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Draft Guidance on Diclofenac Potassium

November 2021

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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.

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This is a new draft product-specific guidance for industry on generic diclofenac potassium.

Active Ingredient: Diclofenac potassium

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two treatment, two-period, crossover in vivo
   Strength: 50 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: None

2. Type of study: Fed
   Design: Single-dose, two treatment, two-period, crossover in vivo
   Strength: 50 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: None

Analyte to measure: Diclofenac in plasma

Bioequivalence based on (90% CI): Diclofenac

Waiver request of in vivo testing: 25 mg based on (i) acceptable bioequivalence studies on the 50 mg strength, (ii) acceptable in vitro dissolution testing of both strengths and (iii) proportionally similar 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 for each of the test and reference products of both strengths. Specifications will be determined upon review of the abbreviated new drug application.

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