Draft Guidance on Fluoxetine Hydrochloride

Active ingredient: Fluoxetine Hydrochloride

Form/Route: Capsule/Oral

Recommended study: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: Eq 40 mg base
   Subjects: Healthy males and nonpregnant females, general population
   Additional comments: Please refer to the Amiodarone Tablet Draft Guidance for additional information regarding long half-life drugs.

2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: Eq 40 mg base
   Subjects: Healthy males and nonpregnant females, general population
   Additional comments: Please refer to the Amantadine Hydrochloride Tablet Draft Guidance for additional information regarding fed studies.

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

Bioequivalence based on (90% CI): Fluoxetine

Waiver request of in-vivo testing: Eq 10 mg and 20 mg base, based on (i) acceptable bioequivalence studies on the Eq 40 mg base strength, (ii) acceptable in-vitro dissolution testing of all strengths, and (iii) proportional similarity in the formulations across all strengths. Please refer to the Mirtazapine Tablet Draft Guidance for additional information regarding waivers of in-vivo testing.

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 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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