Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Lenacapavir Sodium

May 2026

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form: Tablet

Route: Oral

Strength: EQ 300 mg Base

Reference Listed Drugs: NDA 215974; NDA 220020

Recommended Studies: Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. Class of study: Bioequivalence
   Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 300 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Safety recommendations:
   - Exclude subjects with abnormal liver function tests.

   Study design recommendations:
   - $AUC_{(0\text{-}72h)}$ may be used in place of $AUC_{(0\text{-}t)}$ for comparing the extent of absorption due to lenacapavir's long half-life. Ensure adequate washout periods between treatments in the crossover study.
   - Alternatively, a parallel study design may be considered.

2. Class of study: Bioequivalence
Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 300 mg Base
Subjects: Healthy males and non-pregnant, non-lactating females
Safety recommendations: See recommendations under Study #1.
Study design recommendations: See recommendations under Study #1.

Analyte to measure: Lenacapavir in plasma

Bioequivalence based on (90% CI): Lenacapavir

Waiver request of in vivo testing: An applicant may request a waiver of in vivo bioequivalence testing for an abbreviated new drug application (ANDA) referencing NDA 220020 or NDA 215974 by cross-referencing an approved ANDA for lenacapavir sodium tablets, EQ 300 mg Base that references the other NDA.

Waiver request of in vivo testing of additional strength: Not applicable

Dissolution: Dissolution test(s) should be included for quality control. Provide a dissolution method development report for the test product containing information and data that demonstrate appropriateness of the selected dissolution method[1] and sampling times, such as the discriminating ability to detect changes in critical quality attributes that could potentially impact drug product performance.

Document History: Recommended February 2024; Revised May 2026

[1] Applicant-developed, United States Pharmacopeia drug product monograph or Dissolution Methods database, https://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm