

## Draft Guidance on Idelalisib

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

**Active Ingredient:** Idelalisib

**Dosage Form; Route:** Tablet; oral

**Recommended Studies:** Two studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover in vivo  
Strength: 150 mg  
Subjects: Healthy males and nonpregnant females, general population  
Additional comments:
  - 1) Females should practice abstinence or contraception during the study.
  - 2) 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.
  - 3) Bioequivalence (BE) 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.

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2. Type of study: Fed  
Design: Single-dose, two-way crossover in vivo  
Strength: 150 mg  
Subjects: Healthy males and nonpregnant females, general population  
Additional comments: Same as comments above

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**Analytes to measure (in appropriate biological fluid):** Idelalisib in plasma

**Bioequivalence based on (90% CI):** Idelalisib

**Waiver request of in vivo testing:** 100 mg strength based on (i) acceptable BE studies on the 150 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 on the FDA-Recommended Dissolution Methods Web site, available to the

public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>.  
Conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).