Guidance on Toremifene Citrate

This guidance represents 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: Toremifene Citrate

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 60 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments: Due to the long elimination half-life of toremifene, the firm may consider a parallel study design.

2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 60 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments: Please see comment above.

Analytes to measure (in appropriate biological fluid): Toremifene in plasma.

Bioequivalence based on (90% CI): Toremifene

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.

Finalized Oct 2011