

Draft Guidance on Tenofovir Disoproxil Fumarate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Tenofovir Disoproxil Fumarate

Form/Route: Tablet/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover *in-vivo*
Strength: 300 mg
Subjects: Healthy males and nonpregnant females, general population.
Additional Comments: None

2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover *in-vivo*
Strength: 300 mg
Subjects: Healthy males and nonpregnant females, general population.
Additional Comments: None

Analytes to measure (in appropriate biological fluid): Tenofovir in serum

Bioequivalence based on (90% CI): Tenofovir

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

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/>. 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.