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Draft Guidance on Idelalisib

October 2024

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Active Ingredient: Idelalisib

Dosage Form: Tablet

Route: Oral

Strengths: 100 mg, 150 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: 150 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments:
   a. Females of reproductive potential should use effective contraception during the study.
   b. Investigators should refer to the FDA-approved labeling and apply appropriate screening and monitoring recommendations for changes in the liver function tests and blood counts along with other relevant recommendations described in the product's package insert.
   c. Bioequivalence study protocols should include provisions for adequate treatment and discontinuation of subjects from the study upon development of hypersensitivity or other adverse reactions, as appropriate.

Analyte to measure: Idelalisib in plasma

Bioequivalence based on (90% CI): Idelalisib

Waiver request of in vivo testing: 100 mg strength based on (i) acceptable bioequivalence study on the 150 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*.