

## Draft Guidance on Omeprazole; Sodium Bicarbonate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

**Form/Route:** Capsule/Oral

**Recommended studies:** 1 study

Type of study: Fasting

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

Strength: 40 mg/1.1 gm

Subjects: Normal healthy males and females, general population

Additional Comments: Although sodium bicarbonate is important for the buffering capacity of the product, a comparative test [acid neutralizing capacity (ANC)] of the sodium bicarbonate is not considered necessary to assure equivalence of this component. The sodium bicarbonate is intended to raise gastric pH to protect omeprazole from acid degradation. A degradation problem would be detectable in the bioequivalence study for omeprazole.

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**Analytes to measure:** Omeprazole in plasma

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

**Waiver request of in-vivo testing:** 20 mg/1.1 gm based on (i) acceptable bioequivalence studies on the 40 mg/1.1 gm 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.