Active Ingredient: Alendronate sodium

Dosage Form; Route: Effervescent tablet; oral

Recommended Studies: In vitro dissolution or in vivo study

I. In vitro dissolution option

To demonstrate bioequivalence (BE) via the in vitro dissolution option, a generic alendronate sodium effervescent tablet should demonstrate that it is fully dissolved in water at the time of administration, per administration instructions provided in the approved drug label, and does not contain any excipients that may significantly affect drug absorption and systemic availability.

II. In vivo study option

Type of study: Fasting
Design: Single-dose, two-way in vivo
Strength: EQ 70 mg base
Subjects: Healthy males and nonpregnant females, general population
Additional comments: The BE study may be waived based on acceptable in vitro dissolution testing

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

Bioequivalence based on (90% CI): Alendronate

Waiver request of in vivo testing: See comments above

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