Contains Nonbinding Recommendations

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Draft Guidance on Cobicistat

October 2024

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Active Ingredient: Cobicistat

Dosage Form: Tablet

Route: Oral

Strength: 150 mg

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of Study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 150 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   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^2; 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.

Analyte to measure: 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 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 the test product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

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[1] 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*.