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Draft Guidance on Imatinib Mesylate

February 2026

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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.

Active Ingredient: Imatinib mesylate

Dosage Form: Solution

Route: Oral

Strength: EQ 80 mg Base/mL

Recommended Study: Request for waiver of in vivo bioequivalence study requirements

To qualify for a waiver of in vivo bioequivalence study requirements under 21 CFR 320.22(b)(3), the test product must contain the same active ingredient in the same concentration and dosage form as the reference listed drug (RLD) and must not contain any inactive ingredient or other change in formulation from the RLD that may significantly affect absorption of the active ingredient.

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