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Draft Guidance on Sertraline Hydrochloride

October 2024

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Active Ingredient: Sertraline hydrochloride

Dosage Form: Tablet

Route: Oral

Strengths: EQ 25 mg Base, EQ 50 mg Base, EQ 100 mg Base, EQ 150 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 100 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Due to safety concerns, bioequivalence studies should be conducted on the 100 mg strength.

Analyte to measure: Sertraline in plasma

Bioequivalence based on (90% CI): Sertraline

Waiver request of in vivo testing: EQ 25 mg Base, EQ 50 mg Base, EQ 150 mg Base, and EQ 200 mg Base based on (i) acceptable bioequivalence study on the EQ 100 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.*