Contains Nonbinding Recommendations

Guidance on Desmopressin Acetate

This guidance represents 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; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way, 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.

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2. Type of study: Fed
   Design: Single-dose, two-way, 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: 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).