

*Contains Nonbinding Recommendations*  
*Draft - Not for Implementation*  
**Draft Guidance on Solifenacin Succinate**  
**May 2022**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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.

This guidance, which interprets the Agency's regulations on bioequivalence at 21 CFR part 320, provides product-specific recommendations on, among other things, the design of bioequivalence studies to support abbreviated new drug applications (ANDAs) for the referenced drug product. FDA is publishing this guidance to further facilitate generic drug product availability and to assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating evidence needed to support ANDA approval for generic versions of this product.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in FDA guidances means that something is suggested or recommended, but not required.

In February 2008, FDA issued a draft product-specific guidance for industry on generic solifenacin succinate. We are now issuing revised draft guidance for industry that replaces the previously issued guidance.

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**Active Ingredient:** Solifenacin succinate

**Dosage Form; Route:** Tablet; oral

**Recommended Studies:** Two options: (1) Biopharmaceutics Classification System (BCS)-based biowaiver or (2) two in vivo bioequivalence studies with pharmacokinetic endpoints

**I. Option 1: BCS Class I-based biowaiver**

A waiver request of in vivo testing for this product may be considered provided that the appropriate documentation regarding high solubility, high permeability and rapid dissolution as detailed in the most recent version of the FDA guidance for industry on *M9 Biopharmaceutics Classification System-Based Biowaivers*<sup>a</sup> is submitted in the application. Applicants may use information contained in the approved labeling of the reference product. Peer-reviewed articles may not contain the necessary details of the testing for the FDA to

make a judgement regarding the quality of the studies. A decision regarding the acceptability of the waiver request will be made upon assessing the data submitted in the application.

## II. Option 2: Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. Type of study: Fasting  
Design: Single-dose, two-treatment, two-period crossover in vivo  
Strength: 10 mg  
Subjects: Healthy males and non-pregnant, non-lactating females  
Additional comments: Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of solifenacin. Alternatively, a parallel study design may be considered. Subjects should be instructed not to engage in potentially hazardous activities requiring complete mental alertness, such as driving a motor vehicle or operating machinery until they have completely returned to their level of baseline cognitive functioning after taking solifenacin succinate.
2. Type of study: Fed  
Design: Single-dose, two-treatment, two-period crossover in vivo  
Strength: 10 mg  
Subjects: Healthy males and non-pregnant, non-lactating females  
Additional comments: See comments above.

**Analyte to measure:** Solifenacin in plasma

**Bioequivalence based on (90% CI):** Solifenacin

**Waiver request of in vivo testing:** 5 mg strength based on (i) acceptable bioequivalence studies on the 10 mg strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both strengths

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution/> Conduct comparative dissolution testing on 12 dosage units for each of both strengths of the test and reference products. Specifications will be determined upon evaluation of the ANDA.

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**Revision History:** Recommended February 2008; Revised May 2022

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<sup>3</sup>For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.