

Contains Nonbinding Recommendations
Guidance on Gemifloxacin Mesylate

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: Gemifloxacin Mesylate

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: 320 mg (base equivalent)
Subjects: Normal healthy males and females, general population. Females should not be pregnant, and if applicable, should practice abstinence or contraception during the study.
Additional Comments: Females should not be lactating. Subjects should not have a history of prolongation of the QTc interval, or ongoing proarrhythmic conditions such as clinically significant bradycardia or acute myocardial ischemia.

2. Type of study: Fed
Design: Single-dose, two-way crossover *in-vivo*
Strength: 320 mg
Subjects: Normal healthy males and females, general population. Females should not be pregnant, and if applicable, should practice abstinence or contraception during the study.
Additional Comments: Females should not be lactating. Subjects should not have a history of prolongation of the QTc interval, or ongoing proarrhythmic conditions such as clinically significant bradycardia or acute myocardial ischemia.

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

Bioequivalence based on (90% CI): Gemifloxacin

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.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.