Contains Nonbinding Recommendations

Draft Guidance on Pantoprazole Sodium

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Delayed-release granules for oral suspension; oral

Recommended Studies: Three studies

1. Type of study: Fasting with apple juice
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 40 mg Base
   Subjects: Healthy males and non-pregnant females, general population
   Additional comments: The entire contents of the unit dose packet should be suspended in 5 mL of apple juice, not in water or other liquids. The granules should not be crushed or chewed.

---

2. Type of study: Fasting sprinkle over applesauce
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 40 mg Base
   Subjects: Healthy males and non-pregnant females, general population
   Additional comments: Please administer the dose after sprinkling the entire contents of the unit dose packet on a teaspoonful of applesauce in accordance with the approved labeling of the RLD. The granules should not be crushed or chewed.

---

3. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 40 mg Base
   Subjects: Healthy males and non-pregnant females, general population
   Additional comments: The entire contents of the unit dose packet should be suspended in 5 mL of apple juice, not in water or other liquids. The granules should not be crushed or chewed.

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

Bioequivalence based on (90% CI): Pantoprazole

Waiver request of in vivo testing: Not applicable

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 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) (16 French or larger) or gastric (G) tube. Conduct in vitro feeding tube studies including comparative recovery testing, particle size distribution study, comparative acid resistance stability testing, and sedimentation volume 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), G tube (16 French)

Testing strength: EQ 40 mg Base

Dispersion medium: 10 mL apple juice

Testing conditions for acid resistance stability testing**:** 750 mL of 0.1 N HCl maintained at 37 ± 0.5°C; USP Apparatus II at 100 rpm. Analyze the amount of pantoprazole released at 60, 90, and 120 minutes.