*Contains Nonbinding Recommendations*

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**Draft Guidance on Lasmiditan Succinate**

**October 2024**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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**Active Ingredient:** Lasmiditan succinate

**Dosage Form:** Tablet

**Route:** Oral

**Strengths:** EQ 50 mg Base, EQ 100 mg Base, EQ 200 mg Base

**Recommended Study:** One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 200 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Exclude geriatric subjects. Subjects should not engage in potentially hazardous activities requiring complete mental alertness, such as driving a motor vehicle or operating machinery until they have completely returned to their level of baseline cognitive functioning after taking lasmiditan.

**Analyte to measure:** Lasmiditan in plasma

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

**Waiver request of in vivo testing:** EQ 50 mg Base and EQ 100 mg Base strengths based on (i) acceptable bioequivalence study on the EQ 200 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 product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

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**Document History:** Recommended August 2021; Revised October 2024

**Unique Agency Identifier:** PSG_211280

[1] If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.