

Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Dasatinib

May 2021

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This guidance, which interprets the Agency’s regulations on bioequivalence at 21 CFR part 320, provides product-specific recommendations on, among other things, the design of bioequivalence studies to support abbreviated new drug applications (ANDAs) for the referenced drug product. FDA is publishing this guidance to further facilitate generic drug product availability and to assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating evidence needed to support ANDA approval for generic versions of this product.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in FDA guidances means that something is suggested or recommended, but not required.

In September 2015, FDA issued a draft product-specific guidance for industry on generic dasatinib. We are now issuing revised draft guidance for industry that replaces the previously issued guidance.

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: Males, and females not of reproductive potential, general population
Additional comments: Exclude subjects taking strong CYP3A4 inhibitors. Consider using a reference-scaled average bioequivalence approach for dasatinib. If using this approach, provide evidence of high variability in the bioequivalence parameters of area under the plasma concentration time curve and peak concentration (i.e., within-subject variability $\geq 30\%$). For detailed information on this approach, refer to the guidance for progesterone oral capsule.

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2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 100 mg
Subjects: Males and females, not of reproductive potential, general population
Additional comments: See comments above.
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Analyte to measure: 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 in the FDA's Dissolution Methods database, <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.

Revision History: Recommended August 2010; Revised September 2015, May 2021

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