Contains Nonbinding Recommendations

Draft Guidance on Amiloride Hydrochloride

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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: Amiloride Hydrochloride

Form/Route: Tablet; Oral

Recommended studies: 2 Studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: EQ 5 mg Base
   Subjects: Healthy males, nonpregnant females and non-elderly, general population.
   Additional Comments: Subjects with impaired renal function, diabetes mellitus, should be excluded from the study. As amiloride treatment may cause hyperkalemia, serum potassium levels should be monitored carefully during the bioequivalence study.

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2. Type of study: Fed
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: EQ 5 mg Base
   Subjects: Healthy males, nonpregnant females and non-elderly, general population.
   Additional Comments: Please see above.

Analytes to measure (in appropriate biological fluid): Amiloride in plasma

Bioequivalence based on (90% CI): Amiloride

Waiver request of in-vivo testing: Not applicable

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.accessdata.fda.gov/scripts/cder/dissolution/. 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.