

Draft Guidance on Perampanel

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Active Ingredient: Perampanel

Dosage Form; Route: Suspension; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in-vivo
Strength: 0.5 mg/mL at a dose of 12 mg (24 mLx0.5 mg/mL)
Subjects: Healthy males and non-pregnant, non-lactating females, general population.

Additional Comments: Perampanel has a long terminal elimination half-life (>24 hrs). Ensure an adequate washout period between treatments in the crossover studies. If the crossover study is problematic, applicants may also consider using a parallel study design due to perampanel's long half-life. For long half-life drug products, an AUC truncated to 72 hours may be used in place of AUC_{0-t} or $AUC_{0-\infty}$. Collect sufficient blood samples in the bioequivalence studies to adequately characterize the peak concentration (C_{max}) and time to reach peak concentration (T_{max}).

2. Type of study: Fed
Design: Single-dose, two-way crossover in-vivo
Strength: 0.5 mg/mL at a dose of 12 mg (24 mLx0.5 mg/mL)
Subjects: Healthy males and non-pregnant, non-lactating females, general population.
Additional Comments: See comments above

Analytes to measure (in appropriate biological fluid): Perampanel in plasma

Bioequivalence based on (90% CI): Perampanel

Waiver request of in-vivo testing: Not Applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website, available to the

public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>.
Conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Note that a dosage unit for a suspension is the labeled strength (mL).
Specifications will be determined upon review of the abbreviated new drug application (ANDA).