

## Guidance on Telithromycin

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:** Telithromycin

**Form/Route:** Tablets/Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting  
Design: single-dose, two-way crossover *in-vivo*  
Strength: 400 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: The study design should include a screen for signs and symptoms of possible hepatotoxicity prior to administering each subsequent dose of telithromycin in a crossover or replicate crossover design. In order to minimize the risk of hepatotoxicity, please do not exceed a 400 mg dose in the BE study. Subjects who consume alcohol should be excluded from BE studies of telithromycin.

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2. Type of study: Fed  
Design: single-dose, two-way crossover *in-vivo*  
Strength: 400 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: Please see comments above.
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**Analytes to measure (in appropriate biological fluid):** Telithromycin in plasma

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

**Waiver request of in-vivo testing:** 300 mg based on (i) acceptable bioequivalence studies on the 400 mg strength, (ii) proportionally similar across both strengths, and (iii) acceptable in vitro dissolution testing of both 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.