Contains Nonbinding Recommendations

Guidance on Mercaptopurine

This guidance represents 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: Mercaptopurine

Form/Route: Tablet /Oral

Recommended studies: 1 study

Submission of an Investigational New Drug Application (IND) is required prior to the conduct of a bioequivalence study for a cytotoxic drug product such as Mercaptopurine (See 21 C.F.R § 320.31).

Type of study: Steady-state study in patients
Strength: 50 mg
Studies may be conducted at steady state in patients receiving therapeutic doses (usually 100 to 200 mg/day in the average adult) or maintenance daily doses (usually 50 to 100 mg/day in the average adult). Patients should be in a stable regimen using the same dosage unit (multiples of the same strength).
Additional Comments:

- Patients with inherited deficiency of the enzyme thiopurine methyl transferase must be excluded from these studies.
- The protocol may exclude concomitant chemotherapy and should exclude prior exposure to doxorubicin.
- The informed consent should include a description of the known genotoxicity of 6-mercaptopurine in human cells and animal models.

Analytes to measure (in appropriate biological fluid): Mercaptopurine in plasma.

Bioequivalence based on (90% CI): Mercaptopurine

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.