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Draft Guidance on Baclofen

May 2024

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Active Ingredient: Baclofen

Dosage Form: Suspension

Route: Oral

Strength: 25 mg/5 mL

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: 25 mg/5 mL at a dose of 20 mg (4 mL)
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Due to drowsiness and sedation, subjects should avoid the operation of automobiles, other dangerous machinery, or activities made hazardous by decreased alertness during study.

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 25 mg/5 mL at a dose of 20 mg (4 mL)
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: See comment above.

Analyte to measure: Baclofen in plasma

Bioequivalence based on (90% CI): Baclofen

Waiver request of in vivo testing: Not applicable

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 the test and reference products. Note that a dosage unit for a suspension is the labeled strength (5 mL). Specifications will be determined upon review of the abbreviated new drug application.

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