

Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Nitrofurantoin

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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.

In October 2011, FDA issued a final product-specific guidance for industry on generic nitrofurantoin. We are now issuing revised draft guidance for industry that replaces the previously issued guidance.

Active Ingredient: Nitrofurantoin

Dosage Form; Route: Suspension; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way, crossover in vivo
Strength: 25 mg; 5 mL
Subjects: Healthy males and nonpregnant, non-lactating females
Additional comments: None

2. Type of study: Fed
Design: Single-dose, two-way, crossover in vivo
Strength: 25 mg; 5 mL

Subjects: Healthy males and nonpregnant, non-lactating females
Additional comments: None

Analyte to measure: Nitrofurantoin in plasma

Bioequivalence based on (90% CI): Nitrofurantoin

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: <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. Note that a dosage unit is based on the labeled concentration of the suspension product. Use the dosage unit (5 mL). Specifications will be determined upon review of the abbreviated new drug application.

Revision History: Recommended April 2009; Finalized October 2011; Revised May 2021

Unique Agency Identifier: PSG_009175