

*Contains Nonbinding Recommendations*

**Draft Guidance on Amoxicillin; Clavulanate Potassium**

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

**Form/Route:** Tablet/Oral

**Recommended study:** 2 studies

1. Type of study: Fasting  
Design: Single-dose, two-treatment, two-period crossover in-vivo  
Strength: 875 mg; 125 mg base  
Subjects: Healthy males and nonpregnant females, general population  
Additional comments:

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2. Type of study: Fed  
Design: Single-dose, two-treatment, two-period crossover in-vivo  
Strength: 875; 125 mg base  
Subjects: Healthy males and nonpregnant females, general population  
Additional comments:

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**Analytes to measure (in appropriate biological fluid):** Amoxicillin and clavulanic acid in plasma

**Bioequivalence based on (90% CI):** Amoxicillin and clavulanic acid

**Waiver request of in-vivo testing:** 250 mg/125 mg base and 500 mg/125 mg base, based on (i) acceptable bioequivalence studies on the 875 mg/125 mg base strength, (ii) acceptable in-vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths.

**Dissolution test method and sampling times:**

Please note that a **Dissolution Methods Database** is available to the public at the OGD website <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.