

*Contains Nonbinding Recommendations*

**Draft Guidance on Posaconazole**

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

**Active ingredient:** Posaconazole

**Form/Route:** Suspension/Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting  
Design: Single-dose, two-treatment, two-period crossover *in-vivo*  
Strength: 40 mg/ml (dose 400 mg)  
Subjects: Normal healthy males and females, general population.  
Additional Comments: Females must have a negative baseline pregnancy test within 24 hours prior to receiving the drug. Females should not be pregnant or lactating, and if applicable, should practice abstinence or contraception during the study.

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2. Type of study: Fed  
Design: Single-dose, two-treatment, two-period crossover *in-vivo*  
Strength: 40 mg/ml (dose 400 mg)  
Subjects: Normal healthy males and females, general population.  
Additional comments: Please see comment above.

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

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

**Waiver request of in-vivo testing:** Not Applicable

**Dissolution test method and sampling times:**

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.fda.gov/cder/ogd/index.htm>. Please find the dissolution information for this product at this website. Please note that a dosage unit for a suspension is the labeled strength (ml). A total of 12 units from 12 different bottles should be used. Specifications will be determined upon review of the application.