

Draft Guidance on Azithromycin

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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: Azithromycin

Dosage Form; Route: For suspension; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-way crossover in-vivo
Strength: EQ 1GM BASE/PACKET
Subjects: Adult males and non-pregnant, non-lactating females, general population
Additional Comments: Considering the long half-life of azithromycin, adequate washout periods should be included. The applicant may also consider using a parallel study design due to azithromycin's long half-life.
2. Type of study: Fed
Design: Single-dose, two-treatment, two-way crossover in-vivo
Strength: EQ 1GM BASE/PACKET
Subjects: Adult males and non-pregnant, non-lactating females, general population
Additional Comments: See comments above

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

Bioequivalence based on (90% CI): Azithromycin

Waiver request of in-vivo testing: Not applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, 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).