*Contains Nonbinding Recommendations*

**Draft Guidance on Hydrochlorothiazide and Telmisartan**

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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:** Hydrochlorothiazide and Telmisartan

**Form/Route:** Tablets/Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting
   Design: Single-dose, two way crossover *in-vivo*
   Strength: 25mg/80 mg
   Subjects: Normal healthy males and females, general population
   Additional comments: Females should not be pregnant or lactating, and if applicable, should practice abstention or contraception during the study.

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2. Type of Study: Fed
   Design: Single-dose, two way crossover *in-vivo*
   Strength: 25mg/80 mg
   Subjects: Normal healthy males and females, general population
   Additional Comments: Please see comment above.

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**Analytes to measure (in appropriate biological fluid):** Hydrochlorothiazide and Telmisartan in plasma

**Bioequivalence based on (90% CI)**: Hydrochlorothiazide and Telmisartan

**Waiver request of in-vivo testing:** 12.5 mg/40mg and 12.5 mg/80 mg based on (i) acceptable bioequivalence studies on the 25mg/ 80 mg strength, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity in 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.fda.gov/cder/ogd/index.htm. 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.