

*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

**Draft Guidance on Tadalafil**

**February 2026**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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**Active Ingredient:** Tadalafil

**Dosage Form:** Suspension

**Route:** Oral

**Strength:** 20 mg/5 mL

**Recommended Study:** One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting  
Design: Single-dose, two-treatment, two-period, two sequence, crossover in vivo  
Strength: 20 mg/5 mL at the administered dose of 20 mg  
Subjects: Healthy males and non-pregnant, non-lactating females  
Additional comment: None

**Analyte to measure:** Tadalafil in plasma

**Bioequivalence based on (90% CI):** Tadalafil

**Waiver request of in vivo testing of additional strength:** Not applicable

**Dissolution test method and sampling times:** Dissolution test(s) should be included for quality control. Provide a dissolution method development report for the test product containing information and data that demonstrate appropriateness of the selected dissolution method<sup>1</sup> and sampling times, such as the discriminating ability to detect changes in critical quality attributes that could potentially impact drug product performance.

Conduct comparative dissolution testing on 12 dosage units for each of the test product and reference listed drug. Note that a dosage unit for a suspension is the labeled strength (20 mg/5 mL). Specifications will be determined upon evaluation of the abbreviated new drug application.

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**Document History:** Recommended February 2026

**Unique Agency Identifier:** PSG\_214522

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<sup>1</sup> Applicant-developed, United States Pharmacopeia drug product monograph or Dissolution Methods database, <https://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm>