

## Draft Guidance on Aliskiren Hemifumarate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

**Form/Route:** Tablet/Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover *in-vivo*  
Strength: 300 mg  
Subjects: Healthy males and nonpregnant females, general population.
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2. Type of study: Fed  
Design: single-dose, two-way crossover *in-vivo*  
Strength: 300 mg  
Subjects: Normal healthy males and females, general population. Females should not be pregnant, and if applicable, should practice abstinence or contraception during the study.
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**Analytes to measure (in appropriate biological fluid):** Aliskiren in plasma

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

**Waiver request of in-vivo testing:** 150 mg based on (i) acceptable in vivo bioequivalence study/ies on the 300 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing on 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.accessdata.fda.gov/scripts/cder/dissolution/>. 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.