

**Draft Guidance on Eluxadoline**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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

**Recommended Studies:** Two studies

1. Type of study: Fasting  
Design: Single-dose, two-treatment, two-period crossover in vivo  
Strength: 100 mg  
Subjects: Normal healthy males and females (nonpregnant), general population.

Additional Comments: N/A

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2. Type of study: Fed  
Design: Single-dose, two-treatment, two-period crossover in vivo  
Strength: 100 mg  
Subjects: Normal healthy males and females (nonpregnant), general population.

Additional Comments: N/A

**Analytes to measure (in appropriate biological fluid):** Eluxadoline in plasma

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

**Waiver request of in-vivo testing:** 75 mg strength Eluxadoline tablet based on i) acceptable bioequivalence studies on the 100 mg strength, ii) proportional similarity of formulations across strengths and iii) acceptable dissolution among 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).