Guidance on Emtricitabine

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Active Ingredient: Emtricitabine

Form/Route: Capsule/Oral

Recommended Studies: 2 Options: BCS or In-Vivo Studies

I. BCS Waiver option:

It may be possible to request a waiver of in-vivo testing for all the strengths of this product provided that the appropriate documentation regarding high solubility, high permeability and rapid dissolution as detailed in the Guidance for Industry: *Waiver of In-Vivo Bioavailability and Bioequivalence for Immediate – Release Solid Oral Dosage Forms Based on the Biopharmaceutics Classification System* is submitted in the application. You may use information contained in the approved labeling of the reference product. Peer reviewed articles may not contain the necessary details of the testing for the Agency to make a judgment regarding the quality of the studies. A decision regarding the acceptability of the waiver request can only be made upon review of the data submitted in the application.

II. In-Vivo option:

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: 200 mg
   Subjects: Healthy males and nonpregnant females, general population
   Additional Comments: Alternatively, BCS Class 1 Waiver Request

2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: 200 mg
   Subjects: Healthy males and nonpregnant females, general population
   Additional Comments: Please see comment above

Analytes to measure (in appropriate biological fluid): Emtricitabine in plasma
Bioequivalence based on (90% CI): Emtricitabine

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.accessdata.fda.gov/scripts/cder/dissolution/index.cfm. 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.