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Draft Guidance on Cimetidine

November 2023

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Active Ingredient: Cimetidine

Dosage Form: Tablet

Route: Oral

Strengths: 200 mg, 300 mg, 400 mg, 800 mg

Recommended Studies: Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 800 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 800 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

Analyte to measure: Cimetidine in plasma

Bioequivalence based on (90% CI): Cimetidine

Waiver request of in vivo testing: 200 mg, 300 mg, and 400 mg strengths based on (i) acceptable bioequivalence studies on the 800 mg 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 each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

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