Active ingredient: Olanzapine

Form/Route: Orally Disintegrating Tablet/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in-vivo
   Strength: 5 mg
   Subjects: Normal healthy males and females, general population
   Additional Comments: Due to safety concerns, studies should be conducted using the 5 mg strength.

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in-vivo
   Strength: 5 mg
   Subjects: Normal healthy males and females, general population
   Additional comments: Please see above comment.

Analytes to measure: Olanzapine in plasma

Bioequivalence based on (90% CI): Olanzapine

Waiver request of in-vivo testing: 10 mg, 15 mg and 20 mg based on (i) acceptable bioequivalence studies on the 5 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.

Finalized May 2008