Draft Guidance on Avatrombopag Maleate

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.

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/](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.