Contains Nonbinding Recommendations

Draft Guidance on Risedronate Sodium

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Delayed Release Tablet/Oral

Recommended studies: 1 study

Type of study: Fed
Design: Single-dose, two-way crossover in-vivo
Strength: 35 mg
Subjects: Healthy males and nonpregnant females, general population.
Additional Comments: Since the drug has a relatively long half-life, please refer to the Draft Individual Product Bioequivalence Recommendation Guidance for Amiodarone Hydrochloride Tablet for information on alternative study designs for long half-life drugs.

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.accessdata.fda.gov/scripts/cder/dissolution/. 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.