

Draft Guidance on Atazanavir Sulfate; Cobicistat

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Active Ingredient: Atazanavir Sulfate; Cobicistat

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in vivo*
Strength: EQ 300 mg base/150 mg
Subjects: Healthy males and nonpregnant females, general population
Additional comments: Females should not be pregnant or lactating, and, if applicable, should practice abstinence or contraception during the study.

2. Type of study: Fed
Design: Single-dose, two-way crossover *in vivo*
Strength: EQ 300 mg base/150 mg
Subjects: Healthy males and nonpregnant females, general population
Additional comments: See comments above.

Analytes to measure (in appropriate biological fluid): Atazanavir and cobicistat in plasma

Bioequivalence based on (90% CI): Atazanavir and 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 (ANDA).