Active ingredient: Aliskiren Hemifumarate

Form/Route: Tablet/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover \textit{in-vivo}
   Strength: 300 mg
   Subjects: Healthy males and nonpregnant females, general population.

2. Type of study: Fed
   Design: single-dose, two-way crossover \textit{in-vivo}
   Strength: 300 mg
   Subjects: Normal healthy males and females, general population. Females should not be pregnant, and if applicable, should practice abstention or contraception during the study.

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

Bioequivalence based on (90\% CI): Aliskiren

Waiver request of \textit{in-vivo} testing: 150 mg based on (i) acceptable in vivo bioequivalence study/ies on the 300 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing on all strengths.

Dissolution test method and sampling times:

Please note that a \textbf{Dissolution Methods Database} is available to the public at the OGD website at \url{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.

\textit{Recommended Aug 2009}