

Draft Guidance on Cephalexin

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Suspension; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: Eq 250 mg base/ 5 mL
Subjects: Healthy males and nonpregnant females, general population
Additional Comments: None

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2. Type of study: Fed
Design: Single-dose, two-way crossover *in-vivo*
Strength: Eq 250 mg base/ 5 mL
Subjects: Healthy males and nonpregnant females, general population
Additional Comments: None
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Analytes to measure (in appropriate biological fluid): Cephalexin in plasma

Bioequivalence based on (90% CI): Cephalexin

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

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website 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 the test and reference products. A dosage unit for a suspension is the labeled strength (5 mL). Twelve (12) units from 12 different bottles should be used. Specifications will be determined upon review of the abbreviated new drug application (ANDA).