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Draft Guidance on Nitrofurantoin

May 2024

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Active Ingredient: Nitrofurantoin

Dosage Form: Suspension

Route: Oral

Strengths: 25 mg/5 mL, 50 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: 50 mg/5 mL
   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: 50 mg/5 mL
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

Analyte to measure: Nitrofurantoin in plasma

Bioequivalence based on (90% CI): Nitrofurantoin

Waiver request of in vivo testing: 25 mg/5 mL strength based on (i) acceptable bioequivalence studies on the 50 mg/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 and reference products. Note that a dosage unit for a suspension is the labeled strength (5 mL). Specifications will be determined upon evaluation of the abbreviated new drug application.

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