

Contains Nonbinding Recommendations

Draft – Not for Implementation

## Draft Guidance on Acalabrutinib Maleate

November 2024

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

In general, FDA’s guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

---

**Active Ingredient:** Acalabrutinib maleate

**Dosage Form:** Tablet

**Route:** Oral

**Strength:** EQ 100 mg Base

**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: EQ 100 mg Base  
Subjects: Healthy males and non-pregnant, non-lactating females  
Additional comments: Exclude subjects with abnormal liver function tests. Females of reproductive potential should use non-hormonal contraception during the study and continue to use effective contraception for one week after the last dose.

**Analytes to measure:** Acalabrutinib and active metabolite, ACP-5862 (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 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 the test product and reference listed drug (RLD).<sup>1</sup> Specifications will be determined upon review of the abbreviated new drug application.

---

**Document History:** Recommended November 2024

**Unique Agency Identifier:** PSG\_216387

---

<sup>1</sup> 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*.