Active ingredients: Atovaquone; Proguanil

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two way crossover in-vivo
   Strength: 250 mg/100 mg
   Subjects: Normal healthy males and females, general population
   Additional comments: 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 way crossover in-vivo
   Strength: 250 mg/100 mg
   Subjects: Normal healthy males and females, general population
   Additional Comments: Please see comment above.

Analytes to measure (in appropriate biological fluid): Atovaquone and Proguanil in plasma

Bioequivalence based on (90% CI): Atovaquone and Proguanil

Waiver request of in-vivo testing: 62.5 mg/25 mg based on (i) acceptable bioequivalence studies on the 250/100 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of 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. 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 Jul 2008