

Guidance on Didanosine

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Active ingredient: Didanosine

Form/Route: Delayed-Release Capsules Enteric-Coated Beadlets/Oral

Recommended studies: 1 study

Type of study: Fasting

Design: Single-dose, two-treatment, two-period crossover *in-vivo*

Strength: 400 mg

Subjects: Normal healthy males and females, general population

Additional Comments:

Analytes to measure (in appropriate biological fluid): Didanosine in plasma using an achiral method

Bioequivalence based on (90% CI): Didanosine

Waiver request of in-vivo testing: 125 mg, 200 mg, and 250 mg, based on (i) acceptable bioequivalence studies on the 400 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.