

Draft Guidance on Amoxicillin; Clavulanate Potassium

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Recommended study: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in-vivo
Strength: 250 mg/5 mL; Eq. 62.5 mg base/5 mL
Subjects: Healthy males and nonpregnant females, general population
Additional comments:

2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in-vivo
Strength: 250 mg/5 mL; Eq. 62.5 mg base/5 mL
Subjects: Healthy males and nonpregnant females, general population
Additional Comments: Please refer to the Amantadine Hydrochloride Draft Guidance for additional information regarding fed studies.

Analytes to measure (in appropriate biological fluid): Amoxicillin and clavulanate potassium in plasma

Bioequivalence based on (90% CI): Amoxicillin and clavulanate potassium

Waiver request of in-vivo testing: 125 mg/5 mL; Eq. 31.25 mg base/5 mL, based on (i) acceptable bioequivalence studies on the 250 mg/5 mL; Eq. 62.5 mg base/5 mL 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 Please refer to the Mirtazapine Tablet Draft Guidance for additional information regarding dose proportionality.

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.