

Contains Nonbinding Recommendations

Draft Guidance on Rabeprazole

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Rabeprazole Sodium

Form/Route: Delayed Release Tablet/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in-vivo
Strength: 20 mg
Subjects: Healthy males and nonpregnant females, general population.
Additional Comments: Applicants may consider using a reference-scaled average bioequivalence approach for this drug product. If using this approach, the applicant should provide evidence of high variability in the bioequivalence parameters AUC and/or C_{max} (i.e., within-subject variability $\geq 30\%$). For general information on this approach, please refer to Haidar et al., Bioequivalence Approaches for Highly Variable Drugs and Drug Products, Pharm. Res. 25:237-241(2008). For the statistical analysis method using the reference-scaled average bioequivalence approach, please refer to The Draft Individual Product Bioequivalence Recommendations Guidance on Progesterone Capsule (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM209294.pdf>).

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2. Type of study: Fed
Design: Single-dose, two-way crossover in-vivo
Strength: 20 mg
Subjects: Healthy males and nonpregnant females, general population.
Additional Comments: Please refer to the Amantadine Hydrochloride Tablet Draft Guidance for additional information regarding fed studies.

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

Bioequivalence based on (90% CI): Rabeprazole

Waiver request of in-vivo testing: Not applicable

Dissolution test method and sampling times:

Please note that a **Dissolution Method Database** is available to the public at the OGD website at <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Please find the dissolution information for this product at this website. Please 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 application.