*Contains Nonbinding Recommendations*

**Draft Guidance on Ritonavir**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Active Ingredient:** Ritonavir

**Dosage Form; Route:** Powder; oral

**Recommended Studies:** Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: 100 mg
   Subjects: Males and non-pregnant, non-lactating females, general population.
   Additional Comments: Suspend the drug powder (100 mg) in 30 mL of water; administer the dose orally; follow with approximately 240 mL of water.

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2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: 100 mg
   Subjects: Males and non-pregnant, non-lactating females, general population.
   Additional Comments: See above

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**Analyte to measure (in appropriate biological fluid):** Ritonavir in plasma

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

**Waiver request of in-vivo testing:** Not Applicable

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units each of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).

**Product-specific testing conditions for in vitro feeding tube studies:**

The approved labeling for the reference product states that the product may be administered via a feeding tube. Conduct the in vitro feeding tube studies including comparative recovery testing and sedimentation volume testing. Refer to the Lansoprazole Delayed-Release Orally Disintegrating Tablet Draft Guidance for additional information regarding procedures of in vitro feeding tube studies.

Testing tube: Nasogastric (NG) tube (6 French) and gastrostomy (G) tube (12 French)

Testing strength: 100 mg/packet

Dispersion medium: Disperse the packet contents in 10 mL water followed by flushing with additional 10 mL water.

Incubation time: 0 and 120 minutes