

Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Zanubrutinib

May 2026

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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:	Zanubrutinib
Dosage Form:	Tablet
Route:	Oral
Strength:	160 mg
Reference Listed Drug:	NDA 218785
Recommended Studies:	Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. Class of study: Bioequivalence
Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 160 mg
Subjects: Healthy males and non-pregnant, non-lactating females
Safety recommendations:
 - Exclude subjects with abnormal complete blood counts, liver function tests, or electrocardiogram findings, or those with risk factors for cardiac arrhythmia.
 - Exclude subjects who have undergone or plan to undergo elective surgery including dental procedures for at least one week prior to and after the study.
 - Monitor for signs and symptoms of infection during the study.
 - Females of reproductive potential should use effective contraception during the study and for one week after the last dose. Males with female partners of reproductive potential should use effective contraception during the study and for one week after the last dose.

2. Class of study: Bioequivalence
Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 160 mg
Subjects: Healthy males and non-pregnant, non-lactating females
Safety recommendations: See recommendations under Study #1.

Analyte to measure: Zanubrutinib in plasma

Bioequivalence based on (90% CI): Zanubrutinib

Waiver request of in vivo testing of additional strength: Not applicable

Dissolution: Dissolution tests should be included for quality control. Provide a dissolution method development report for the test product containing information and data that demonstrate appropriateness of the selected dissolution method¹ and sampling times, such as the discriminating ability to detect changes in critical quality attributes that could potentially impact drug product performance.

If the strength of the tablet product has a functional score, additional dissolution profile testing should be conducted for each segment of the split tablet after manual and mechanical splitting as per the guidance for industry *Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation*.^a

Document History: Recommended May 2026

^a We update guidances periodically. For the most recent version of a guidance, refer to the FDA guidance webpage at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

¹ Applicant-developed, United States Pharmacopeia drug product monograph or Dissolution Methods database, <https://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm>