Contains Nonbinding Recommendations

Guidance on Exemestane

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: Exemestane

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way, crossover *in-vivo*
   Strength: 25 mg
   Subjects: Normal healthy post-menopausal women, general population
   Additional Comments: This product is indicated for use in post-menopausal women. Because of teratogenicity concerns with this product, females in these studies should not be of childbearing potential. We recommended that you attempt to include as many post-menopausal women as possible.

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2. Type of study: Fed
   Design: Single-dose, two-way, crossover *in-vivo*
   Strength: 25 mg
   Subjects: Normal healthy post-menopausal women, general population
   Additional comments: Please see comments above.

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

Bioequivalence based on (90% CI): Exemestane

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.