Contains Nonbinding Recommendations

Guidance on Amoxicillin and Clavulanate Potassium

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; Clavulanate potassium

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 875 mg; EQ 125 mg Base
   Subject: Healthy males and nonpregnant females, general population
   Additional Comments: None

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2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 875 mg; EQ 125 mg Base
   Subjects: Healthy males and nonpregnant females, general population
   Additional Comments: None

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; EQ 125 mg Base and 500 mg; EQ 125 mg Base, based on (i) acceptable bioequivalence studies on the 875 mg; EQ 125 mg Base strength (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of 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).