*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

**Draft Guidance on Bictegravir Sodium; Emtricitabine; Tenofovir Alafenamide Fumarate**

**November 2024**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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.

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| **Active Ingredients:** | Bictegravir sodium; Emtricitabine; Tenofovir alafenamide fumarate |
| **Dosage Form:** | Tablet |
| **Route:** | Oral |
| **Strengths:** | EQ 30 mg Base; 120 mg; EQ 15 mg Base<br>EQ 50 mg Base; 200 mg; EQ 25 mg Base |
| **Recommended Study:** | One in vivo bioequivalence study with pharmacokinetic endpoints |

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: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

**Analytes to measure:** Bictegravir, emtricitabine, and tenofovir alafenamide in plasma

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

**Waiver request of in vivo testing:** EQ 30 mg Base; 120 mg; EQ 15 mg Base strength based on (i) an acceptable bioequivalence study on the EQ 50 mg Base; 200 mg; EQ 25 mg Base strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both strengths

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units for each of both strengths of the test product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

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**Document History:** Recommended May 2019; Revised November 2024

**Unique Agency Identifier:** PSG_210251

[1] If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*