

Draft Guidance on Nitrofurantoin Macrocrystalline

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Active Ingredient: Nitrofurantoin macrocrystalline

Dosage Form; Route: Capsule; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way, crossover in vivo
Strength: 100 mg
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: 100 mg
Subjects: Healthy males and nonpregnant, non-lactating females
Additional comments: None

Analyte to measure (in appropriate biological fluid): Nitrofurantoin in plasma

Bioequivalence based on (90% CI): Nitrofurantoin

Waiver request of in vivo testing: 25 mg and 50 mg based on (i) acceptable bioequivalence studies on the 100 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths

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. Specifications will be determined upon review of the abbreviated new drug application.