

Contains Nonbinding Recommendations
Draft Guidance on Afatinib Dimaleate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies: One study

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: 40 mg (eq base)
Subjects: Normal healthy males and females, general population
Additional comments: Females should not be pregnant or lactating, and, if applicable, should practice abstention or contraception during the study

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

Bioequivalence based on (90% CI): Afatinib

Waiver request of in vivo testing: 20 mg (eq base) and 30 mg (eq base) strengths based on (i) acceptable bioequivalence study on the 40 mg (eq base) strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

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 flavors of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).