**Draft Guidance on Fluoxetine Hydrochloride**

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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\(_{\infty}\) for long half-life drug products. Collect sufficient blood samples in the bioequivalence studies to adequately characterize the peak concentration (C\(_{\text{max}}\)) and time to reach peak concentration (T\(_{\text{max}}\)).

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/](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.

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