

**Draft Guidance on Lopinavir; Ritonavir**

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**Active ingredient:** Lopinavir; Ritonavir

**Form/Route:** Tablets/Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting  
Design: Single-dose, two-treatment, two-period crossover *in-vivo*  
Strength: 200 mg/50 mg (400 mg/100 mg dose)  
Subjects: Healthy males and non-pregnant females, general population.  
Additional Comments: Females must have a negative baseline pregnancy test prior to receiving the drug and, if applicable, should practice abstinence or contraception during the study.

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2. Type of study: Fed  
Design: Single-dose, two-treatment, two-period crossover *in-vivo*  
Strength: 200 mg/50 mg (400 mg/100 mg dose)  
Subjects: Healthy males and non-pregnant females, general population.  
Additional Comments: Please refer to the Amantadine Hydrochloride Tablet Draft Guidance for additional information regarding fed studies. See comments above.

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**Analytes to measure (in appropriate biological fluid):** Lopinavir and ritonavir in plasma.

**Bioequivalence based on (90% CI):** Lopinavir and ritonavir

**Waiver request of in-vivo testing:** 100 mg/25 mg based on (1) acceptable bioequivalence studies on the 200 mg/50 mg strength, (2) acceptable dissolution testing across both strengths, and (3) proportional similarity in the formulations across both strengths. Please refer to the Mirtazapine Tablet Draft Guidance for additional information regarding waivers of in-vivo testing.

**Dissolution test method and sampling times:**

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.fda.gov/cder/ogd/index.htm>. Please find the dissolution information for this product at this website. Please 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 application.