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Draft Guidance on Eltrombopag Choline

November 2025

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Active Ingredient: Eltrombopag choline

Dosage Form: Tablet

Route: Oral

Strengths: EQ 9 mg Base, EQ 18 mg Base, EQ 36 mg Base, EQ 54 mg Base

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: EQ 54 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments:
   - Exclude subjects with abnormal hepatic function. Monitor platelet counts before and after the study.
   - Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of eltrombopag. Alternatively, a parallel study design may be considered.

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 54 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: See comments above.

Analyte to measure: Eltrombopag in plasma

Bioequivalence based on (90% CI): Eltrombopag

Waiver request of in vivo testing: EQ 9 mg Base, EQ 18 mg Base, and EQ 36 mg Base strengths based on (i) acceptable bioequivalence studies on the EQ 54 mg Base strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units each of all strengths of the test product and the reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

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Unique Agency Identifier: PSG_216774

[1] If the RLD is not available, refer to the most recent version of the guidance for industry *Referencing Approved Drug Products in ANDA Submissions*.