Contains Nonbinding Recommendations

Draft Guidance on Penicillamine

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended studies: One study

Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: 250 mg
Subjects: Healthy males and non-pregnant, non-lactating females
Additional Comments: None

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

Bioequivalence based on (90% CI): Penicillamine

Waiver request of in-vivo testing: N/A

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).