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Draft Guidance on Riluzole

November 2021

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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 riluzole.

Active Ingredient: Riluzole

Dosage Form; Route: Suspension; oral

Recommended Study: One study

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 50 mg/10 mL
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: Not applicable

Analyte to measure: Riluzole in plasma

Bioequivalence based on (90% CI): Riluzole

Waiver request of in vivo testing: Not applicable

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 the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).

Product-specific testing conditions for in vitro enteral tube studies: The reference product can be administered via a percutaneous endoscopic gastric (PEG) tube. Conduct the in vitro feeding tube studies including comparative recovery testing with two repeated administrations and sedimentation volume testing. Refer to the FDA guidance for industry on *Oral Drug Products Administered Via Enteral Feeding Tube: In Vitro Testing and Labeling Recommendations*.

Testing Tube: PEG tube (12 French)
Note: At least one tube should be tested with an inflated balloon configuration. Both polyurethane and silicone tubes should be used.

Testing Strength: 50 mg/10 mL

Hold Time: Day 0 and 15

Additional Information

Device:

This product is a drug-device combination product. Refer to the FDA guidance for industry on *Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA.* An ANDA for a proposed generic drug-device combination product should include complete comparative analyses.

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