Contains Nonbinding Recommendations

Draft Guidance on Azithromycin

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 600 mg
   Subjects: Normal healthy males and females, general population.
   Additional Comments:

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2. Type of study: Fed
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 600 mg
   Subjects: Normal healthy males and females, general population.
   Additional comments:

Analytes to measure: Azithromycin

Bioequivalence based on (90% CI): Azithromycin

Waiver request of in-vivo testing*: 250 mg and 500 mg based on (i) acceptable bioequivalence studies on the 600 mg strength, (ii) proportionally similar across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

* Since Azithromycin Tablets, 250 mg, 500 mg, and 600 mg, are the subject of three separate New Drug Applications (NDA's), three separate Abbreviated New Drug Applications (ANDA's) must be submitted. You may request a waiver of *in vivo* bioequivalence testing of the 250 mg and the 500 mg strengths if you meet the criteria. In addition, please cross-reference the *in vivo* bioequivalence studies conducted on the higher strength along with your waiver request. Please refer to the Guidance for Industry, *Variations in Drug Products that May Be Included in a Single ANDA* located at: http://www.fda.gov/cder/guidance.

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.