Active ingredient: Tipranavir

Form/Route: Capsules/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in-vivo
   Strength: 250 mg (please administer a 500 mg dose; 2 X 250 mg)
   Subjects: Normal healthy males and females, general population.
   Additional Comments: Females must have a negative baseline pregnancy test within 24 hours prior to receiving the drug. Females should not be pregnant or lactating, and if applicable, should practice abstention or contraception during the study.

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in-vivo
   Strength: 250 mg (please administer a 500 mg dose; 2 X 250 mg)
   Subjects: Normal healthy males and females, general population.
   Additional comments: Please see comment above.

Analytes to measure (in appropriate biological fluid): Tipranavir in plasma

Bioequivalence based on (90% CI): Tipranavir

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.fda.gov/cder/ogd/index.htm. 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 Nov 2007