

## Draft Guidance on Acalabrutinib

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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:** Acalabrutinib

**Dosage Form; Route:** Capsule; Oral

**Recommended Studies:** Two studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover in-vivo  
Strength: 100 mg  
Subjects: Males and females of non-child bearing potential (post-menopausal or surgically sterile), general population  
Additional Comments: None

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2. Type of study: Fed  
Design: Single-dose, two-way crossover in-vivo  
Strength: 100 mg  
Subjects: Males and females of non-child bearing potential (post-menopausal or surgically sterile), general population  
Additional Comments: None

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**Analytes to measure (in appropriate biological fluid):** Acalabrutinib and active metabolite M27 in plasma

Submit the metabolite data as supportive evidence of comparable therapeutic outcome. For the metabolite, the following data should be submitted: individual and mean concentrations, individual and mean pharmacokinetic parameters, and geometric means and ratios of means for AUC and C<sub>max</sub>.

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

**Waiver request of in-vivo testing:** Not applicable

**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 the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).