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 abstention 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.

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

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/](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).