*Contains Nonbinding Recommendations*

**Guidance on Sertraline Hydrochloride**

This guidance represents 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:** Sertraline Hydrochloride

**Form/Route:** Tablets/Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover *in-vivo*
   Strength: 100 mg
   Subjects: Normal healthy males and females, general population
   Additional Comments: Due to safety concerns, bioequivalence studies should be conducted on the 100 mg strength.

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2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover *in-vivo*
   Strength: 100 mg
   Subjects: Normal healthy males and females, general population
   Additional comments:

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**Analytes to measure (in appropriate biological fluid):** Sertraline in plasma.

**Bioequivalence based on (90% CI):** Sertraline

**Waiver request of in-vivo testing:** 25 mg, 50 mg, 150 mg and 200 mg based on (i) acceptable bioequivalence studies on the 100 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

**Dissolution test method and sampling times:**

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at http://www.fda.gov/cder/ogd/index.htm. 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.