

## Guidance on Glimepiride

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:** Glimepiride

**Form/Route:** Tablets/Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover *in-vivo*  
Strength: 1 mg  
Subjects: Normal healthy males and females, general population.  
Additional Comments: Because of the potential for hypoglycemia from using a dose of 4 mg of glimepiride tablets, you should conduct the bioequivalence studies using the 1 mg dose. Each dose in the studies should be administered with 240 mL of 20% glucose solution to minimize hypoglycemic effects. After dosing, 60 mL of 20% glucose solution should be given to each subject every 15 minutes for the following 4 hours.

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2. Type of study: Fed  
Design: Single-dose, two-way crossover *in-vivo*  
Strength: 1 mg  
Subjects: Normal healthy males and females, general population.  
Additional comments: Please comment above.

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**Analytes to measure:** Glimepiride in plasma

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

**Waiver request of in-vivo testing:** 2 mg and 4 mg based on (i) acceptable bioequivalence studies on the 1 mg strength, (ii) proportionally similar across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

**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.