Contains Nonbinding Recommendations

Draft Guidance on Avanafil

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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 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: Avanafil

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 200 mg
   Subjects: Healthy males, general population
   Additional comments: Coadministration of avanafil with any form of organic nitrate is contraindicated due to the potentiation of hypotension. Nitrates should not be administered to subjects for at least 12 hours after the last dose of avanafil and should be administered under close medical supervision with appropriate hemodynamic monitoring.

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2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 200 mg
   Subjects: Healthy males, general population
   Additional comments: Same as above

Analytes to measure (in appropriate biological fluid): Avanafil in plasma

Bioequivalence based on (90% CI): Avanafil

Waiver request of in vivo testing: 50 mg and 100 mg based on (i) acceptable bioequivalence studies on the 200 mg strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths.

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).