

Draft Guidance on Ganciclovir

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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: Ganciclovir

Form/Route: Capsules/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: 500 mg
Subjects: Due to safety concerns with the use healthy subjects, the study population should be patients with advanced HIV+ infection, who are at risk for developing cytomegalovirus disease.
Additional Comments:

2. Type of study: Fed
Design: Single-dose, two-way crossover *in-vivo*
Strength: 500 mg
Subjects: There are safety concerns with using healthy subjects. Therefore, the study population should be patients with advance HIV+ infection who are at risk for developing cytomegalovirus disease.
Additional comments:

Analytes to measure: Ganciclovir in plasma.

Bioequivalence based on (90% CI): Ganciclovir

Waiver request of in-vivo testing: 250 mg based on (i) acceptable bioequivalence studies on the 500 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

Dissolution test method and sampling times:

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.fda.gov/cder/ogd/index.htm>. 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.