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Draft Guidance on Azilsartan Kamedoxomil

October 2024

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Active Ingredient: Azilsartan kamedoxomil

Dosage Form: Tablet

Route: Oral

Strengths: EQ 40 mg medoxomil, EQ 80 mg medoxomil

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 80 mg medoxomil
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Female subjects of reproductive potential should practice abstention or contraception during the study.

Analyte to measure: Azilsartan in plasma

Bioequivalence based on (90% CI): Azilsartan

Waiver request of in vivo testing: EQ 40 mg medoxomil strength based on (i) acceptable bioequivalence study on the EQ 80 mg medoxomil strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both strengths

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution. Conduct comparative dissolution testing on 12 dosage units for each of both strengths of the test product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

If any strength of the tablet product has a functional score, additional dissolution profile testing should be conducted for each segment of the split tablet after manual and mechanical splitting as per the most recent version of the FDA guidance for industry on *Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation*.[a]

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[a] For the most recent version of a guidance, check the FDA guidance website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[1] If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions.*