution information for this product at this website. Please 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 application.