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*Draft – Not for Implementation*

## **Draft Guidance on Imatinib Mesylate**

**February 2026**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

In general, FDA’s guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended but not required.

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**Active Ingredient:** Imatinib mesylate

**Dosage Form:** Tablet

**Route:** Oral

**Strengths:** EQ 100 mg Base, EQ 400 mg Base

**Recommended Study:** One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting  
Design: Single-dose, two-treatment, two-period crossover in vivo  
Strength: EQ 100 mg Base  
Subjects: Healthy males and non-pregnant, non-lactating females  
Additional comments:
  - Exclude subjects with abnormal liver function tests or cardiovascular risk factors. Females of reproductive potential should use effective contraception during treatment and for two weeks after the last dose.
  - If there are gastrointestinal tolerability concerns on this product, a fed study can be conducted as an alternative approach.

**Analyte to measure:** Imatinib in plasma

**Bioequivalence based on (90% CI):** Imatinib

**Waiver request of in vivo testing of additional strength:** Justification based on (i) an acceptable bioequivalence study on the EQ 100 mg Base strength, (ii) acceptable comparative in vitro dissolution studies between additional strength and the EQ 100 mg Base strength using 12 units per strength, and (iii) proportional similarity of the formulations between both strengths

**Dissolution:** Dissolution tests should be included for quality control and to support waiver request of in vivo testing of additional strengths.

**Dissolution test method and sampling times:** Provide a dissolution method development report for the test product containing information and data that demonstrate appropriateness of the selected dissolution method<sup>1</sup> and sampling times, such as the discriminating ability to detect changes in critical quality attributes that could potentially impact drug product performance.

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**Document History:** Recommended April 2013; Revised July 2014, February 2026

**Unique Agency Identifier:** PSG\_021588

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<sup>1</sup> Applicant-developed, United States Pharmacopeia drug product monograph or Dissolution Methods database, <https://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm>