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Draft – Not for Implementation

Draft Guidance on Pirfenidone

October 2024

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Active Ingredient: Pirfenidone

Dosage Form: Capsule

Route: Oral

Strength: 267 mg

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 267 mg at a dose of 801 mg (3 x 267 mg)
   Subjects: Healthy males and non-pregnant non-lactating females
   Additional comments: Sponsors should follow the recommendations indicated in the product's prescribing information. The liver enzymes, including alanine aminotransferase (ALT), alanine transaminase (AST), and bilirubin, should be checked at baseline and monitored during treatment. Adequate precautions should be taken to avoid or minimize the photosensitivity associated with the product's use.

Analyte to measure: Pirfenidone in plasma

Bioequivalence based on (90% CI): Pirfenidone

Waiver request of in vivo testing: Not applicable

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.

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[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*.