

Draft Guidance on Dolutegravir Sodium

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 50 mg Base
Subjects: Males and females, general population
Additional comments: Exclude females of reproductive potential due to the risk of embryo-fetal toxicity.

2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 50 mg Base
Subjects: Males and females, general population
Additional comments: See comments above

Analyte to measure: Dolutegravir in plasma

Bioequivalence based on (90% CI): Dolutegravir

Waiver request of in vivo testing: EQ 10 mg Base and Eq 25 mg Base, based on (i) acceptable bioequivalence studies on the EQ 50 mg Base strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths

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