

Draft Guidance on Omeprazole

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Delayed release, orally disintegrating tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 20 mg
Subjects: Males and non-pregnant, non-lactating females, general population

Additional comments: The orally disintegrating tablet should be placed on the tongue and allowed to disintegrate without water.

-
2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 20 mg
Subjects: Males and non-pregnant, non-lactating females, general population

Additional comments: See comments above.

Analytes to measure (in appropriate biological fluid): 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 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).