

Draft Guidance on Nitrofurantoin Macrocrystalline

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Active ingredient: Nitrofurantoin Macrocrystalline

Form/Route: Capsule/Oral

Recommended studies: 1 study

Type of study: Fed

Design: Single-dose, two-way, crossover *in-vivo*

Strength: 100 mg

Subjects: Healthy males and nonpregnant females, general population.

Additional comments:

Analytes to measure: 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:

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.fda.gov/cder/ogd/index.htm>. Please find the dissolution information for this product at this website. Please 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 application.