

Draft Guidance on Darunavir Ethanolate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Darunavir ethanolate

Dosage Form; Route: Suspension; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: EQ 100 mg base/mL (recommended dose: 800 mg)
Subjects: Healthy males and nonpregnant females, general population
Additional comments: Single doses of both the test and reference listed drug (RLD) should be administered with ritonavir 100 mg twice daily. The ritonavir dosing should be started at least two days before administration of darunavir ethanolate oral suspension and maintained until the end of pharmacokinetic sampling of each treatment.

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2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: EQ 100 mg base/mL (recommended dose: 800 mg)
Subjects: Healthy males and nonpregnant females, general population
Additional comments: See additional comment above.
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Analytes to measure (in appropriate biological fluid): Darunavir in plasma

Bioequivalence based on (90% CI): 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 website 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).