

Draft Guidance on Griseofulvin, Microcrystalline

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Griseofulvin, Microcrystalline

Form/Route: Suspension/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in-vivo
Strength: 125 mg/5 mL x10 mL (250 mg dose)
Subjects: Healthy males and nonpregnant females, general population.
Additional Comments: Concomitant administration of penicillin with griseofulvin should be avoided due to potential for cross reactivity.

2. Type of study: Fed
Design: Single-dose, two-way crossover in-vivo
Strength: 125 mg/5 mL x10 mL (250 mg dose)
Subjects: Healthy males and nonpregnant females, general population.
Additional Comments: Please see comment above.

Analytes to measure: Griseofulvin in plasma

Bioequivalence based on (90% CI): Griseofulvin

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 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.

Please note that a dosage unit for a suspension is the labeled strength (mL). A total of 12 units from 12 different bottles should be used. Specifications will be determined upon review of the application.