

Draft Guidance on Eltrombopag Olamine

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Refer to the mirtazapine tablet draft guidance for additional information regarding waivers of in vivo testing.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

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).