

Draft Guidance on Emtricitabine and Tenofovir Disoproxil Fumarate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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 Ingredient: Emtricitabine; Tenofovir disoproxil fumarate

Dosage Form; Route: Tablets; 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: Normal, healthy males and nonpregnant 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 must be incorporated into the protocol and informed consent.
2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: 200 mg/300 mg
Subjects: Healthy males and nonpregnant females, general population
Additional comments: Same as above

Analytes to measure (in appropriate biological fluid): Emtricitabine and tenofovir in plasma

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

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 Web site 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).