

## Draft Guidance on Dapagliflozin

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

**Active Ingredient:** Dapagliflozin

**Dosage Form; Route:** Tablet; oral

**Recommended Studies:** Two studies

1. Type of study: Fasting  
Design: Single-dose, two-treatment, two-period crossover in vivo  
Strength: 10 mg  
Subjects: Males and non-pregnant, non-lactating females, general population  
Additional comments: To avoid hypoglycemic episodes, 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.

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2. Type of study: Fed  
Design: Single-dose, two-treatment, two-period crossover in vivo  
Strength: 10 mg  
Subjects: Males and non-pregnant, non-lactating females, general population  
Additional comments: See comments above
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**Analyte to measure (in appropriate biological fluid):** Dapagliflozin in plasma

**Bioequivalence based on (90% CI):** Dapagliflozin

**Waiver request of in vivo testing:** The 5 mg strength based on (i) acceptable bioequivalence studies on the 10 mg strength, (ii) proportionally similar between both strengths, and (iii) acceptable in vitro dissolution testing of both strengths

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each strength of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.