Contains Nonbinding Recommendations

Draft Guidance on Indapamide

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Indapamide

Form/Route: Tablet/Oral

Recommended studies: 1 study

Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: 2.5 mg
Subjects: Normal healthy males and females, general population.

Analytes to measure (in appropriate biological fluid): Indapamide in whole blood

Bioequivalence based on (90% CI): Indapamide

Waiver request of *in-vivo* testing: 1.25 mg may be considered for a waiver of in vivo bioequivalence testing based on (i) acceptable bioequivalence studies on the 2.5 mcg strength, (ii) proportionally similar across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

Dissolution test method: Please note that **Dissolution Method** 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.