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.

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.