Contains Nonbinding Recommendations

Guidance on Ziprasidone Hydrochloride

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: Ziprasidone Hydrochloride

Form/Route: Capsules/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 20 mg
   Subjects: Normal healthy males and females, general population.
   Additional Comments: Given that the risk of QT prolongation is associated with higher doses and little, if any, such effect is expected with a 20 mg dose, a screening EKG to exclude subjects with prolonged QT or other EKG abnormality is recommended, along with monitoring of vital signs and adverse events. Females should not be pregnant or lactating, and if applicable, should practice abstention or contraception during the study.

---

2. Type of study: Fed
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 20 mg
   Subjects: Normal healthy males and females, general population.
   Additional comments: Please see comment above.

Analytes to measure: Ziprasidone in plasma

Bioequivalence based on (90% CI): Ziprasidone

Waiver request of in-vivo testing: 40 mg, 60 mg and 80 mg based on (i) acceptable bioequivalence studies on the 20 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.fda.gov/cder/ogd/index.htm. 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.