

Draft Guidance on Amantadine Hydrochloride

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Capsule; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover
Strength: 100 mg
Subjects: Healthy males and nonpregnant females, general population
Additional comments: Since amantadine is known to be excreted in human milk, FDA recommends that the study exclude lactating women. In addition, due to the potential risk to the embryo or fetus, the study should exclude pregnant women, and other female study subjects should be counseled to practice abstinence or an appropriate form of contraception.

2. Type of study: Fed
Design: Single-dose, two-way crossover
Strength: 100 mg
Subjects: Healthy males and nonpregnant females, general population
Additional comments: Same as above

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

Bioequivalence based on (90% CI): Amantadine

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