Contains Nonbinding Recommendations

Draft Guidance on Zolpidem Tartrate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Sublingual Tablet; Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 3.5mg
   Subjects: Healthy males and non-pregnant females, general population
   Additional Comments: Patients should be advised not to drive if they are experiencing drowsiness and/or dizziness at the end of the study.

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2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 3.5mg
   Subjects: Healthy males and non-pregnant females, general population
   Additional Comments: See comment above.

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

Bioequivalence based on (90% CI): Zolpidem

Waiver request of in-vivo testing: 1.75mg based on (i) acceptable bioequivalence studies on the 3.5mg strength, (ii) formulation proportionally similar for both 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 and disintegration testing information for this product at this website. Please conduct comparative dissolution and disintegration testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the application