Contains Nonbinding Recommendations

Draft Guidance on Ceritinib

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Recommended studies: Two Studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 150 mg
Subjects: Healthy males
Additional Comments: Due to the embryofetal toxicity of Ceritinib, the study should be conducted in healthy male subjects. See additional warnings and precautions in the approved drug label.

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2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 150 mg
Subjects: Healthy males
Additional Comments: Same as above

Analytes to measure (in appropriate biological fluid): Ceritinib in plasma

Bioequivalence based on (90% CI): Ceritinib

Waiver request of in-vivo testing: N/A

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website 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).