

Guidance on Cefditoren Pivoxil

This guidance represents the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Cefditoren pivoxil

Dosage Form; Route: Tablet; oral

Recommended Studies: Two 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:

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.

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 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.