

*Contains Nonbinding Recommendations*  
*Draft – Not for Implementation*  
**Draft Guidance on Zolpidem Tartrate**  
**October 2024**

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**Active Ingredient:** Zolpidem tartrate

**Dosage Form:** Tablet

**Route:** Oral

**Strengths:** 5 mg, 10 mg

**Recommended Study:** One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting  
Design: Single-dose, two-treatment, two-period crossover in vivo  
Strength: 10 mg  
Subjects: Healthy males and non-pregnant, non-lactating females  
Additional comments: Subjects should be advised not to drive if they are experiencing drowsiness and/or dizziness at the end of the study.

**Analyte to measure:** Zolpidem in plasma

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

**Waiver request of in vivo testing:** 5 mg strength based on (i) acceptable bioequivalence study on the 10 mg strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both strengths

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found in the FDA’s Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each of both strengths of the test product and reference listed drug (RLD).<sup>1</sup> Specifications will be determined upon review of the abbreviated new drug application.

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**Document History:** Recommended May 2007; Revised October 2024

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<sup>1</sup> If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.