

Contains Nonbinding Recommendations

Draft Guidance on Finasteride

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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: Finasteride

Form/Route: Tablet/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: 5 mg
Subjects: Healthy males, general population
Additional Comments: None

2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: 5 mg
Subjects: Healthy males, general population
Additional Comments: Please refer to the Amantadine Hydrochloride Tablet Guidance for additional information regarding fed studies.

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

Bioequivalence based on (90% CI): Finasteride

Waiver request of in-vivo testing: 1 mg based on (i) acceptable bioequivalence studies on the 5 mg strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths. Please refer to the Mirtazapine Tablet Draft Guidance for additional information regarding waivers of in-vivo testing.

Since Finasteride Tablets, 1 mg and 5 mg, are the subject of two separate New Drug Applications (NDAs), two separate Abbreviated New Drug Applications (ANDAs) must be submitted. As stated above, a waiver of in vivo testing may be requested for the 1 mg strength. Please cross-reference the application that contains the in vivo bioequivalence studies along with your bio-waiver request. Please refer to *Guidance for Industry, Variations in Drug Products that May Be Included in a Single ANDA* located at <http://www.fda.gov/cder/guidance>.

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.