

Draft Guidance on Bictegravir Sodium; Emtricitabine; Tenofovir Alafenamide Fumarate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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 Ingredients: Bictegravir sodium; Emtricitabine; Tenofovir alafenamide 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: EQ 50 mg Base; 200 mg; EQ 25 mg Base
Subjects: Males and non-pregnant, non-lactating females, general population
Additional comments: None

2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 50 mg Base; 200 mg; EQ 25 mg Base
Subjects: Males and non-pregnant, non-lactating females, general population
Additional comments: None

Analytes to measure (in appropriate biological fluid): Bictegravir, emtricitabine, tenofovir alafenamide, and tenofovir in plasma

Bioequivalence based on (90% CI): Bictegravir, emtricitabine, and tenofovir alafenamide

Submit the metabolite (Tenofovir) data as supportive evidence of comparable therapeutic outcome. For the metabolite, the following data should be submitted: individual and mean concentrations, individual and mean pharmacokinetic parameters, and geometric means and ratios of means for AUC and C_{max} .

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).