Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Sunvozertinib

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form: Tablet

Route: Oral

Strengths: 150 mg | 200 mg

Reference Listed Drug: NDA 219839

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Class of study: Bioequivalence
   Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 200 mg
   Subjects: Healthy males and healthy females not of reproductive potential
   Safety recommendation:
   - Males with female partners of reproductive potential should use effective contraception during the study and for 2 weeks after the last dose.

   Study design recommendations:
   - $AUC_{(0\text{-}72h)}$ may be used in place of $AUC_{(0\text{-}t)}$ for comparing the extent of absorption due to sunvozertinib's long half-life. Ensure adequate washout periods between treatments in the crossover study.
   - Alternatively, a parallel study design may be considered.

Analyte to measure: Sunvozertinib in plasma

Bioequivalence based on (90% CI): Sunvozertinib

Bioequivalence of additional strength: Waiver request of in vivo testing of additional strength based on (i) an acceptable bioequivalence study on the 200 mg strength, (ii) acceptable comparative in vitro dissolution studies between the additional strength and the 200 mg strength using 12 units per strength, and (iii) proportional similarity of the formulations between both strengths

Dissolution: Dissolution test(s) should be included for quality control and to support a waiver request of in vivo testing of an additional strength. For the quality control dissolution method, provide a dissolution method development report for the test product containing information and data that demonstrate appropriateness of the selected dissolution method[1] and sampling times, such as the discriminating ability to detect changes in critical quality attributes that could potentially impact drug product performance.

Document History: Recommended August 2026

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