Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Ceritinib

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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: 150 mg
   Subjects: Males and females, general population
   Additional comments: Exclude females of reproductive potential and subjects with risk factors for prolonged QTc interval and Torsades de Pointes. Monitor subjects during the study for electrocardiogram changes. Based on the potential for genotoxicity, males with female partners of reproductive potential should be advised to use effective contraception during the study and for 3 months following completion of the study. Subjects should be evaluated before enrollment to ensure normal transaminase (ALT, AST), alkaline phosphatase, and total bilirubin levels. Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of ceritinib. Alternatively, a parallel study design may be considered.

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2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 150 mg
   Subjects: Males, and females of non-reproductive potential, general population
   Additional comments: See comments above.

Analyte to measure: Ceritinib in plasma

Bioequivalence based on (90% CI): Ceritinib

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 each of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.