

Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Pemigatinib

November 2021

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

This guidance, which interprets the Agency’s regulations on bioequivalence at 21 CFR part 320, provides product-specific recommendations on, among other things, the design of bioequivalence studies to support abbreviated new drug applications (ANDAs) for the referenced drug product. FDA is publishing this guidance to further facilitate generic drug product availability and to assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating evidence needed to support ANDA approval for generic versions of this product.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in FDA guidances means that something is suggested or recommended, but not required.

This is a new draft product-specific guidance for industry on generic pemigatinib.

Active Ingredient: Pemigatinib

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 13.5 mg
Subjects: Males and non-pregnant, non-lactating females, general population
Additional comments: Perform a comprehensive ophthalmological examination prior to enrollment and exclude subjects with ophthalmological abnormalities (e.g., corneal or retinal disorders). Females of reproductive potential and males with female partners of reproductive potential should use effective contraception during the study and for 1 week after the final dose.

2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 13.5 mg
Subjects: Males and non-pregnant, non-lactating females, general population
Additional comments: See comments above

Analyte to measure: Pemigatinib in plasma

Bioequivalence based on (90% CI): Pemigatinib

Waiver request of in vivo testing: 4.5 mg and 9 mg based on (i) acceptable bioequivalence studies on the 13.5 mg strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all 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 each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

Unique Agency Identifier: PSG_213736