

Draft Guidance on Ziprasidone Hydrochloride

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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: Suspension/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: single-dose, two-way crossover *in-vivo*
Strength: 10 mg/mL (20 mg dose)
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 10 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: 10 mg/mL (20 mg dose)
Subjects: Normal healthy males and females, general population.
Additional Comments: See above Additional Comments

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

Bioequivalence based on (90% CI): Ziprasidone

Waiver request of in-vivo testing: Not Applicable

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. Please note that a dosage unit for a suspension is the labeled strength (ml). A total of 12 units from 12 different bottles should be used. Specifications will be determined upon review of the application.