

*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

## **Draft Guidance on Eltrombopag Olamine**

**August 2021**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

This guidance, which interprets the Agency's regulations on bioequivalence at 21 CFR part 320, provides product-specific recommendations on, among other things, the design of bioequivalence studies to support abbreviated new drug applications (ANDAs) for the referenced drug product. FDA is publishing this guidance to further facilitate generic drug product availability and to assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating evidence needed to support ANDA approval for generic versions of this product.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

In March 2015, FDA issued a draft product-specific guidance for industry on generic eltrombopag olamine. We are now issuing revised draft guidance for industry that replaces the previously issued guidance.

**Active Ingredient:** Eltrombopag olamine

**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 75 mg Acid  
Subjects: Males and non-pregnant, non-lactating females, general population  
Additional comments: Exclude subjects with abnormal hepatic function. Monitor platelet counts before and after the study. Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of eltrombopag. Alternatively, a parallel study design may be considered.

2. Type of study: Fed  
Design: Single-dose, two treatment, two-period, crossover in vivo  
Strength: EQ 75 mg Acid  
Subjects: Males and non-pregnant, non-lactating females, general population  
Additional comments: See comments above.
- 

**Analyte to measure:** Eltrombopag in plasma

**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 bioequivalence studies on the EQ 75 mg Acid strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

**Revision History:** Recommended June 2013; Withdrawn April 2014; Revised March 2015, August 2021

**Unique Agency Identifier:** PSG\_022291