Active Ingredient: Azilsartan kamedoxomil; chlorthalidone

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: Eq 40 mg medoxomil; 25 mg.
   Subjects: Healthy males and nonpregnant females, general population.
   Additional comments: For long half-life drugs like chlorthalidone, an AUC truncated at 72 hours may be used in place of AUC₀₋ₜ or AUC₀₋∞. Refer to the amantadine hydrochloride tablet draft guidance for additional information regarding long half-life drugs

   Females should not be pregnant, and, if applicable, should practice abstention or contraception during the study

2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: Eq 40 mg medoxomil; 25 mg
   Subjects: Healthy males and nonpregnant females, general population
   Additional comments: Refer to the amantadine hydrochloride tablet draft guidance for additional information regarding fed studies

Analytes to measure (in appropriate biological fluid): Azilsartan and chlorthalidone in plasma

Bioequivalence based on (90% CI): Azilsartan and chlorthalidone

Waiver request of in vivo testing: Eq 40 mg/12.5 mg, based on (i) acceptable bioequivalence studies on the Eq 40 medoxomil mg/25 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: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website available to the public at

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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).