Active ingredient: Fluoxetine Hydrochloride; Olanzapine

Form/Route: Capsules/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: 50 mg/6 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments:

2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: 50 mg/6 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional comments:

Analytes to measure: Fluoxetine and Olanzapine in plasma

Bioequivalence based on (90% CI): Fluoxetine and Olanzapine

Waiver request of in-vivo testing: 25 mg/3 mg, 25 mg/6 mg, 25 mg/12 mg and 50 mg/12 mg based on (i) acceptable bioequivalence studies on the 50 mg/6 mg strength, (ii) proportionally similar 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.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.