

**Draft Guidance on Clomiphene Citrate**

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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:** Clomiphene Citrate

**Form/Route:** Tablet/Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover in-vivo  
Strength: 50 mg  
Subjects: The study population should encompass a general population of non-pregnant female subjects to include healthy adult post-menopausal females, healthy adult female subjects who are regular nonhormonal contraceptive users and remain on the regimen for at least three months after the study; and/or healthy adult female subjects with surgical sterilization by tubal or hysterectomy for at least 3-6 months before the start of the bioequivalence study.  
Additional Comments: Please refer to the Amiodarone Hydrochloride Tablet Draft Guidance for additional information regarding long half-life drug studies.

- 
2. Type of study: Fed  
Design: Single-dose, two-way crossover in-vivo  
Strength: 50 mg  
Subjects: As above.  
Additional Comments: Please refer to the Amantadine Hydrochloride Tablet Draft Guidance for additional information regarding fed studies.

---

**Analytes to measure (in appropriate biological fluid):** Zuclomiphene and enclomiphene in plasma

**Bioequivalence based on (90% CI):** Zuclomiphene and enclomiphene

**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.accessdata.fda.gov/scripts/cder/dissolution/>. Please find the dissolution information for this product at this website. Please 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 application.