Contains Nonbinding Recommendations

Draft Guidance on Emtricitabine; Tenofovir Disoproxil Fumarate

Active ingredient: Emtricitabine; Tenofovir disoproxil fumarate

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: 200 mg/300 mg
   Subjects: Healthy males and non-pregnant, non-lactating females, general population
   Additional Comments: Truvada® (emtricitabine and tenofovir disoproxil fumarate) tablet was approved with a risk evaluation and mitigation strategy (REMS) that includes elements to assure safe use (ETASU). All pertinent elements of the REMS should be incorporated into the protocol and informed consent.

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2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in-vivo
   Strength: 200 mg/300 mg
   Subjects: Healthy males and non-pregnant, non-lactating females, general population
   Additional Comments: Same as above

Analytes to measure: Emtricitabine and Tenofovir in plasma.

Bioequivalence based on (90% CI): Emtricitabine and Tenofovir

Waiver request of in-vivo testing: 100 mg/150 mg, 133 mg/200 mg and 167 mg/250 mg based on (i) acceptable bioequivalence studies on the 200 mg/300 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

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