Contains Nonbinding Recommendations

Draft Guidance on Gilteritinib Fumarate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, parallel, in vivo
   Strength: EQ 40 mg Base
   Subjects: Healthy males and females
   Additional comments: Exclude males with pregnant female sexual partners, females of reproductive potential, elderly, and subjects with risk factors for prolonged QTc interval and Torsades de Pointes. Subjects should be appropriately monitored for electrocardiogram changes during the study. Males with female partners of reproductive potential should use effective contraception during treatment and for at least 4 months after the last dose.

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2. Type of study: Fed
   Design: Single-dose, two-treatment, parallel, in vivo
   Strength: EQ 40 mg Base
   Subjects: Healthy males and females
   Additional comments: See comments above

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

Bioequivalence based on (90% CI): Gilteritinib

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 for each of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.