Contains Nonbinding Recommendations

Draft Guidance on Tafenoquine Succinate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Tafenoquine succinate

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two- treatment, randomized, parallel in vivo
   Strength: EQ 150 mg Base
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: Due to the risk of hemolytic anemia, conduct a Glucose-6-Phosphate Dehydrogenase (G6PD) testing and exclude subjects with G6PD deficiency. Females of reproductive potential should practice abstinence or effective contraception during the study and three months after the study.

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2. Type of study: Fed
   Design: Single-dose, two- treatment, randomized, parallel in vivo
   Strength: EQ 150 mg Base
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: See comment above

Analyte to measure (in appropriate biological fluid): Tafenoquine in plasma

Bioequivalence based on (90% CI): Tafenoquine

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units for the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.