Contains Nonbinding Recommendations

Draft Guidance on Baricitinib

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 2 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: 1) Prospective study participants should be tested and confirmed negative for latent tuberculosis before enrolling in a bioequivalence study; 2) Enrolled study participants should have normal liver function tests, blood counts, and lipid profiles at baseline prior to study drug administration; 3) Exclude subjects at an increased risk for thrombosis.

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2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 2 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: See comments above

Analyte to measure (in appropriate biological fluid): Baricitinib in plasma

Bioequivalence based on (90% CI): Baricitinib

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.