

## **Draft Guidance on Mitotane**

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

**Form/Route:** Tablets; Oral

**Recommended studies:** 1 study

1. Type of study: Steady-state  
Design: Parallel, in vivo  
Strength: 500 mg  
Subjects: Cancer patients who are already on an established dosing regimen of mitotane.  
Additional Comments: The study may use cancer patients on various dosing regimens of the reference listed drug. It would be acceptable to include patients who are stabilized on mitotane as part of their normal therapy. The parallel groups should be well-balanced with respect to patients' dosing regimen and study population demographics.

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**Special Considerations:** 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 mitotane (See 21 C.F.R § 320.31).

**Analytes to measure:** Mitotane in plasma.

**Bioequivalence based on (90% CI):** Mitotane

**Waiver request of in-vivo testing:** N/A

**Dissolution test method and sampling times:**

Please note that **Dissolution Methods Database** is available to the public at the OGD website at <http://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm> 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.