Active ingredient: Vorinostat

Form/Route: Capsules/Oral

Recommended studies: 2 studies

1. Type of study: Fasting  
   Design: Single-dose, two-way, crossover in-vivo  
   Strength: 100 mg  
   Additional Comments: Submission of an Investigational New Drug Application (IND) is required prior to the conduct of a bioequivalence study for a cytotoxic drug product (See 21 C.F.R § 320.31).

2. Type of study: Fed  
   Design: Single-dose, two-way, crossover in-vivo  
   Strength: 100 mg  
   Additional comments: Please see comment above.

Analytes to measure (in appropriate biological fluid): Vorinostat in serum

Bioequivalence based on (90% CI): Vorinostat

Waiver request of in-vivo testing: Not Applicable

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.

Recommended Aug 2008