

*Contains Nonbinding Recommendations*  
*Draft – Not for Implementation*  
**Draft Guidance on Delavirdine Mesylate**  
**October 2024**

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**Active Ingredient:** Delavirdine mesylate

**Dosage Form:** Tablet

**Route:** Oral

**Strengths:** 100 mg, 200 mg

**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: 200 mg  
Subjects: Healthy males and non-pregnant, non-lactating females  
Additional comments: Female subjects of reproductive potential should practice abstinence or contraception during the study.

**Analyte to measure:** Delavirdine in plasma

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

**Waiver request of in vivo testing:** 100 mg strength based on (i) acceptable bioequivalence study on the 200 mg strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both 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 for each of both strengths of the test product and reference listed drug (RLD).<sup>1</sup> Specifications will be determined upon review of the abbreviated new drug application.

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**Document History:** Recommended November 2007; Revised October 2024

**Unique Agency Identifier:** PSG\_020705

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<sup>1</sup> If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.