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Draft Guidance on Dapsone

October 2024

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Active Ingredient: Dapsone

Dosage Form: Tablet

Route: Oral

Strengths: 25 mg, 100 mg

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 100 mg
   Subjects: Healthy males and non-pregnant non-lactating females
   Additional comments: Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of dapsone. Alternatively, a parallel study design may be considered.

Analyte to measure: Dapsone in plasma

Bioequivalence based on (90% CI): Dapsone

Waiver request of in vivo testing: 25 mg strength based on (i) acceptable bioequivalence study on the 100 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 RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions.*