Contains Nonbinding Recommendations

Draft Guidance on Calcium Acetate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Capsule; oral

Recommended Studies: One study

Type of study: In vitro phosphate binding

Design: The study should be conducted by incubating test (T) and reference (P) products with at least eight different phosphate concentrations for each product. The highest phosphate concentration should be selected to achieve complete phosphate precipitation (i.e., maximum phosphate binding) capacity and a meaningful phosphate binding profile. The mean phosphate binding profile for the test and reference products should be determined. The mean of the maximum phosphate binding for the test and reference products (T/R binding ratio) should be compared. The binding study should be replicated for 12 units each of the T and R products.

Strength: 667 mg (EQ 169 mg calcium)

Subjects: Not applicable

Additional comments: None

Analytes to measure: Free calcium and free phosphate in the supernatant should be measured using a validated analytical method.

Bioequivalence based on point estimate: T/R binding ratio within ± 10% (0.9 to 1.1)

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. Specifications will be determined upon review of the abbreviated new drug application (ANDA).

In addition to the method above, please conduct dissolution profiles on 12 dosage units each of the test and reference products using USP Apparatus II at 50 rpm in the following dissolution media: 0.1 N HCl, pH 4.5 Acetate Buffer and pH 6.8 Borate Buffer.