

Contains Nonbinding Recommendations

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Draft Guidance on Omeprazole; Sodium Bicarbonate

December 2025

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Active Ingredients: Omeprazole; Sodium bicarbonate

Dosage Form: For suspension

Route: Oral

Strengths: 20 mg; 1.68 gm/packet, 40 mg; 1.68 gm/packet

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 40 mg; 1.68 gm/packet
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: None

Analyte to measure: Omeprazole in plasma

Bioequivalence based on (90% CI): Omeprazole

Waiver request of in vivo testing: 20 mg; 1.68 gm/packet strength based on (i) an acceptable bioequivalence study on the 40 mg; 1.68 gm/packet strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both strengths

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each of both strengths of the test product and reference listed drug (RLD).¹ Specifications will be determined upon review of the abbreviated new drug application.

Product-specific testing conditions for in vitro enteral tube studies: The approved labeling for the RLD states that the product may be administered by a nasogastric (NG) or orogastric (OG) tube. Conduct the in vitro enteral tube studies listed below. For general procedures of in vitro enteral tube studies, refer to the FDA guidance *Oral Drug Products Administered Via Enteral Feeding Tube: In Vitro Testing and Labeling Recommendations*.^a

Testing tube: NG tube or OG tube (8 French)

Testing strength: 40 mg; 1.68 gm/packet

In vitro enteral tube testing:

1. Comparative recovery testing
 - Three types of tube configurations including different materials and/or different designs
 - Report pH value of the water
 - Holding times: 0 and 15 minutes
2. Sedimentation volume and redispersibility testing
3. In-use stability in designated dispersion media (i.e., water)
4. Particle size distribution study

Dispersion and rinse media: Add 20 mL of water to a catheter tipped syringe and then add contents of the packet. Shake the syringe to dissolve the powder. After administered through the NG or OG tube, refill the syringe with 20 mL of water. Shake and flush contents to rinse NG or OG tube.

Document History: Recommended May 2005; Revised July 2009, December 2025

Unique Agency Identifier: PSG_021636

^a For the most recent version of a guidance, check the FDA guidance website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

¹ If the RLD is not available, refer to the most recent version of the guidance for industry *Referencing Approved Drug Products in ANDA Submissions*.