Contains Nonbinding Recommendations

Draft Guidance on Vorinostat

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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: 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
   Subjects: Subjects with cutaneous T-cell lymphoma (CTCL) on stable regimens of vorinostat for the treatment of lymphoma.
   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).

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2. Type of study: Fed
   Design: Single-dose, two-way, crossover *in-vivo*
   Strength: 100 mg
   Subjects: Subjects with cutaneous T-cell lymphoma (CTCL) on stable regimens of vorinostat for the treatment of lymphoma.
   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.