Active ingredient: Boceprevir

Form/Route: Capsule; Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 200mg
   Subjects: Healthy males and non-pregnant females, general population
   Additional Comments:

2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 200 mg
   Subjects: Healthy males and non-pregnant females, general population
   Additional Comments:

Analytes to measure (in appropriate biological fluid): Boceprevir (the sum of two diastereomers SCH 534128 and SCH 534129) in plasma

Bioequivalence based on (90% CI): Boceprevir

Waiver request of in vivo testing: Not Applicable

Dissolution test method and sampling times:
Please note that a Dissolution Methods Database is available to the public at the OGD website at http://www.accessdata.fda.gov/scripts/cder/dissolution/. Please find the dissolution information for this product at this website. Please 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 application.

Recommended Jun 2012