

Draft Guidance on Avatrombopag Maleate

August 2026

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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: Avatrombopag maleate

Dosage Form: Granule

Route: Oral

Strength: EQ 10 mg Base

Reference Listed Drug: NDA 219696

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Class of study: Bioequivalence
Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 10 mg Base
Subjects: Healthy males and non-pregnant, non-lactating females
Study design recommendation:
 - Applicants may consider using a reference-scaled average bioequivalence approach for avatrombopag. If using this approach, provide evidence of high variability in the pharmacokinetic parameters (i.e., within-subject variability $\geq 30\%$) for the reference listed product. For detailed information on this approach, refer to the guidance for industry *Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA*.^a

Analyte to measure: Avatrombopag in plasma

Bioequivalence based on (90% CI): Avatrombopag

Dissolution: Dissolution tests 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 method¹ 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 August 2026

^a We update guidances periodically. For the most recent version of a guidance, refer to the FDA guidance webpage at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

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