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Draft – Not for Implementation

Draft Guidance on Pirfenidone

October 2024

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Active Ingredient: Pirfenidone

Dosage Form: Tablet

Route: Oral

Strengths: 267 mg, 534 mg, 801 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: 801 mg
   Subjects: Healthy males and non-lactating, non-pregnant 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: 267 mg and 534 mg strengths based on (i) acceptable bioequivalence study on the 801 mg strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths

The 534 mg strength is currently listed as 'discontinued' in the Orange Book and for its approval, the sponsors are requested to petition the FDA to determine if the discontinuation/withdrawal of the strength is not due to Safety and or Efficacy reasons.

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 all strengths 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*.