Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Amoxicillin; Clavulanate Potassium

October 2024

Active Ingredients: Amoxicillin; Clavulanate potassium

Dosage Form: For suspension

Route: Oral

Strengths: 125 mg/5 mL; EQ 31.25mg Base/5 mL,
250 mg/5 mL; EQ 62.5 mg Base/5 mL

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/5 mL; EQ 62.5 mg Base/5 mL
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

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/5 mL; EQ 31.25 mg Base/5 mL strength, based on (i) acceptable bioequivalence study on the 250 mg/5 mL; EQ 62.5 mg Base/5 mL 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 September 2012; Revised October 2024

Unique Agency Identifier: PSG_050575

[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.*