

Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Elafibranor

December 2025

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Active Ingredient:	Elafibranor
Dosage Form:	Tablet
Route:	Oral
Strength:	80 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: 80 mg
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments:
 - Exclude subjects with abnormal liver function tests. Female subjects of reproductive potential should use effective non-hormonal contraceptives during the study and continue contraceptive use for three weeks after the last dose of the study. $AUC_{(0-72h)}$ may be used in place of $AUC_{(0-t)}$ when comparing the extent of absorption, due to long half-life of elafibranor. Ensure an adequate washout period between treatments in the crossover study. Alternatively, a parallel study design may be considered.

Analyte to measure: Elafibranor in plasma

Bioequivalence based on (90% CI): Elafibranor

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 each of the test 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 guidance for industry *Referencing Approved Drug Products in ANDA Submissions*.