

Draft Guidance on Didanosine

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Tablet, For Suspension/Oral

Recommended studies: 1 study

Type of study: Fasting

Design: Single-dose, two-way crossover in-vivo

Strength: 2 x 200 mg (400 mg dose)

Subjects: Healthy males and nonpregnant females, general population.

Additional Comments:

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

Bioequivalence based on (90% CI): Didanosine

Waiver request of in-vivo testing: 100 mg and 150 mg strengths are eligible for a waiver of in-vivo bioequivalence testing based on (i) an acceptable bioequivalence study on the 200 mg strength, (ii) acceptable in-vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths. Please refer to the Mirtazapine Tablet Draft Guidance for additional information regarding waivers of in vivo testing.

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.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.