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Draft Guidance on Citalopram Hydrobromide

November 2023

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Active Ingredient: Citalopram hydrobromide

Dosage Form: Capsule

Route: Oral

Strength: EQ 30 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 30 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Exclude subjects with risk factors for prolonged QTc interval and Torsades de Pointes. Exclude geriatric subjects. Consider excluding CYP2C19 poor metabolizers. Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of citalopram. Alternatively, a parallel study design may be considered.

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 30 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: See comments above.

Analyte to measure: Citalopram in plasma

Bioequivalence based on (90% CI): Citalopram

Waiver request of in vivo testing: Not applicable

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 the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

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