Contains Nonbinding Recommendations

Draft Guidance on Tadalafil

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

Type of study: Fasting
Design: Single-dose, two-way crossover in-vivo
Strength: 20 mg
Subjects: Males, general population
Additional Comments: none

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1. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: 20 mg
   Subjects: Males, general population
   Additional Comments: Please refer to the Amantadine Hydrochloride Tablet Draft Guidance for additional information regarding fed studies.

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

Bioequivalence based on (90% CI): Tadalafil

Waiver request of in-vivo testing: 2.5 mg, 5 mg and 10 mg based on (i) acceptable bioequivalence studies on the 20 mg strength, (ii) acceptable in-vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths

Please note that Tadalafil Tablets, 20 mg, and Tadalafil Tablets, 2.5 mg, 5 mg, 10 mg and 20 mg are the subject of two separate reference products. Please submit a separate application for each reference product. An applicant may request a waiver of in vivo bioequivalence testing for the single 20 mg strength reference product provided that it (1) submits acceptable bioequivalence studies of this strength in the related ANDA; (2) cross-references the studies submitted in the ANDA for this 20-mg strength; and (3) meets the criteria of 21 CFR § 320.22(d) (2). Please refer to the Guidance for Industry,

Variations in Drug Products that May Be Included in a Single ANDA located at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072892.pdf

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).