Draft Guidance on Hydrochlorothiazide; Moexipril Hydrochloride

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Active ingredient: Hydrochlorothiazide; Moexipril Hydrochloride

Form/Route: Tablet/Oral

Recommended studies: 1 study

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 25 mg/15 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments:

Analytes to measure (in appropriate biological fluid): Hydrochlorothiazide and Moexipril in plasma.

Bioequivalence based on (90% CI): Hydrochlorothiazide and Moexipril

Waiver request of in vivo testing: 12.5 mg/7.5 mg and 12.5 mg/15 mg based on (i) acceptable bioequivalence studies on the 25 mg/15 mg strength, (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.