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Draft Guidance on Cefuroxime Axetil

October 2024

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Active Ingredient: Cefuroxime axetil

Dosage Form: Tablet

Route: Oral

Strengths: EQ 125 mg Base, EQ 250 mg Base, EQ 500 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: EQ 500 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

Analyte to measure: Cefuroxime in plasma

Bioequivalence based on (90% CI): Cefuroxime

Waiver request of in vivo testing: EQ 125 mg Base and EQ 250 mg Base strengths based on (i) acceptable bioequivalence study on the EQ 500 mg Base strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all 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 all strengths of the test product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

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[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*.