

Draft Guidance on Candesartan Cilexetil; Hydrochlorothiazide

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Active Ingredient: Candesartan Cilexetil; Hydrochlorothiazide

Form/Route: Tablets/Oral

Recommended Studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: 32 mg/25 mg
Subjects: Normal, healthy, males and females, general population
Additional comments: Female subjects should be excluded from the bioequivalence studies if they are pregnant.

2. Type of study: Fed
Design: Single-dose, two-way crossover *in-vivo*
Strength: 32 mg/25 mg
Subjects: Normal, healthy, males and females, general population
Additional comments: Female subjects should be excluded from the bioequivalence studies if they are pregnant.

Analytes to measure (in appropriate biological fluid): Candesartan and hydrochlorothiazide in plasma.

Bioequivalence based on (90% CI): Candesartan and hydrochlorothiazide

Requests of Waivers of in-vivo Testing: 16 mg/12.5 mg and 32 mg/12.5 mg based on (i) acceptable bioequivalence studies on the 32 mg/25 mg strength, (ii) formulation proportionality across all strengths, and (iii) acceptable in vitro dissolution testing of 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.