Active ingredient: Enalapril Maleate

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting  
   Design: Single-dose, two-way, crossover *in-vivo*  
   Strength: 20 mg  
   Subjects: Normal healthy males and females, general population  
   Additional Comments: Females should not be pregnant, and if applicable, should practice abstention or contraception during the study.

2. Type of study: Fed  
   Design: Single-dose, two-way, crossover *in-vivo*  
   Strength: 20 mg  
   Subjects: Normal healthy males and females, general population  
   Additional comments: Please see comment above.

**Analytes to measure (in appropriate biological fluid):** Enalapril and active metabolite, enalaprilat in plasma.

Please submit the metabolite data as supportive evidence of comparable therapeutic outcome. For the metabolite, the following data should be submitted: individual and mean concentrations, individual and mean pharmacokinetic parameters, and geometric means and ratios of means for AUC and Cmax.

**Bioequivalence based on (90% CI):** Enalapril

**Waiver request of in-vivo testing:** 10 mg, 5 mg, and 2.5 mg based on (i) acceptable bioequivalence studies on the 20 mg strength, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity in the formulations across all strengths.

**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](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.

*Recommended Aug 2008*
of all strengths of the test and reference products. Specifications will be determined upon review of the application.