Contains Nonbinding Recommendations

Draft Guidance on Omeprazole; Sodium Bicarbonate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Omeprazole; sodium bicarbonate

Dosage Form; Route: Powder for suspension; oral

Recommended Studies: One study

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 20 mg/packet; 1.68 gm/packet
   Subjects: Healthy males and nonpregnant 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 (BE) study for omeprazole.

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

Bioequivalence based on (90% CI): Omeprazole

Waiver request of in vivo testing: Since over-the-counter (OTC) omeprazole and sodium bicarbonate powder for oral suspension, 20 mg/packet and 1680 mg/packet, is identical to the Rx omeprazole and sodium bicarbonate powder for oral suspension, 20 mg/packet and 1680 mg/packet, a waiver of in vivo BE testing of OTC omeprazole and sodium bicarbonate powder for oral suspension, 20 mg/packet and 1680 mg/packet, may be eligible if the criteria set forth in 21 CFR §320.22(d) (2) are met. Cross-reference the in vivo BE study conducted on the higher strength of the Rx test product and Rx reference listed drug (RLD), omeprazole and sodium bicarbonate powder for oral suspension, 40 mg/packet and 1680 mg/packet, along with the waiver request. Two separate abbreviated new drug applications (ANDAs) must be submitted, since they reference two separate new drug applications (NDAs).

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods Web site available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution

testing on 12 dosage units each of the test and reference products. Specifications will be determined upon review of the ANDA.