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Draft Guidance on Bexagliflozin

May 2024

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Active Ingredient:	Bexagliflozin
Dosage Form:	Tablet
Route:	Oral
Strength:	20 mg
Recommended Studies:	Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 20 mg
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: Monitor blood glucose levels and symptoms of hypoglycemia during the study.
2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 20 mg
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: See comment above.

Analyte to measure: Bexagliflozin in plasma

Bioequivalence based on (90% CI): Bexagliflozin

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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