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Draft Guidance on Daridorexant Hydrochloride

August 2023

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Active Ingredient: Daridorexant hydrochloride

Dosage Form: Tablet

Route: Oral

Strengths: EQ 25 mg Base, EQ 50 mg Base

Recommended Studies: Two in vivo bioequivalence studies 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 comment: Screen for and exclude subjects with narcolepsy.

2. Type of study: Fed
   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 comment: See comment above.

Analyte to measure: Daridorexant in plasma

Bioequivalence based on (90% CI): Daridorexant

Waiver request of in vivo testing: EQ 25 mg Base based on (i) acceptable bioequivalence studies on the EQ 50 mg Base strength, (ii) acceptable in vitro dissolution testing between two strengths, and (iii) proportional similarity of the formulations between two 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 each of both strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

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