

Guidance on Nitrofurantoin

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Active ingredient: Nitrofurantoin

Form/Route: Suspension/Oral

Recommended studies: 1 study

Type of study: Fed

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

Strength: 25 mg/5 mL

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: Not Applicable

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.accessdata.fda.gov/scripts/cder/dissolution/>. Please find the dissolution information for this product at this website. Please note that a dosage unit is based on the labeled concentration of the suspension product. Please use the dosage unit (5 ml). A total of 12 units from 12 different bottles should be used. Specifications will be determined upon review of the application.