Contains Nonbinding Recommendations

Guidance on Clomiphene Citrate

This guidance represents 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: Clomiphene citrate

Dosage Form; Route: Tablet; oral

Recommended Studies: Two 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.

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2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 50 mg
   Subjects: As above.

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: 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).