Contains Nonbinding Recommendations

Draft Guidance on Lopinavir; Ritonavir

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

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: Normal healthy males and females, general population.
   Additional Comments: Pregnant and lactating women should be excluded from participation in studies. Women must have a negative baseline pregnancy test prior to receiving the drug.

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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: Normal healthy males and females, general population.
   Additional comments: Please see comments above.

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: Not Applicable

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.