Contains Nonbinding Recommendations

Draft Guidance on Avatrombopag Maleate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Active Ingredient: Avatrombopag maleate

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 20 mg Base
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: Applicants may consider using a reference-scaled average bioequivalence approach. If using this approach, provide evidence from the bioequivalence studies of high variability in the bioequivalence parameters of AUC and/or Cmax (i.e., within-subject variability ≥ 30%). For the method for statistical analysis using the reference-scaled average bioequivalence approach, refer to the detailed information described in the Product Specific Guidance for Progesterone Capsules.

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2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 20 mg Base
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: See comments above

Analyte to measure (in appropriate biological fluid): Avatrombopag in plasma

Bioequivalence based on (90% CI): Avatrombopag

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. 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 abbreviated new drug application.