

Guidance on Amoxicillin; Clavulanate Potassium

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Active ingredient: Amoxicillin; Clavulanate Potassium

Form/Route: Suspension/Oral

Recommended studies: 3 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: 600 mg/EQ 42.9 mg (base)/5 mL
Subjects: Normal healthy males and females, general population.
Additional Comments:

2. Type of study: Fed
Design: Single-dose, two-way crossover *in-vivo*
Strength: 600 mg/EQ 42.9 mg (base)/5 mL
Subjects: Normal healthy males and females, general population.
Additional comments:

3. Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: 400 mg/EQ 57 mg (base)/5 mL
Subjects: Normal healthy males and females, general population.
Additional Comments:

Analytes to measure: Amoxicillin and clavulanate potassium in plasma

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

Waiver request of in-vivo testing: 200 mg/EQ 28.5 mg (base)/5 mL based on (i) acceptable bioequivalence studies on the 400 mg/EQ 57 mg (base)/5 mL strength, (ii) proportional similarity of the 200 mg/EQ 28.5 mg (base)/5 mL and 400 mg/EQ 57 mg (base)/5 mL strengths, and (iii) acceptable in vitro dissolution testing of the 200 mg/EQ 28.5 mg (base)/5 mL and 400 mg/EQ 57 mg (base)/5 mL strengths.

Dissolution test method and sampling times:

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.fda.gov/cder/ogd/index.htm>. 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.