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Draft Guidance on Candesartan Cilexetil

October 2024

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Active Ingredient: Candesartan cilexetil

Dosage Form: Tablet

Route: Oral

Strengths: 4 mg, 8 mg, 16 mg, 32 mg

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: 32 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Females of reproductive potential should use effective contraception during the study.

Analyte to measure: Candesartan in plasma

Bioequivalence based on (90% CI): Candesartan

Requests for waivers of in vivo testing: 4 mg, 8 mg, and 16 mg strengths based on (i) acceptable bioequivalence study on the 32 mg strength, (ii) an acceptable in vitro dissolution testing of all the strengths, and (iii) proportional similarity in the formulations of all 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 all strengths of the test product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

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[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*.