

Draft Guidance on Ceritinib

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: 150 mg
Subjects: Healthy males, general population
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.

Analytes to measure (in appropriate biological fluid): 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 on the FDA-Recommended Dissolution Methods Web site, 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 the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).