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Draft Guidance on Opicapone

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 opicapone.

Active Ingredient: Opicapone

Dosage Form; Route: Capsule; oral

Recommended Study: One study

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: Subjects should be instructed not to engage in potentially hazardous activities requiring complete mental alertness, such as driving a motor vehicle or operating machinery until they have completely returned to their level of baseline cognitive functioning after taking opicapone.

Analyte to measure: Opicapone in plasma

Bioequivalence based on (90% CI): Opicapone

Waiver request of in vivo testing: 25 mg based on (i) acceptable bioequivalence study on the 50 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 all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

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