

Draft Guidance on Ombitasvir; Paritaprevir; and Ritonavir

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: 12.5 mg ombitasvir; 75 mg paritaprevir; 50 mg ritonavir at a dose of 25 mg; 150 mg; 100 mg (2x12.5 mg; 75 mg; 50 mg)
Subjects: Healthy males and females (nonpregnant), general population
Additional comments: Female subjects should not be pregnant or lactating, and if applicable, should practice abstinence or contraception during the study.

2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: 12.5 mg ombitasvir; 75 mg paritaprevir; 50 mg ritonavir at a dose of 25 mg; 150 mg; 100 mg (2x12.5 mg; 75 mg; 50 mg)
Subjects: Healthy males and females (nonpregnant), general population
Additional comments: See comments above.

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

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

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 website 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).