This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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:** Sofosbuvir  
**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:** 400 mg  
   **Subjects:** Healthy males and nonpregnant females, general population  
   **Additional comments:** Sovaldi® is also recommended for use in combination with ribavirin or in combination with pegylated interferon and ribavirin. Subjects should follow Sovaldi® label to ensure adequate contraception.

2. **Type of study:** Fed  
   **Design:** Single-dose, two-treatment, two-period crossover in vivo  
   **Strength:** 400 mg  
   **Subjects:** Healthy males and nonpregnant females, general population  
   **Additional comments:** Same as above

**Analytes to measure (in appropriate biological fluid):** Sofosbuvir in plasma  
**Bioequivalence based on (90% CI):** Sofosbuvir  
**Waiver request of in vivo testing:** Not applicable  
**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/](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).