Contains Nonbinding Recommendations

Draft Guidance on Fluoxetine Hydrochloride

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Fluoxetine Hydrochloride

Form/Route: Delayed Release Capsule/Oral

Recommended study: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: 90 mg
   Subjects: Healthy males and nonpregnant females, general population
   Additional comments: 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}).

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2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: 90 mg
   Subjects: Healthy males and nonpregnant females, general population
   Additional comments: Please see comment above

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

Bioequivalence based on (90% CI): Fluoxetine

Waiver request of in-vivo testing: Not applicable

Dissolution test method and sampling times:
Please note that a **Dissolution Methods Database** is available to the public at the OGD website http://www.accessdata.fda.gov/scripts/cder/dissolution/. Please find the dissolution information for this product at this website. Please 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 application.