Contains Nonbinding Recommendations

Guidance on Anastrozole

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: Anastrozole

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 1 mg
   Subjects: Please conduct the studies in post-menopausal subjects or surgically sterile females.
   Additional Comments: Please do not include subjects who are using female hormone replacement therapies, thyroid hormone replacement therapies, or antihypertensive therapies in the study population.
   Anastrozole has a long terminal elimination half-life. Please ensure adequate washout periods between treatments in the crossover studies. You may also consider using a parallel study design due to anastrozole's long half-life. For long half-life drug products, an AUC truncated to 72 hours may be used in place of AUC_{0-t} or $AUC_{0-\infty}$.
   Please collect sufficient blood samples in the bioequivalence studies to adequately characterize the peak concentration (C_{max}) and time to reach peak concentration (t_{max}).

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2. Type of study: Fed
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 1 mg
   Subjects: Please see comments above.
   Additional comments: Please see comments above.

Analytes to measure (in appropriate biological fluid): Anastrozole in plasma

Bioequivalence based on (90% CI): Anastrozole

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 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.