

Guidance on Etidronate Disodium

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: Etidronate Disodium

Form/Route: Tablets/Oral

Recommended studies: 1 study

Type of study: Fasting

Design: Single-dose, two-way crossover *in-vivo*

Strength: 400 mg

Subjects: Normal healthy males and females, general population

Additional Comments:

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

Bioequivalence based on (90% CI): Etidronate

Waiver request of in-vivo testing: 200 mg based on (i) acceptable bioequivalence study on the 400 mg strength, (ii) proportionally similar across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

Dissolution test method and sampling times:

Please conduct comparative dissolution testing on 12 dosage units of all strengths of the test and reference products using the following USP method.