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Draft Guidance on Ropinirole Hydrochloride

October 2024

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Active Ingredient: Ropinirole hydrochloride

Dosage Form: Tablet

Route: Oral

Strengths: EQ 0.25 mg Base, EQ 0.5 mg Base, EQ 1 mg Base, EQ 2 mg Base, EQ 3 mg Base, EQ 4 mg Base, EQ 5 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 0.25 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments:
   a. Due to safety concerns, bioequivalence studies should be conducted using the EQ 0.25 mg Base strength.
   b. The subjects should remain in a comfortable recumbent position for up to 8 hours after dosing and remain under medical surveillance for up to 12 hours after dosing. Before they are allowed to ambulate, they should sit up with legs in a dependent position for one minute prior to standing up. While standing immobile, they should be closely observed for blood pressure changes and/or orthostatic symptoms, including nausea, dizziness, or faintness for at least three minutes.

Analyte to measure: Ropinirole in plasma

Bioequivalence based on (90% CI): Ropinirole

Waiver request of in vivo testing: EQ 0.5 mg Base, EQ 1 mg Base, EQ 2 mg Base, EQ 3 mg Base, EQ 4 mg Base, and EQ 5 mg Base strengths based on (i) acceptable bioequivalence study on the EQ 0.25 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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[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*.