*Contains Nonbinding Recommendations*

**Guidance on Valsartan**

This guidance represents 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:** Valsartan

**Form/Route:** Tablets/Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover *in-vivo*
   Strength: 320 mg
   Subjects: Normal healthy males and females, general population
   Additional Comments: A dose of 320 mg can be safely administered to healthy subjects. Please include provisions for appropriate monitoring and intervention in the case of possible drug-related adverse events (e.g. subjects complaining of dizziness/ lightheadedness should have blood pressure/heart rate assessed).
   Females should not be pregnant, and if applicable, should practice abstention or contraception during the study.

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2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover *in-vivo*
   Strength: 320 mg
   Subjects: Normal healthy males and females, general population
   Additional comments: Please see comment above.

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

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

**Waiver request of in-vivo testing:** 40mg, 80 mg and 160 mg based on (i) acceptable bioequivalence studies on the 320 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.