

Draft Guidance on Omeprazole Sodium Bicarbonate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Since Omeprazole Powder for Oral Suspension, 20 mg/packet and 40 mg/packet, are the subject of two separate New Drug Applications (NDA's), two separate Abbreviated New Drug Applications (ANDA's) must be submitted. You may request a waiver of *in vivo* bioequivalence testing of the 20 mg strength if you meet the criteria. In addition, please cross-reference the *in vivo* bioequivalence study conducted on the higher strength along with your waiver request. Please refer to the Guidance for Industry, *Variations in Drug Products that May Be Included in a Single ANDA* located at: <http://www.fda.gov/cder/guidance>.

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 all strengths of the test and reference products. Specifications will be determined upon review of the application.