

Draft Guidance on Dasatinib

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 100 mg
Subjects: Healthy males and nonpregnant females, general population
Additional comments: Women of child-bearing potential and nursing mothers should be excluded from the study given the potential for embryo-fetal toxicity and secretion of the drug into breast milk. Males and their female partners need to practice adequate contraception for at least one week after the last dasatinib dose.

2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 100 mg
Subjects: Healthy males and nonpregnant females, general population
Additional comments: Same as comments above

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

Bioequivalence based on (90% CI): Dasatinib

Waiver request of in vivo testing: 20 mg, 50 mg, 70 mg, 80 mg, and 140 mg strength tablets based on i) acceptable bioequivalence studies on the 100 mg tablet, ii) proportional similarity of formulations across all strengths, and iii) acceptable dissolution among 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 strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).