Contains Nonbinding Recommendations

Draft Guidance on Lansoprazole

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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: Lansoprazole

Form/Route: Delayed Release, Orally Disintegrating Tablet/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way, crossover *in-vivo*
   Strength: 30 mg
   Subjects: Normal healthy males and females, general population
   Additional Comments: Available data indicate that this product may be highly variable in the bioequivalence parameters AUC and/or Cmax. You may consider conducting bioequivalence studies using a replicate design approach. These replicate design studies may be analyzed using the reference scaled approach. The reference-scaled approach adjusts the bioequivalence limits of highly variable drugs by scaling to the within-subject variability of the reference product in the study, and imposes a limit of 0.8 to 1.25 on the geometric mean ratio. The within-subject variability of the reference product is determined in a 3-way modified replicate-design study in which the reference product is given twice and the test product is given once. For general information on this approach, please refer to Haidar et al., Bioequivalence Approaches for Highly Variable Drugs and Drug Products, Pharm. Res. 25:237-241(2008).

---

2. Type of study: Fed
   Design: Single-dose, two-way, crossover *in-vivo*
   Strength: 30 mg
   Subjects: Normal healthy males and females, general population
   Additional comments: See comment above.

Analytes to measure: Lansoprazole in plasma

Bioequivalence based on (90% CI): Lansoprazole

Waiver request of in-vivo testing: 15 mg based on (i) acceptable bioequivalence studies on the 30 mg strength, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity in the formulations across 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.fda.gov/cder/ogd/index.htm. 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.