

Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Zonisamide

May 2025

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Active Ingredient: Zonisamide

Dosage Form: Suspension

Route: Oral

Strength: 100 mg/5 mL

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: 100 mg/5 mL at a dose of 100 mg (5 mL)
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: Females of reproductive potential should have a negative pregnancy test within 24 hours prior to receiving the drug. Females of reproductive potential should use non-hormonal contraception during the study and continue to use effective contraception for one month after the last dose. Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of zonisamide. Alternatively, a parallel study design may be considered.

Analyte to measure: Zonisamide in serum

Bioequivalence based on (90% CI): Zonisamide

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)¹. Specifications will be determined upon review of the abbreviated new drug application.

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Unique Agency Identifier: PSG_214273

¹ 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*.