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Draft Guidance on Ampicillin/Ampicillin Trihydrate

August 2022

This guidance, which interprets the Agency's regulations on bioequivalence at 21 CFR part 320, provides product-specific recommendations on, among other things, the design of bioequivalence studies to support abbreviated new drug applications (ANDAs) for the referenced drug product. FDA is publishing this guidance to further facilitate generic drug product availability and to assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating evidence needed to support ANDA approval for generic versions of this product.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in FDA guidances means that something is suggested or recommended, but not required.

This is a new draft product-specific guidance for industry on generic ampicillin/ampicillin trihydrate.

Active Ingredients: Ampicillin/Ampicillin trihydrate

Dosage Form; Route: Capsule; oral

Recommended Studies: 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 500 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Comment: None

Analyte to measure: Ampicillin in plasma

Bioequivalence based on (90% CI): Ampicillin

Waiver request of in vivo testing: EQ 250 mg Base strength based on (i) acceptable bioequivalence study on the 500 mg strength, (ii) acceptable in vitro dissolution testing of both strengths and, (iii) proportional similarity of the formulations between both 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 each of both strengths of the test and reference products. Specifications will be determined upon review of the ANDA.

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