

## Draft Guidance on Cobicistat

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Dosage Form; Route:** Tablet; oral

**Recommended Studies:** Two studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover in vivo  
Strength: 150 mg  
Subjects: Healthy males and nonpregnant females, general population  
Additional comments: The study population should be healthy subjects at least 18 years old; with body mass index (BMI) between 19 and 30 kg/m<sup>2</sup>; in good general health, with no clinically relevant health conditions identified by a detailed medical history, full physical examination, and laboratory screening; and not on any of the drugs or herbal products contraindicated on the labeling. At a minimum, prescreening laboratory evaluation should include pregnancy testing for women, a complete blood count, liver and renal function testing, and hepatitis screening. The warnings and precautions described in the product's labeling should be taken into consideration upon enrollment and during the study conduct.

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2. Type of Study: Fed  
Design: Single-dose, two-way crossover in vivo  
Strength: 150 mg  
Subjects: Healthy males and nonpregnant females, general population  
Additional comments: Same as comments above

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**Analytes to measure (in appropriate biological fluid):** Cobicistat in plasma

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

**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 all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.