

**Draft Guidance on Letemovir**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Dosage Form; Route:** Tablet; oral

**Recommended Studies:** Two studies

1. Type of study: Fasting  
Design: Single-dose, two-treatment, two-period crossover in vivo  
Strength: 480 mg  
Subjects: Females of non-child bearing potential, general population  
Additional comments: Due to potential for impairment of male fertility and embryo-fetal toxicity, studies should not be conducted in males and females of child bearing potential.

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2. Type of study: Fed  
Design: Single-dose, two-treatment, two-period crossover in vivo  
Strength: 480 mg  
Subjects: Females of non-child bearing potential, general population  
Additional comments: See comments above.
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**Analytes to measure (in appropriate biological fluid):** Letemovir in plasma

**Bioequivalence based on (90% CI):** Letemovir

**Waiver request of in vivo testing:** 240 mg based on (i) acceptable bioequivalence studies on the 480 mg strength, (ii) proportional similarity of the formulations across both strengths, and (iii) acceptable in vitro dissolution testing of both strengths.

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).