

Draft Guidance on Canagliflozin

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Canagliflozin

Form/Route: Tablet/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single -dose, two-way crossover, in vivo
Strength: 300 mg tablet
Subjects: Healthy males and non-pregnant females, general population.
Additional Comments: 1) Females should practice abstention or contraception during the study. 2) To avoid hypoglycemic episodes in healthy volunteers, the drug products should be administered with 240 mL of a 20% glucose solution in water, followed by 60 mL of the glucose solution administered every 15 minutes for up to 4 hours after dosing.

2. Type of study: Fed
Design: Single -dose, two-way crossover, in vivo
Strength: 300 mg tablet
Subjects: Healthy males and non-pregnant females, general population.
Additional Comments: 1) Females should practice abstention or contraception during the study. 2) To avoid hypoglycemic episodes in healthy volunteers, the drug products may be administered with 240 mL of a 20% glucose solution in water, followed by 60 mL of the glucose solution administered every 15 minutes for up to 4 hours after dosing.

Analytes to measure (in appropriate biological fluid): Canagliflozin in plasma

Bioequivalence based on (90% CI): Canagliflozin

Waiver request of in vivo testing: 100 mg tablet strength based on (i) acceptable bioequivalence studies on the 300 mg tablet, (ii) acceptable in vitro dissolution testing of all strengths and (iii) proportional similarity of the formulations across all strengths.

Dissolution test method and sampling times:

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Please find the dissolution information for this product at this website. Please conduct comparative dissolution testing on 12

dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the application.