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Draft Guidance on Olutasidenib

February 2024

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Active Ingredient: Olutasidenib

Dosage Form: Capsule

Route: Oral

Strength: 150 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: 150 mg
Subjects: Healthy males and healthy females not of reproductive potential
Additional comments: Exclude subjects with abnormal liver function tests and monitor liver function during the study. Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of olutasidenib. Alternatively, a parallel study design may be considered.

Analyte to measure: Olutasidenib in plasma

Bioequivalence based on (90% CI): Olutasidenib

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

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