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Draft Guidance on Daridorexant Hydrochloride

May 2025

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Active Ingredient: Daridorexant hydrochloride

Dosage Form: Tablet

Route: Oral

Strengths: EQ 25 mg Base, EQ 50 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 50 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Screen for and exclude subjects with narcolepsy.

Analyte to measure: Daridorexant in plasma

Bioequivalence based on (90% CI): Daridorexant

Waiver request of in vivo testing: EQ 25 mg Base strength based on (i) an acceptable bioequivalence study on the EQ 50 mg Base strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between 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 product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

Document History: Recommended August 2023; Revised May 2025

Unique Agency Identifier: PSG_214985

[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*.