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Draft Guidance on Eltrombopag Olamine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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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In October 2016, 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 We are now issuing revised draft guidance for industry that replaces the previously issued guidance.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: For suspension; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two treatment, two-period, crossover in vivo
   Strength: EQ 25 mg Acid/packet
   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 25 mg Acid/packet
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/packet based on (i) acceptable bioequivalence studies on the EQ 25 mg Acid/packet strength, (ii) proportional similarity of the formulations between both strengths, and (iii) acceptable in vitro dissolution testing of both 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 both strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

Revision History: Recommended October 2016; Revised August 2021

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