

Draft Guidance on Esomeprazole Magnesium

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Delayed release tablet; oral

Recommended Studies: One study

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: EQ 20 mg Base
Subjects: Healthy males and non-pregnant, non-lactating females, general population
Additional Comments: Applicants may consider using a reference-scaled average bioequivalence approach for alendronate. For the method of statistical analysis using the reference-scaled average bioequivalence approach, refer to the Progesterone Capsule Guidance.

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

Bioequivalence based on (90% CI): Esomeprazole

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