Active ingredient: Abacavir Sulfate and Lamivudine

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in-vivo
   Strength: 600 mg/300 mg
   Subjects: Normal healthy males and females, general population.
   Additional Comments:

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in-vivo
   Strength: 600 mg/300 mg
   Subjects: Normal healthy males and females, general population.
   Additional comments:

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

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

Waiver request of in-vivo testing: Not Applicable

Dissolution test method and sampling times:

Please note that a Dissolution Methods Database is available to the public at the OGD website at http://www.fda.gov/cder/ogd/index.htm. Please find the dissolution information for this product at this website. Please 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 application.