

## Guidance on Cephalexin

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**Active ingredient:** Cephalexin

**Form/Route:** Capsule/Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting  
Design: Single-dose, two-way, crossover *in-vivo*  
Strength: 750 mg  
Subjects: Healthy males and nonpregnant females, general population.  
Additional Comments:
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2. Type of study: Fed  
Design: Single-dose, two-way, crossover *in-vivo*  
Strength: 750 mg  
Subjects: Healthy males and nonpregnant females, general population.  
Additional comments:
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**Analytes to measure:** Cephalexin in plasma

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

**Waiver request of in-vivo testing:** 250 mg, 333 mg and 500 mg based on (i) acceptable bioequivalence studies on the 750 mg strength, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity in the formulations across 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 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.