Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Cephalexin

October 2024

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Active Ingredient: Cephalexin

Dosage Form: Suspension

Route: Oral

Strengths: EQ 100 mg Base/5 mL, EQ 125 mg Base/5 mL, EQ 250 mg Base/5 mL

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 250 mg Base/5 mL
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

Analyte to measure: Cephalexin in plasma

Bioequivalence based on (90% CI): Cephalexin

Waiver request of in vivo testing: EQ 100 mg Base/5 mL and EQ 125 mg Base/5 mL strengths based on (i) acceptable bioequivalence study on the EQ 250 mg Base/5 mL strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution. Conduct comparative dissolution testing on 12 dosage units for each of all strengths of the test product and reference listed drug (RLD)[1] Specifications will be determined upon review of the abbreviated new drug application.

Document History: Recommended December 2016; Revised October 2024

Unique Agency Identifier: PSG_050406

[1] If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions.*