

*Contains Nonbinding Recommendations*  
**Draft Guidance on Cefditoren Pivoxil**

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

**Form/Route:** Tablet (oral)

**Recommended studies:** 2 studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover *in-vivo*  
Strength: 400 mg  
Subjects: Healthy males and non-pregnant females, general population.  
Additional Comment:

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2. Type of study: Fed  
Design: Single-dose, two-way crossover *in-vivo*  
Strength: 400 mg  
Subjects: Healthy males and non-pregnant females, general population.  
Additional Comments: The test and reference products should be administered 30 minutes after start of the meal.

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

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

**Waiver request of in-vivo testing:** 200 mg, based on i) acceptable bioequivalence studies on the 400 mg strength tablets, ii) proportional similarity of formulations across all strengths, and iii) acceptable *in vitro* drug release testing of all strengths.

**Dissolution test method and sampling times:**

Please note that a **Dissolution Method 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.