Contains Nonbinding Recommendations

Draft Guidance on Solifenacin Succinate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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: 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.

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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/cder/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.