Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Letermovir

August 2026

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Active Ingredient: Letermovir

Dosage Form: Tablet

Route: Oral

Strengths: 240 mg | 480 mg

Reference Listed Drug: NDA 209939

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Class of study: Bioequivalence
   Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 480 mg
   Subjects: Healthy males not of reproductive potential (e.g., surgically sterile) and females not of reproductive potential

Analyte to measure: Letermovir in plasma

Bioequivalence based on (90% CI): Letermovir

Bioequivalence of additional strength: Waiver request of in vivo testing of additional strength based on (i) an acceptable bioequivalence study on the 480 mg strength, (ii) acceptable comparative in vitro dissolution studies between the additional strength and the 480 mg strength using 12 units per strength, and (iii) proportional similarity of the formulations between both strengths

Dissolution: Dissolution test(s) should be included for quality control and to support a waiver request of in vivo testing of an additional strength. For the quality control dissolution method, 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 November 2018; Revised October 2024, August 2026

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