

Draft Guidance on Dutasteride; Tamsulosin Hydrochloride

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Capsules/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: 0.5mg; 0.4mg
Subjects: Healthy males
Additional comments:

2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: 0.5mg; 0.4mg
Subjects: Healthy males
Additional comments: Please refer to the Amantadine Hydrochloride Tablet Draft Guidance for additional information regarding fed studies.

Note: Due to the relatively long half-life, it is recommended to conduct these studies using a parallel design. As an additional option, for either the crossover or parallel design, please consider to truncate the AUC to 72 hours. Please refer to the Amiodarone Hydrochloride Tablet Draft Guidance for additional information regarding long half-life drugs.

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

Bioequivalence based on (90% CI): Dutasteride and tamsulosin

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.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 strength of the test and reference products. Specifications will be determined upon review of the application.