

## Draft Guidance on Eslicarbazepine Acetate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Dosage Form; Route:** Tablet; oral

**Recommended Studies:** Two studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover in vivo  
Strength: 800 mg  
Subjects: Healthy males and nonpregnant females, general population  
Additional comments: Females should not be pregnant or lactating, and, if applicable, should practice abstinence or contraception during the study
2. Type of study: Fed  
Design: Single-dose, two-way crossover in vivo  
Strength: 800 mg  
Subjects: Healthy males and nonpregnant females, general population  
Additional comments: Same comments as above

**Analytes to measure (in appropriate biological fluid):** Eslicarbazepine (active metabolite) in plasma using an achiral assay

**Bioequivalence based on (90% CI):** Eslicarbazepine

**Waiver request of in vivo testing:** 200 mg, 400 mg and 600 mg strengths based on (i) acceptable bioequivalence studies on the 800 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods Web site, 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. Specifications will be determined upon review of the abbreviated new drug application (ANDA).