

**Draft Guidance on Aliskiren Hemifumarate; Valsartan**

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

**Form/Route:** Tablet/Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover in-vivo  
Strength: Eq. 300 mg base/320 mg  
Subjects: Healthy males and nonpregnant females, general population  
Additional Comments:

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2. Type of study: Fed  
Design: Single-dose, two-way crossover in-vivo  
Strength: Eq. 300 mg base/320 mg  
Subjects: Healthy males and nonpregnant females, general population  
Additional Comments: Please refer to the Amantadine Hydrochloride Tablet Draft Guidance for additional information regarding fed studies.

**Analytes to measure (in appropriate biological fluid):** Aliskiren and valsartan in plasma

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

**Waiver request of in-vivo testing:** Eq. 150 mg base/160 mg based on (i) acceptable bioequivalence studies on the eq. 300 mg base/320 mg strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths. Please refer to the Mirtazapine Tablet Draft Guidance for additional information regarding waivers of in-vivo testing.

**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.