

Draft Guidance on Tadalafil

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in-vivo
Strength: 20 mg
Subjects: Healthy males, general population
Additional Comments:

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Additional Comments: Please refer to the Amantadine Hydrochloride Tablet Draft Guidance for additional information regarding fed studies.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

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Please find the dissolution information for this product at this website. Please 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 application.