Contains Nonbinding Recommendations

Draft Guidance on Iloperidone

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

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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/. 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.