Guidance on Etidronate Disodium

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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.

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