Contains Nonbinding Recommendations

Draft Guidance on Captopril

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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: Captopril

Dosage Form; Route: Tablet; oral

Recommended Studies: One study

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 100 mg
   Subjects: Healthy males and non-pregnant, non-lactating females, general population
   Additional comments: Captopril is excreted in human milk. Due to the potential risk for fetal harm, pregnant and lactating women should be excluded from the BE study.

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

Bioequivalence based on (90% CI): Captopril

Waiver request of in vivo testing: 12.5 mg, 25 mg and 50 mg strengths based on (i) acceptable bioequivalence study on the 100 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website 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. Specifications will be determined upon review of the abbreviated new drug application (ANDA).