

*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

## **Draft Guidance on Lomitapide Mesylate**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Dosage Form; Route:** Capsule; oral

**Recommended Study:** One study

1. Type of study: Fasting  
Design: Single-dose, two-treatment, two-period crossover in vivo  
Strength: EQ 30 mg Base  
Subjects: Healthy males and females  
Additional comments: Exclude females of reproductive potential due to the risk of embryo-fetal toxicity. Exclude any subjects with abnormal liver function tests.  
Lomitapide mesylate is approved under a Risk Evaluation and Mitigation Strategy (REMS) with Elements to Assure Safe Use (ETASU), which restricts its use. All pertinent elements of the REMS/ETASU must be incorporated into the protocol and informed consent.

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**Analyte to measure:** Lomitapide in plasma

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

**Waiver request of in vivo testing:** EQ 5 mg Base, EQ 10 mg Base, and EQ 20 mg Base based on (i) acceptable bioequivalence study on the EQ 30 mg Base strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across 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.