Contains Nonbinding Recommendations

Draft Guidance on Letermovir

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Active Ingredient:	Letermovir
Dosage Form; Route:	Solution; IV (infusion)
Strength:	240mg/12mL (20mg/mL); 480 mg/24mL (20mg/mL)
Recommended Study:	Request for waiver of in vivo bioequivalence study requirements

I. Waiver:

To qualify for a waiver of the in vivo bioequivalence (BE) study requirement, a generic letermovir IV infusion solution product should be qualitatively (Q1)[1] and quantitatively (Q2)[2] the same as the Reference Listed Drug (RLD).

An applicant may seek approval of a drug product that differs from the RLD in preservative, buffer, or antioxidant if the applicant identifies and characterizes the differences and provides information demonstrating that the differences do not affect the safety or efficacy of the proposed drug product.[3]

[1] Q1 (Qualitative sameness) means that the test product uses the same inactive ingredient(s) as the reference product.
[2] Q2 (Quantitative sameness) means that concentrations of the inactive ingredient(s) used in the test product are within ±5% of those used in the reference product.
[3] 21 CFR 314.94(a)(9)(iii)