Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Abacavir Sulfate; Dolutegravir Sodium; Lamivudine

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Active Ingredients: Abacavir sulfate; Dolutegravir sodium; Lamivudine

Dosage Form: Tablet, for suspension

Route: Oral

Strength: EQ 60 mg Base; EQ 5 mg Base; 30 mg

Recommended Studies: Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 60 mg Base; EQ 5 mg Base; 30 mg
   Subjects: Healthy males and healthy females not of reproductive potential
   Additional comments: None

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 60 mg Base; EQ 5 mg Base; 30 mg
   Subjects: Healthy males and healthy females not of reproductive potential
   Additional comments: None

Analytes to measure: Abacavir, dolutegravir, and lamivudine in plasma

Bioequivalence based on (90% CI): Abacavir, dolutegravir, and lamivudine

Waiver request of in vivo testing: Not applicable

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

Additional information:

Device:
The reference listed drug (RLD) is presented as tablets for oral suspension co-packaged with a dosing cup. The dosing cup is the device constituent part.

FDA recommends that prospective applicants examine the size and shape, the external critical design attributes, and the external operating principles of the RLD device when designing the test device including:

- Multi-use design
- Volume markings

User interface assessment:
An ANDA for this product should include complete comparative analyses so FDA can determine whether any differences in design for the user interface of the proposed generic product, as compared to the RLD, are acceptable and whether the product can be expected to have the same clinical effect and safety profile as the RLD when administered to patients under the conditions specified in the labeling. For additional information, refer to the most recent version of the FDA guidance for industry on *Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA*.[a]

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[a] For the most recent version of a guidance, check the FDA guidance website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.