Contains Nonbinding Recommendations

Draft Guidance on Cefdinir

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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: Cefdinir

Dosage Form; Route: Powder for suspension; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-way crossover *in-vivo*
   Strength: 250 mg/5 mL
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments:

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2. Type of study: Fed
   Design: Single-dose, two-treatment, two-way crossover *in-vivo*
   Strength: 250 mg/5 mL
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments:

Analytes to measure (in appropriate biological fluid): Cefdinir in plasma.

Bioequivalence based on (90% CI): Cefdinir

Waiver request of in-vivo testing: 125 mg/5 mL based on (i) acceptable bioequivalence studies on the 250 mg/5 mL strength, (ii) acceptable in vitro dissolution testing of 125 mg/5 mL and 250 mg/5 mL strengths, and (iii) proportional similarity of the formulations between 125 mg/5 mL and 250 mg/5 mL strengths.

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. 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 abbreviated new drug application (ANDA).