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.

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).