

## Guidance on Olmesartan Medoxomil

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:** Olmesartan Medoxomil

**Form/Route:** Tablets/Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover *in-vivo*  
Strength: 40 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.  
Additional Comments: Labeling for this drug contains a Black Box regarding pregnancy and fetal/neonatal morbidity and mortality.

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2. Type of study: Fed  
Design: Single-dose, two-way crossover *in-vivo*  
Strength: 40 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.  
Additional comments: Please see comments above.

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

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

**Waiver request of in-vivo testing:** 20 mg and 5 mg based on (i) acceptable bioequivalence studies on the 40 mg strength, (ii) proportionally similar 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.