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Draft Guidance on Daprodustat

October 2024

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Active Ingredient: Daprodustat

Dosage Form: Tablet

Route: Oral

Strengths: 1 mg, 2 mg, 4 mg, 6 mg, 8 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: 8 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Exclude subjects with a history of gastrointestinal bleeding or peptic ulcer disease.

Analyte to measure: Daprodustat in plasma

Bioequivalence based on (90% CI): Daprodustat

Waiver request of in vivo testing: 1 mg, 2 mg, 4 mg, and 6 mg strengths based on (i) acceptable bioequivalence study on the 8 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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[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*.