

Guidance on Dutasteride

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: Dutasteride

Form/Route: Capsules/Oral

Recommended studies: 2 studies

1. Type of Study: Fasting
Design: Single-dose, two-way crossover *in vivo*
Strength: 0.5 mg
Subjects: Normal healthy males
Additional Comments:

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2. Type of Study: Fed
Design: Single-dose, two-way crossover *in vivo*
Strength: 0.5 mg
Subjects: Normal healthy males
Additional Comments:
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Note: As an option, due to the relatively long half-life, the firm may wish to conduct these studies using a parallel design. As an additional option for either the crossover or parallel design, the firm may wish to truncate the AUC at 72 hours.

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

Bioequivalence based on (90% CI): Dutasteride

Waiver request of in vivo testing: Not Applicable

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.