

## Draft Guidance on Lansoprazole

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Dosage Form; Route:** Delayed Release Capsule; Oral

**Recommended Studies:** Three studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover in vivo  
Strength: 30 mg  
Subjects: Healthy males and nonpregnant females, general population.  
Additional Comments: Applicants may consider using a reference-scaled average bioequivalence approach for lansoprazole. If using this approach, the applicant should provide evidence, from the same bioequivalence study, of high variability in the bioequivalence parameters AUC and/or  $C_{max}$  (i.e., within-subject variability  $\geq 30\%$ ). Refer to the Progesterone Capsule Guidance for additional information regarding highly variable drugs.

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2. Type of study: Fed  
Design: Single-dose, two-way crossover in vivo  
Strength: 30 mg  
Subjects: Healthy males and nonpregnant females, general population.  
Additional Comments: See comment above. Refer to the Amantadine Hydrochloride Tablet Draft Guidance for additional information regarding fed studies.

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3. Type of study: Fasting sprinkle-in-applesauce  
Design: Single-dose, two-way crossover in vivo  
Strength: 30 mg  
Subjects: Healthy males and nonpregnant females, general population.  
Additional Comments: See comment above. Administer the dose after sprinkling the entire contents of the capsule on a teaspoonful of applesauce in accordance with the approved labeling of the RLD.

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**Analytes to measure (in appropriate biological fluid):** Lansoprazole in plasma

**Bioequivalence based on (90% CI):** Lansoprazole

**Waiver request of in vivo testing:** 15 mg based on (i) acceptable bioequivalence studies on the 30 mg strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both strengths. Please refer to the Mirtazapine Tablet Draft Guidance for additional information regarding waivers of in vivo testing.

**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 all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).

**Product-specific testing conditions for in vitro feeding tube studies:**

The approved labeling for the reference product states that the product may be administered by a nasogastric (NG) tube (16 French or greater). Conduct the in vitro feeding tube studies including comparative recovery testing with three repeated administrations, particle size distribution, comparative acid resistance stability testing, and sedimentation volume testing. For risk assessment, perform comparative recovery testing of the test products in a minimum of three brands of apple juice and justify the brands chosen for testing. Refer to the Lansoprazole Delayed-Release Orally Disintegrating Tablet Draft Guidance for additional information regarding procedures of in vitro feeding tube studies.

Testing tube: NG tube (16 French)

Testing strength: 30 mg

Dispersion medium: 40 mL apple juice

Testing conditions for acid resistance stability testing: 500 mL of 0.1 N HCl maintained at  $37 \pm 0.5^\circ\text{C}$ ; USP Apparatus II at 75 rpm. Analyze the amount of lansoprazole released at 60 minutes.