

Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Gefitinib

February 2022

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

In July 2017, FDA issued a draft product-specific guidance for industry on generic gefitinib. We are now issuing revised draft guidance for industry that replaces the previously issued guidance.

Active Ingredient: Gefitinib

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: 250 mg
Subjects: Healthy males and healthy females not of reproductive potential
Additional comments: Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of gefitinib. Alternatively, a parallel study design may be considered.

2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 250 mg
Subjects: Healthy males and healthy females not of reproductive potential
Additional comments: See comments above.

Analyte to measure: Gefitinib in plasma

Bioequivalence based on (90% CI): Gefitinib

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 and reference products. Specifications will be determined upon evaluation of the abbreviated new drug application.

Product-specific testing conditions for in vitro feeding tube studies: The approved labeling for the reference product states that the product may be administered via a nasogastric (NG) tube. Conduct in vitro feeding tube studies including comparative recovery testing and sedimentation volume and redispersibility testing. For general procedures of in vitro feeding tube studies, refer to the most recent version of the FDA guidance for industry on *Oral Drug Products Administered Via Enteral Feeding Tube: In Vitro Testing and Labeling Recommendations*.^a

Testing tube: NG tube (8 French)

Testing strength: 250 mg

Dispersion medium: 250 mg strength in 4-8 ounces (120-240 mL) water with pH >7

Incubation times: 0 and 15 minutes

Revision History: Recommended April 2016; Revised July 2017, February 2022

Unique Agency Identifier: PSG_206995

^a For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>