

Draft Guidance on Pirfenidone

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Pirfenidone

Dosage Form; Route: Capsule; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 267 mg at a dose of 801 mg (3x267 mg)
Subjects: Healthy males and nonpregnant females, general population
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.
2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 267 mg at a dose of 801 mg (3x267 mg)
Subjects: Healthy males and nonpregnant females, general population
Additional comments: Same as above

Analytes to measure (in appropriate biological fluid): 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 on the FDA-Recommended Dissolution Methods Web site, available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. 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 abbreviated new drug application (ANDA).