Contains Nonbinding Recommendations

Guidance on Olanzapine

This guidance represents 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: 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.