This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Dosage Form; Route:** Tablet; Oral

**Recommended Studies:** Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. **Type of study:** Fasting  
   **Design:** Single-dose, two-treatment, two-period crossover in vivo  
   **Strength:** 100 mg  
   **Subjects:** Healthy males not of reproductive potential (i.e., surgically sterile) and females not of reproductive potential  
   **Additional comments:** Exclude subjects with abnormal liver function tests. Monitor liver function tests prior to dosing, one to two weeks post-dosing, and at end of study. Monitor subjects until resolution of adverse events. Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of cidofovir-diphosphate.

2. **Type of study:** Fed  
   **Design:** Single-dose, two-treatment, two-period crossover in vivo  
   **Strength:** 100 mg  
   **Subjects:** Healthy males not of reproductive potential (i.e., surgically sterile) and females not of reproductive potential  
   **Additional comments:** See comments above.

**Analyte to measure:** Brincidofovir in plasma

**Bioequivalence based on (90% CI):** Brincidofovir
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 each of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

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