

Guidance on Hydrochlorothiazide; Irbesartan

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Active ingredient: Hydrochlorothiazide; Irbesartan

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: 25 mg/300 mg
Subjects: Normal healthy males and females, general population.
Additional Comments: Females should not be pregnant, and if applicable, should practice abstinence or contraception during the study.

2. Type of study: Fed
Design: Single-dose, two-way crossover *in-vivo*
Strength: 25 mg/300 mg
Subjects: Normal healthy males and females, general population.
Additional comments: Please see comment above.

Analytes to measure: Hydrochlorothiazide and irbesartan in plasma

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

Waiver request of in-vivo testing: 12.5mg/ 150 mg and 12.5 mg /300 mg based on (i) acceptable bioequivalence studies on the 25 mg/300 mg strength, (ii) proportionally similar 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.