Contains Nonbinding Recommendations

Draft Guidance on Omeprazole

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

---

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 spoonful of applesauce in accordance with the approved labeling of the RLD. If the label of a modified release RLD product states that the product can be administered sprinkled in soft foods, we recommend applicants conduct an additional BE study. For each treatment arm, test and RLD, the product should be sprinkled on one of the soft foods mentioned in the labeling of the RLD, normally applesauce. Aside from administration in the soft food, this additional study should follow the recommendations for the usual fasting BE study.

---

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:

---

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 note that a Dissolution Methods Database is available to the public at the OGD website at http://www.accessdata.fda.gov/scripts/cder/dissolution/. Please find the dissolution information for this product at this website. Please conduct comparative dissolution testing on 12 dosage units each of the test and reference products. Specifications will be determined upon review of the application.