

## Draft Guidance on Omeprazole, Sodium Bicarbonate and Magnesium Hydroxide

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

**Form/Route:** Chewable Tablets/Oral

**Recommended studies:** 1 study

Type of study: Fasting

Design: Single-dose, two way crossover *in-vivo*

Strength: 40 mg/600 mg/700 mg

Subjects: Normal healthy males and females, general population

Additional comments: Females should not be pregnant or lactating, and if applicable, should practice abstention or contraception during the study.

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

**Bioequivalence based on (90% CI):** Omeprazole

**Waiver request of in-vivo testing:** 20 mg/600 mg/700 mg based on (i) acceptable bioequivalence studies on the 40 mg/600 mg/700 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.