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Draft Guidance on Tafenoquine Succinate

October 2024

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Active Ingredient: Tafenoquine succinate

Dosage Form: Tablet

Route: Oral

Strength: EQ 150 mg Base

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fed
   Design: Single-dose, two-treatment, randomized, parallel in vivo
   Strength: EQ 150 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   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 use effective contraception during the study and for three months after the last dose.

Analyte to measure: 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 in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution. Conduct comparative dissolution testing on 12 dosage units for each of the test product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

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[1] If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions.*