

## Guidance on Danazol

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:** Danazol

**Form/Route:** Capsules/Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover *in-vivo*  
Strength: 200 mg  
Subjects: Normal healthy males and females, general population.  
Additional Comments: Due to teratogenicity concerns, females in these studies should not be pregnant.

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2. Type of study: Fed  
Design: Single-dose, two-way crossover *in-vivo*  
Strength: 200 mg  
Subjects: Normal healthy males and females, general population.  
Additional comments: Due to teratogenicity concerns, females in these studies should not be pregnant.

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**Analytes to measure:** Danazol in plasma

**Bioequivalence based on (90% CI):** Danazol

**Waiver request of in-vivo testing:** 50 mg and 100 mg based on (i) acceptable bioequivalence studies on the 200 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

**Dissolution test method and sampling times:**

Please conduct comparative dissolution testing on 12 dosage units of all strengths of the test and reference products using the following USP method.