

Draft Guidance on Eltrombopag Olamine

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: For suspension; oral

Recommended Studies: One study

1. Type of study: Fasting

Design: Single-dose, two-way crossover in vivo

Strength: EQ 25 mg Acid/Package

Subjects: Healthy males and non-pregnant, non-lactating females, general population

Additional Comments: Eltrombopag has a borderline long terminal elimination half-life (plasma elimination half-life of eltrombopag is approximately 21 to 32 hours in healthy subjects); therefore adequate washout periods should be ensured between treatments in the crossover studies. A parallel study design may also be considered due to its long half-life. For either a crossover or parallel study, sample collection time should be adequate to ensure completion of gastrointestinal transit of the drug product and absorption of the drug substance. For long half-life drug products that demonstrate low intra-subject variability in distribution and clearance, an AUC truncated to 72 hours may be used in place of AUC_{0-t} or $AUC_{0-\infty}$. Sufficient blood samples should be collected in the BE studies to adequately characterize the peak concentration (C_{max}) and time to reach peak concentration (T_{max}).

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

Bioequivalence based on (90% CI): Eltrombopag

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 (ANDA).