Contains Nonbinding Recommendations

Draft Guidance on Amoxicillin

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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: Chewable tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 250 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: Tablets should be chewed completely before swallowing.

---

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 250 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: See comments above.

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

Bioequivalence based on (90% CI): Amoxicillin

Waiver request of in vivo testing: 125 mg based on (i) acceptable bioequivalence studies on the 250 mg strength, (ii) formulation proportionality across both strengths, and (iii) acceptable in vitro dissolution testing of both 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 for both strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.