Contains Nonbinding Recommendations

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Draft Guidance on Omeprazole; Sodium Bicarbonate

December 2025

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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Active Ingredients: Omeprazole; Sodium bicarbonate

Dosage Form: For suspension

Route: Oral

Strength: 2 mg/mL; 84 mg/mL

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: 2 mg/mL; 84 mg/mL at a dose of 40 mg; 1680 mg in 20 mL
   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: Not applicable

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 strength 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 most recent version of the FDA guidance for industry *Oral Drug Products Administered Via Enteral Feeding Tube: In Vitro Testing and Labeling Recommendations*.[a]

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

Testing strength: 2 mg/mL; 84 mg/mL at a dose of 40 mg; 1680 mg in 20 mL

In vitro enteral tube testing:

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

For enteral administration (i.e., feeding tube), shake the bottle well prior to dispensing 20 mL suspension with an enteral syringe. Refill the syringe with 20 mL of water and flush any remaining medication with water after enteral administration.

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[a] For the most recent version of a guidance, check the FDA guidance web page 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*.