

## Draft Guidance on Fenofibrate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

**Active Ingredient:** Fenofibrate

**Dosage Form; Route:** Capsule; oral

**Recommended Studies:** Two studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover *in-vivo*  
Strength: 90 mg  
Subjects: Normal healthy males and females, general population.  
Additional Comments: Female subjects should not be pregnant or lactating, and, if applicable, should practice abstention or contraception during the study.

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2. Type of study: Fed  
Design: Single-dose, two-way crossover *in-vivo*  
Strength: 90 mg  
Subjects: Normal healthy males and females, general population.  
Additional comments: as above.
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**Analytes to measure:** Fenofibric acid in plasma

**Bioequivalence based on (90% CI):** Fenofibric acid

**Waiver request of in-vivo testing:** 30 mg based on (i) acceptable bioequivalence studies on the 90 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:** The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website, available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. 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 abbreviated new drug application (ANDA).