Contains Nonbinding Recommendations

Guidance on Bicalutamide

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: Bicalutamide

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 50 mg
   Subjects: Normal healthy males, general population.
   Additional Comments: Female subjects should be excluded from the bioequivalence studies. Bicalutamide 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 bicalutamide's long half-life. For long half-life drug products, an AUC truncated to 72 hours may be used in place of AUC0-t or AUC0-∞.

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2. Type of study: Fed
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 50 mg
   Subjects: Normal healthy males, general population.
   Additional comments: Please see comments above.

Analytes to measure: Bicalutamide, using an achiral assay

Bioequivalence based on (90% CI): Bicalutamide

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.