

**Draft Guidance on Azithromycin**

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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:** Azithromycin

**Form/Route:** Extended Release Suspension/Oral

**Recommended studies:** 1 study

Type of study: Fasting

Design: Single-dose, two-way crossover *in-vivo*

Strength: 2 gm

Subjects: Normal healthy males and females, general population

Additional comments: As an option, due to the relatively long half-life, the firm may wish to conduct this study using a parallel design. As an additional option for either the crossover or parallel design, the firm may wish to truncate the AUC at 72 hours.

---

**Analytes to measure:** Azithromycin in plasma

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

**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.