

Draft Guidance on Cobicistat; Darunavir Ethanolate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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; EQ 800 mg Base;
Subjects: Healthy males and non-pregnant, non-lactating females, general population.
Comments: Applicants may consider using a reference-scaled average bioequivalence approach for darunavir. For the method of statistical analysis using the reference-scaled average bioequivalence approach, refer to the Progesterone Capsule Guidance.
2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: 150 mg; EQ 800 mg Base;
Subjects: Healthy males and non-pregnant, non-lactating females, general population.
Comments: See comments above.

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

Bioequivalence based on (90% CI): Cobicistat and darunavir

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).