Contains Nonbinding Recommendations

Draft Guidance on Spironolactone

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Spironolactone

Dosage Form; Route: Suspension; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 25 mg/5 mL
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: None

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 25 mg/5 mL
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: None

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

Bioequivalence based on (90% CI): Spironolactone

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Note that a dosage unit for a suspension is the labeled strength (5 mL). Specifications will be determined upon review of the abbreviated new drug application (ANDA).