

Draft Guidance on Fluoxetine Hydrochloride

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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.

Active Ingredient: Fluoxetine hydrochloride

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting

Design: Single dose, two-way crossover *in-vivo*

Strength: Eq 60 mg base

Subjects: Healthy males and non-pregnant females, general population

Additional Comments: a. Female subjects should not be pregnant or lactating. b. Fluoxetine has a long terminal elimination half-life, thus consider using a parallel study design. Ensure adequate washout periods between treatments in all crossover studies. An AUC truncated to 72 hours may be used in place of AUC_{0-t} or AUC_∞ for long half-life drug products. Collect sufficient blood samples in the bioequivalence studies to adequately characterize the peak concentration (C_{max}) and time to reach peak concentration (T_{max}). Please, refer to the Amiodarone Tablet Draft Guidance for additional information regarding long half-life drugs.

2. Type of study: Fed

Design: Single dose, two-way crossover *in-vivo*

Strength: Eq 60 mg base

Subjects: Healthy males and non-pregnant females, general population

Additional Comments: Please, see comments above.

Analytes to measure (in appropriate biological fluid): Fluoxetine in plasma

Bioequivalence based on (90% CI): Fluoxetine

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).

Fluoxetine hydrochloride tablets are scored. For additional information on the evaluation of scored tablets, refer to the FDA Guidance on "Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation" issued in March 2013 at

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269921.pdf>.