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Draft Guidance on Stiripentol

October 2024

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Active Ingredient: Stiripentol

Dosage Form: For suspension

Route: Oral

Strengths: 250 mg/packet, 500 mg/packet

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: 500 mg/packet
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

Analyte to measure: Stiripentol in plasma

Bioequivalence based on (90% CI): Stiripentol

Waiver request of in vivo testing: 250 mg strength based on (i) an acceptable bioequivalence study on the 500 mg 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 product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

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[1] If the reference listed drug is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions.*