

## **Draft Guidance on Alendronate Sodium**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

**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).