

## Draft Guidance on Zolpidem

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

**Form/Route:** Sublingual Tablets/ Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover *in-vivo*  
Strength: 10 mg  
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: 10 mg  
Subjects: Healthy males and non-pregnant females, general population.  
Additional Comments: See comment above.

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

**Bioequivalence based on (90% CI):** Zolpidem

**Waiver request of in-vivo testing:** 5 mg based on (i) acceptable bioequivalence studies on the 10 mg 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