Draft Guidance on Ombitasvir; Paritaprevir; Ritonavir; and Dasabuvir Sodium

This draft guidance, once finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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: I. Ombitasvir; paritaprevir; ritonavir, and II. Dasabuvir sodium

Dosage Form: Route: Co-packaged tablets; oral

Recommended Studies: Four in vivo studies

I. Ombitasvir; paritaprevir; ritonavir tablets

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 12.5 mg ombitasvir; 75 mg paritaprevir; 50 mg ritonavir
   Subjects: Healthy males and nonpregnant females, general population
   Additional comments: None

2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 12.5 mg ombitasvir; 75 mg paritaprevir; 50 mg ritonavir
   Subjects: Healthy males and nonpregnant females, general population
   Additional comments: None

II. Dasabuvir sodium tablets

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: EQ 250 mg dasabuvir
   Subjects: Healthy males and nonpregnant females, general population
   Additional comments: None

2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: EQ 250 mg dasabuvir
   Subjects: Healthy males and nonpregnant females, general population
   Additional comments: None

Recommended Sept 2015
Analytes to measure (in appropriate biological fluid): Ombitasvir; paritaprevir; ritonavir; and dasabuvir in plasma

Bioequivalence based on (90% CI): Ombitasvir; paritaprevir; ritonavir; and dasabuvir

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 the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).