

Contains Nonbinding Recommendations
Draft Guidance on Tofacitinib Citrate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Tofacitinib citrate

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: Eq 5 mg base
Subjects: Healthy males and nonpregnant females, general population.
Additional comments: None.

2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: Eq 5 mg base
Subjects: Healthy males and nonpregnant females, general population.
Additional comments: Refer to the Draft Guidance on Amantadine Hydrochloride Tablet for additional information regarding fed studies.

Comments related to bioequivalence study conduct: 1) Study protocol should incorporate appropriate screening and monitoring of subjects as per applicable recommendations from the reference listed drug's label; 2) Prospective study participants should be tested and confirmed negative for latent tuberculosis before enrolling in a bioequivalence study; 3) Enrolled study participants should have normal liver function tests, blood counts, and lipid profiles at baseline prior to study drug administration.

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

Bioequivalence based on (90% CI): Tofacitinib

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 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).