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Draft Guidance on Palovarotene

November 2024

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Active Ingredient: Palovarotene

Dosage Form: Capsule

Route: Oral

Strengths: 1 mg, 1.5 mg, 2.5 mg, 5 mg, 10 mg

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 10 mg
   Subjects: Healthy males and healthy females not of reproductive potential
   Additional comments: Instruct subjects to use appropriate sun protection during the study to prevent photosensitivity reactions.

Analyte to measure: Palovarotene in plasma

Bioequivalence based on (90% CI): Palovarotene

Waiver request of in vivo testing: 1 mg, 1.5 mg, 2.5 mg, and 5 mg strengths based on (i) an acceptable bioequivalence study on the 10 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 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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Unique Agency Identifier: PSG_215559

[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.*