Active Ingredient:  Alendronate Sodium
Form/Route:  Tablet/Oral
Recommended Studies:  1 study

Type of study: Fasting  
Design: Single-dose, two-way crossover in-vivo  
Strength: 70 mg  
Subjects: Healthy males and nonpregnant females, general population  
Additional Comments: (1) A highly selective assay for alendronate capable of at least low ng/mL lower limit of quantitation should be utilized. (2) Applicants may consider using a reference-scaled average bioequivalence approach for alendronate. If using this approach, please provide evidence of high variability in the bioequivalence parameters of AUC and/or Cmax (i.e., within-subject variability ≥ 30%). For details on the method for statistical analysis using the reference-scaled average bioequivalence approach, please refer to the Draft Guidance on Progesterone Oral Capsules at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM209294.pdf.

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

Bioequivalence based on (90% CI): Alendronate

Waiver request of in-vivo testing: 5 mg, 10 mg, 35 mg, and 40 mg based on (i) an acceptable bioequivalence study on the 70 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

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/index.cfm. 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.

Recommended Jan 2008, Revised Oct 2011