Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Magnesium Hydroxide; Omeprazole; Sodium Bicarbonate

May 2026

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

Active Ingredients: Magnesium hydroxide; Omeprazole; Sodium bicarbonate

Dosage Form: Tablet, chewable

Route: Oral

Strengths: 700 mg; 20 mg; 600 mg | 700 mg; 40 mg; 600 mg

Reference Listed Drug: NDA 021850

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Class of study: Bioequivalence
   Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 700 mg; 40 mg; 600 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Study design recommendations:
   - The tablet should be chewed, then swallowed with water.

Analyte to measure: Omeprazole in plasma

Bioequivalence based on (90% CI): Omeprazole

Waiver request of in vivo testing of additional strength: Justification based on (i) an acceptable bioequivalence study on the 700 mg; 40 mg; 600 mg strength, (ii) acceptable comparative in vitro dissolution studies between additional strength and the 700 mg; 40 mg; 600 mg strength using 12 units per strength, and (iii) proportional similarity of the formulations between both strengths

Dissolution: Dissolution test(s) should be included for quality control and to support a waiver request of in vivo testing of additional strengths. For the quality control dissolution method, provide a dissolution method development report for the test product containing information and data that demonstrate appropriateness of the selected dissolution method[1] and sampling times, such as the discriminating ability to detect changes in critical quality attributes that could potentially impact drug product performance.

Document History: Recommended February 2008; Revised May 2026

[1] Applicant-developed, United States Pharmacopeia (USP) drug product monograph or Dissolution Methods database, https://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm