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Draft Guidance on Oxazepam

May 2024

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Active Ingredient: Oxazepam

Dosage Form: Capsule

Route: Oral

Strengths: 10 mg, 15 mg, 30 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: 30 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: 30 mg
   Subjects: Heathy males and non-pregnant, non-lactating females
   Additional comments: None

Analyte to measure: Oxazepam in plasma

Bioequivalence based on (90% CI): Oxazepam

Waiver request of in vivo testing: 10 mg and 15 mg strengths based on (i) acceptable bioequivalence studies on the 30 mg dose 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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