Active ingredient: Solifenacin Succinate

Form/Route: Tablet Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, parallel* in-vivo
   Strength: 10 mg
   Subjects: Normal healthy males and females, general population
   Additional comments: Females should not be pregnant or lactating, and if applicable, should practice abstention or contraception during the study.

   * Note: As an option, you may conduct this study using a single dose, two-way crossover design. As an additional option for either the crossover or parallel design, you may truncate the AUC at 72 hours, provided the drug demonstrates low intrasubject variability in distribution and clearance.

2. Type of Study: Fed
   Design: Single-dose, parallel* in-vivo
   Strength: 10 mg
   Subjects: Normal healthy males and females, general population
   Additional Comments: Please see comments above.

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

Bioequivalence based on (90% CI): Solifenacin

Waiver request of in-vivo testing: 5 mg based on (i) acceptable bioequivalence studies on the 10 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:

Please note that a Dissolution Methods Database is available to the public at the OGD website at http://www.fda.gov/cedr/ogd/index.htm. 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.