This draft guidance, once finalized, will represent the Food and Drug Administration’ (FDA’s) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

**Active Ingredient:** Eltrombopag olamine

**Dosage Form; Route:** Tablet; oral

**Recommended Studies:** Two studies

1. **Type of study:** Fasting  
   **Design:** Single-dose, two-way crossover in vivo  
   **Strength:** Eq 100 mg acid  
   **Subjects:** Healthy males and nonpregnant females, general population  
   **Additional comments:** None

2. **Type of study:** Fasting  
   **Design:** Single-dose, two-way crossover in vivo  
   **Strength:** Eq 75 mg acid  
   **Subjects:** Healthy males and nonpregnant females, general population  
   **Additional comments:** None

**Analytes to measure (in appropriate biological fluid):** Eltrombopag in plasma

Eltrombopag has a long terminal elimination half-life. For further detailed information on long half-life drugs, consult the bioequivalence (BE) recommendations for specific products on amiodarone HCl tablets.

**Bioequivalence based on (90% CI):** Eltrombopag

**Waiver request of in vivo testing:** Eq 12.5 mg acid, Eq 25 mg acid, and Eq 50 mg acid strengths based on (i) acceptable BE study on the Eq 75 mg acid strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths.

Refer to the mirtazapine tablet draft guidance for additional information regarding waivers of in vivo testing.

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website available to the

*Recommended Jun 2013; Revised Mar 2015*
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 (ANDA).