Active ingredient: Tolvaptan

Form/Route: Tablet /Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: 30 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments:

2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: 30 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments

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

Bioequivalence based on (90% CI): Tolvaptan

Waiver request of in-vivo testing: 15 mg based on (i) acceptable bioequivalence studies on the 30 mg strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations across both strengths.

Dissolution test method and sampling times:
Please note that a Dissolution Methods 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 conduct comparative drug 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.

Recommended Mar 2012