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Draft Guidance on Omaveloxolone

May 2024

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Active Ingredient: Omaveloxolone

Dosage Form: Capsule

Route: Oral

Strength: 50 mg

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 50 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Female subjects of reproductive potential should use non-hormonal contraception during the study and continue to use effective contraception for 28 days after the last dose. Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of omaveloxolone. Alternatively, a parallel study design may be considered.

Analyte to measure: Omaveloxolone in plasma

Bioequivalence based on (90% CI): Omaveloxolone

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 each of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

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