Contains Nonbinding Recommendations

Draft Guidance on Dolutegravir Sodium; Lamivudine

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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; 300 mg
   Subjects: Males and females, general population
   Additional comment: Exclude females of reproductive potential due to the risk of embryo-fetal toxicity.

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2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 50 mg Base; 300 mg
   Subjects: Males and females, general population
   Additional comment: See comment above

Analytes to measure (in appropriate biological fluid): Dolutegravir and lamivudine in plasma

Bioequivalence based on (90% CI): Dolutegravir and lamivudine

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