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Draft Guidance on Darunavir

October 2024

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Active Ingredient: Darunavir

Dosage Form: Suspension

Route: Oral

Strength: 100 mg/mL

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: 100 mg/mL at a dose of 800 mg
   Subjects: Healthy males and non-pregnant non-lactating females
   Additional comments: Single doses of both the test product 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 oral suspension and maintained until the end of pharmacokinetic sampling of each treatment.

Analyte to measure: 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 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 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.*