Contains Nonbinding Recommendations

Draft Guidance on Quinine Sulfate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Quinine Sulfate

Form/Route: Capsules/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 324 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. Subjects with a QTc interval of >480 msec by ECG should also be excluded.

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2. Type of study: Fed
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 324 mg
   Subjects: Normal healthy males and females, general population.
   Additional comments: Please see comments above.

Analytes to measure (in appropriate biological fluid): Quinine in plasma.

Bioequivalence based on (90% CI): Quinine

Waiver request of *in-vivo* testing: Not Applicable

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.