

Draft Guidance on Cefixime

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Suspension/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: 500 mg/5 mL (200 mg dose)
Subjects: Healthy males and nonpregnant females, general population
Additional Comments: None

2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: 500 mg/5 mL (200 mg dose)
Subjects: Healthy males and nonpregnant females, general population
Additional Comments: Please refer to the Amantadine Hydrochloride Tablet Draft Guidance for additional information regarding fed studies.

Analytes to measure (in appropriate biological fluid): Cefixime in plasma

Bioequivalence based on (90% CI): Cefixime

Waiver request of in vivo testing: 100 mg/5 mL and 200 mg/5 mL based on (i) acceptable bioequivalence studies on the 500 mg/5 mL strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths. Please refer to the Mirtazapine Tablet Draft Guidance for additional information regarding dose proportionality.

* Since Cefixime Suspension, 500 mg/5 mL, 200 mg/5 mL, and 100 mg/5 mL are the subject of three separate applications (both New Drug Application (NDA) and Abbreviated New Drug Application (ANDA)), therefore three separate ANDA's must be submitted. You may request a waiver of in vivo bioequivalence testing of the 100 mg/5 mL and 200 mg/5 mL strengths if you meet the criteria. In addition, please cross-reference the in vivo bioequivalence studies conducted on the highest strength along with your waiver request. Please refer to the Guidance for Industry, *Variations in Drug Products that May Be Included in a Single ANDA* located at: <http://www.fda.gov/cder/guidance>.

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.