

Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Abacavir Sulfate; Dolutegravir Sodium; Lamivudine

October 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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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:	Abacavir sulfate; Dolutegravir sodium; Lamivudine
Dosage Form:	Tablet, for suspension
Route:	Oral
Strength:	EQ 60 mg Base; EQ 5 mg Base; 30 mg
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 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 product and reference listed drug (RLD).¹ Specifications will be determined upon review of the abbreviated new drug application (ANDA).

Additional information:

Device:

The 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

Document History: Recommended February 2024; Revised October 2024

Unique Agency Identifier: PSG_215413

^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>.

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*.