

Draft Guidance on Sofosbuvir

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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