

## Draft Guidance on Ertugliflozin; Metformin Hydrochloride

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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; Metformin hydrochloride

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

**Recommended studies:** Two studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover *in-vivo*  
Strength: 7.5 mg; 1 GM  
Subjects: Healthy adult males and non-pregnant, non-lactating females.  
Additional Comments: 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-way crossover *in-vivo*  
Strength: 7.5 mg; 1 GM  
Subjects: Healthy adult males and non-pregnant, non-lactating females.  
Additional comments: Same as above

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

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

**Waiver request of in-vivo testing:** 2.5 mg; 500 mg, 2.5 mg; 1 GM, 7.5 mg; 500 mg based on (i) acceptable bioequivalence studies on the 7.5 mg; 1 GM strength, (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).