

**Draft Guidance on Ertugliflozin; Sitagliptin Phosphate**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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:** Ertugliflozin; Sitagliptin phosphate

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

**Recommended studies:** Two studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover *in-vivo*  
Strength: 15 mg; EQ 100 mg Base  
Subjects: Healthy adult males and non-pregnant, non-lactating females.  
Additional Comments: None

2. Type of study: Fed  
Design: Single-dose, two-way crossover *in-vivo*  
Strength: 15 mg; EQ 100 mg Base  
Subjects: Healthy adult males and non-pregnant, non-lactating females.  
Additional comments: Same as above

**Analytes to measure (in appropriate biological fluid):** Ertugliflozin and sitagliptin in plasma

**Bioequivalence based on (90% CI):** Ertugliflozin and sitagliptin

**Waiver request of in-vivo testing:** 5 mg; EQ 100 mg Base based on (i) acceptable bioequivalence studies on the 15 mg; EQ 100 mg Base, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity in the formulations across all strengths.

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. 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 abbreviated new drug application (ANDA).