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: Delayed-release Capsule/Oral

Recommended studies: 4 studies

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

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2. Type of study: Fasting, Sprinkle
   Design: Single-dose, two-treatment, two-period crossover *in-vivo*
   Strength: 40 mg
   Subjects: Normal healthy males and females, general population
   Additional comments: Please administer the dose after sprinkling the entire contents of the capsule on a teaspoonful of applesauce in accordance with the approved labeling of the RLD.

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

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4. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover *in-vivo*
   Strength: 20 mg
   Subjects: Normal healthy males and females, general population
   Additional comments:

Analytes to measure (in appropriate biological fluid): Omeprazole in plasma.

Bioequivalence based on (90% CI): Omeprazole

Waiver request of in-vivo testing: 10 mg based on (i) acceptable bioequivalence studies on the 20 mg strength, (ii) proportional similarity of the formulations on 10 mg and 20 mg strengths, and (iii) acceptable in vitro dissolution testing of 10 mg and 20 mg 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.