Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Griseofulvin, Microcrystalline; Griseofulvin, Microsize

October 2024

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Active Ingredients: Griseofulvin, microcrystalline; Griseofulvin, microsize

Dosage Form: Tablet

Route: Oral

Strengths: 125 mg, 500 mg

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 500 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

Analyte to measure: Griseofulvin in plasma

Bioequivalence based on (90% CI): Griseofulvin

Waiver request of in vivo testing: 125 mg strength based on: (i) acceptable in vivo bioequivalence study on the 500 mg strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both strengths

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units for each of the test product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

Document History: Recommended February 2010; Revised October 2024

Unique Agency Identifier: PSG_062279

[1] If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.