

Draft Guidance on Amoxicillin; Clavulanate Potassium

October 2024

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Active Ingredients: Amoxicillin; Clavulanate potassium

Dosage Form: Tablet, chewable

Route: Oral

Strengths: 125 mg; EQ 31.25 mg Base, 250 mg; EQ 62.5 mg Base

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 250 mg; EQ 62.5 mg Base
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: The tablet should be chewed, then swallowed without water.

Analytes to measure: Amoxicillin and clavulanic acid in plasma

Bioequivalence based on (90% CI): Amoxicillin and clavulanic acid

Waiver request of in vivo testing: 125 mg; EQ 31.25 mg Base strength based on (i) acceptable bioequivalence study on the 250 mg; EQ 62.5 mg Base strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both strengths

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each of both strengths of the test product and reference listed drug (RLD).¹ Specifications will be determined upon review of the abbreviated new drug application.

Document History: Recommended February 2008; Revised October 2024

Unique Agency Identifier: PSG_050597

¹ If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.