Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Apixaban

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Active Ingredient: Apixaban

Dosage Form: For suspension

Route: Oral

Strength: 0.15 mg

Recommended Studies: Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 0.15 mg at the administered dose of 2.4 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: For the 2.4 mg dose (16 capsules), open capsules and sprinkle contents into a medicine cup with 40 mL of water, then stir until powder particles can no longer be seen. Following administration of the initial mixture, add additional water (i.e., 40 mL of water) to the medicine cup and administer to ensure any medicine remaining in the cup is given.

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 0.15 mg at the administered dose of 2.4 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: See comments above.

Analyte to measure: Apixaban in plasma

Bioequivalence based on (90% CI): Apixaban

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[1] and sampling times, such as the discriminating ability to detect changes in critical quality attributes that could potentially impact drug product performance.

Document History: Recommended February 2026

Unique Agency Identifier: PSG_220073

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