

Contains Nonbinding Recommendations
Draft – Not for Implementation
Draft Guidance on Fluoxetine Hydrochloride
October 2024

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Active Ingredient:	Fluoxetine hydrochloride
Dosage Form:	Capsule
Route:	Oral
Strengths:	EQ 10 mg Base, EQ 20 mg Base, EQ 40 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 40 mg Base
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: Fluoxetine has a long terminal half-life. Ensure adequate washout periods between treatments in the crossover studies due to the long elimination half-life of fluoxetine. Alternatively, a parallel study design may be considered.

Analyte to measure: Fluoxetine in plasma

Bioequivalence based on (90% CI): Fluoxetine

Waiver request of in vivo testing: EQ 10 mg Base and EQ 20 mg Base strengths based on (i) acceptable bioequivalence study on the EQ 40 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.

Document History: Recommended June 2013; Revised October 2024

Unique Agency Identifier: PSG_018936

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*.