

Guidance on Amoxicillin

This guidance represents the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Amoxicillin

Dosage Form; Route: Suspension; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: 250 mg/5 mL
Subjects: Healthy males and non-pregnant females, general population.
Additional comments: None

2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: 250 mg/5 mL
Subjects: Healthy males and non-pregnant females, general population.
Additional comments: None

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

Bioequivalence based on (90% CI): Amoxicillin

Waiver request of in-vivo testing: 50 mg/mL and 125 mg/5 mL based on (i) acceptable bioequivalence studies on the 250 mg/5 mL 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: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. 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 abbreviated new drug application (ANDA).