Contains Nonbinding Recommendations

Guidance on Omeprazole

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: Omeprazole

Form/Route: Powder for suspension/Oral

Recommended studies: 1 study

Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover *in-vivo*
Strength: 40 mg/packet
Subjects: Normal healthy males and females, general population
Additional Comments:

Analytes to measure: Omeprazole in plasma

Bioequivalence based on (90% CI): Omeprazole

Waiver request of in-vivo testing: 20 mg/packet based on (i) acceptable bioequivalence study on the 40 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of 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.