Contains Nonbinding Recommendations

Guidance on Ibandronate Sodium

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: Ibandronate Sodium

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, parallel design or two-way crossover *in-vivo*
   Strength: 2.5 mg
   Subjects: Normal healthy males and females, general population.
   Additional Comments: Please include as many postmenopausal women as possible in the studies.

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2. Type of study: Fasting
   Design: Single-dose, parallel design or two-way crossover *in-vivo*
   Strength: 150 mg
   Subjects: Normal healthy males and females, general population.
   Additional Comments: Please include as many postmenopausal women as possible in the studies.

Analytes to measure: Ibandronate in plasma

Bioequivalence based on (90% CI): Ibandronate

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.