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Draft Guidance on Finasteride; Tadalafil

February 2024

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Active Ingredients: Finasteride; Tadalafil

Dosage Form: Capsule

Route: Oral

Strength: 5 mg; 5 mg

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 5 mg; 5 mg
   Subjects: Healthy males
   Additional comments: None

Analytes to measure: Finasteride and tadalafil in plasma

Bioequivalence based on (90% CI): Finasteride and tadalafil

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 and reference products. Specifications will be determined upon review of the abbreviated new drug application.

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