

## Draft Guidance on Lorcaserin Hydrochloride

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

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

**Recommended Studies:** Two options: BCS waiver or in vivo studies

### I. BCS waiver option:

Upon request, it may be possible to receive a waiver of in vivo testing of this product, provided that the appropriate documentation regarding high solubility, high permeability, and rapid dissolution (as detailed in the guidance for industry *Waiver of In Vivo Bioavailability and Bioequivalence for Immediate-Release Solid Oral Dosage Forms Based on the Biopharmaceutics Classification System*) is submitted in the application. Applicants may use the information contained in the approved labeling of the reference product. A decision regarding the acceptability of the waiver request will be made upon review of the data submitted in the application.

### II. In vivo studies:

1. Type of study: Fasting  
Design: Single-dose, two-way crossover in vivo  
Strength: 10 mg  
Subjects: Healthy males and nonpregnant females, general population  
Additional comments: Females should not be pregnant or lactating and, if applicable, should practice abstinence or contraception during the study

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2. Type of study: Fed  
Design: Single-dose, two-way crossover in vivo  
Strength: 10 mg  
Subjects: Healthy males and nonpregnant females, general population  
Additional comments: Females should not be pregnant or lactating, and if applicable, should practice abstinence or contraception during the study.

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**Analytes to measure (in appropriate biological fluid):** Lorcaserin in plasma

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

**Waiver request of in vivo testing:** Not applicable

**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).