Contains Nonbinding Recommendations

Guidance on Risedronate Sodium; Calcium Carbonate

This guidance represents 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: Risedronate Sodium; Calcium Carbonate

Form/Route: Tablets/Oral (co-packaged)

Recommended studies: 1 study

Type of study: Fasting
Design: single-dose, two-way crossover *in-vivo*
Strength: 35 mg (risedronate sodium tablet)
Subjects: Normal healthy males and females, general population
Additional Comments: As an option, due to the relatively long half-life, the firm may wish to conduct this study using a parallel design. As an additional option for either the crossover or parallel design, the firm may wish to truncate the AUC at 72 hours.

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

Bioequivalence based on (90% CI): Risedronate

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.fda.gov/cder/ogd/index.htm. 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.
For calcium carbonate table please conduct comparative dissolution testing on 12 dosage units using the following USP method.