This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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:** Iloperidone

**Form/Route:** Tablet (Oral)

**Recommended studies:** 2 studies

1. **Type of study:** Fasting  
   **Design:** Single-dose, two-way crossover *in-vivo*  
   **Strength:** 1 mg (dose=1 mg*2 or 1 mg*3 depending on the assay sensitivity)  
   **Subjects:** Healthy males and non-pregnant females, general population.  
   **Additional Comment:**

2. **Type of study:** Fed  
   **Design:** Single-dose, two-way crossover *in-vivo*  
   **Strength:** 1 mg (dose=1 mg*2 or 1 mg*3, depending on the assay sensitivity)  
   **Subjects:** Healthy males and non-pregnant females, general population.  
   **Additional Comments:** The test and reference products should be administered 30 minutes after start of the meal.

**Analytes to measure:** Iloperidone and the active P88 metabolite in plasma

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

**Waiver request of in-vivo testing:** 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg, based on (i) acceptable bioequivalence study using the 1 mg tablets, (ii) proportional similarity in the formulations of the 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg strengths and (iii) acceptable comparable in vitro dissolution testing on 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.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 drug 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.

*Recommended Nov 2010*