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Draft Guidance on Sotagliflozin

August 2024

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Active Ingredient: Sotagliflozin

Dosage Form: Tablet

Route: Oral

Strengths: 200 mg, 400 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: 400 mg
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: Monitor blood glucose concentration and signs and symptoms of hypoglycemia during the study. Implement appropriate hypoglycemia management protocol.

Analyte to measure: Sotagliflozin in plasma

Bioequivalence based on (90% CI): Sotagliflozin

Waiver request of in vivo testing: 200 mg strength based on (i) acceptable bioequivalence study on the 400 mg strength, (ii) acceptable in vitro dissolution testing between two strengths, and (iii) proportional similarity of the formulations between two strengths

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

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