Tamoxifen

Standard Operating Procedure

Revision Date: 02/13/24

# This standard operating procedure (SOP) outlines the handling and use of Tamoxifen. In accordance with this document, laboratories should use appropriate controls, personal protective equipment, and disposal techniques when handling Tamoxifen. All laboratory workers must read and understand the [*Laboratory Emergencies SOP*](https://ehs.umich.edu/wp-content/uploads/2022/05/LaboratoryEmergencyProceduresSOP.docx) prior to commencing any work in a laboratory.

# Description [Provide additional information as it pertains to your research protocol]

Tamoxifen is classified as a hazardous drug according to the National Institute for Occupational Safety and Health (NIOSH). Tamoxifen is a triphenyl ethylene derivative with marked anti-estrogen properties, which binds to estrogen receptors and, as a result, has proven useful in the treatment of breast cancer (antineoplastic). Tamoxifen citrate has been used to stimulate ovulation in infertility.

Synonyms: Nolvadex, Istubal, Valodex

## Process [Write the steps for using the chemical in your research protocol]

# Potential Hazards [Provide additional information as it pertains to your research protocol]

* May cause cancer.
* May impair fertility and cause harm to the unborn child or breastfed babies.
* Accidental ingestion of the material may be harmful.
* May cause eye irritation.
* This product may be harmful if inhaled and cause respiratory tract irritation. Persons with impaired respiratory function, airway diseases, and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.
* The material is not thought to be a skin irritant (as classified using animal models). But may be harmful if absorbed through the skin and may cause skin irritation; systemic effects may result following absorption. Entry into the blood-stream through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

# Engineering Controls [Provide additional information as it pertains to your research protocol]

* Use chemical fume hood during weighing, preparation, reconstitution and dilution of this material.
* Syringes used for tamoxifen injection must be safety engineered (self-sheathing syringes, luer-lock syringes, etc.)
* Laboratories and other spaces where handling of tamoxifen occurs must be equipped with an eyewash station.

In animal containment housing:

* Discard needles in proper sharps container without recapping.
* Utilize restraint devices if possible.
* Administer hazards to animals in Biological Safety Cabinet.
* Before working in Containment Housing, staff must complete ULAM Hazard Containment Training Parts 1 & 2.

# Work Practice Controls [Provide additional information as it pertains to your research protocol]

* Avoid inhalation.
* Good hygiene practice requires that exposure be kept to a minimum and that suitable PPE and control measures be used in an occupational setting.
* Decontamination should consist of surface cleaning with water and detergent followed by thorough rinsing. The use of detergent is recommended because there is no single accepted method of chemical deactivation for all agents involved.
* A plastic backed absorbent pad should be placed under the work area during the process. This should be changed at the end of each procedure or when a spill occurs.

# Personal Protective Equipment [Provide additional information as it pertains to your research protocol]

PPE requirements in the lab include double gloves, lab coat, safety glasses or goggles, and closed-toe shoes. Gloves should be changed frequently and should be pulled up over sleeves if possible to reduce the likelihood of any exposed skin. Wash hands and arms immediately after working with the substance.

In animal containment housing PPE includes double gloves, waterproof gown, safety glasses, show covers.

# Transportation and Storage [Provide additional information as it pertains to your research protocol]

* Keep containers tightly closed and in dry, well-ventilated area.
* Keep away from light.
* Avoid strong oxidizing agents.
* Tamoxifen is regulated by DOT as a Hazardous Material as well as IATA for Transport of Dangerous Goods.
* Preparation of syringes and chemical containers must be done in the lab, labeled with chemical name (& concentration, if diluted) and hazard warnings at a minimum.
* Secondary containers must be used to transport hazards to the animal room.

# Waste Disposal [Provide additional information as it pertains to your research protocol]

All hazardous chemical waste should be placed in an appropriate container for disposal (pail or bottle). The container should be closed except when actively adding waste. The container must be located in the area where hazardous drugs are being used.

All items contaminated by hazardous drugs, including gloves, syringes, vials needles, animal bedding and solution containers should be disposed according to Environment, Health & Safety (EHS) guidelines and ULAM Guidelines.

* Sharps – place needles, syringes with needles attached and other breakable items into appropriately labeled sharps containers.
* Empty stock vials, reagent bottles, etc. – triple rinse with copious amounts of water. Deface label with black magic marker or scraper. Place in a cardboard box for disposal.

Because most spent, unused, and expired chemicals/materials are considered hazardous wastes, they must be properly disposed of. **Do not dispose of chemical wastes by dumping them down a sink, flushing in a toilet or discarding in regular trash containers, unless authorized by EHS Hazardous Materials Management (HMM)**. Contact EHS-HMM at (734) 763-4568 for waste containers, labels, manifests, waste collection and for any questions regarding proper waste disposal. Also, refer to the EHS [Hazardous Waste](http://ehs.umich.edu/haz-waste/) Web page for more information.

# Emergency Reporting

Report all emergencies, suspicious activity, injuries, spills, and fires to the University of Michigan Police (DPSS) by calling 911 or texting 377911. Register with the [University of Michigan Emergency Alert System](http://dpss.umich.edu/emergency-management/alert/) via Wolverine Access.

# Training of Personnel

All personnel are required to complete the ***General Laboratory Safety Training*** session (**BLS025w** *or equivalent*) via the [EHS My LINC](http://ehs.umich.edu/education/) Web page. Furthermore, all personnel shall read and fully adhere to this SOP when handling tamoxifen.

# Certification

I have read and understand the above SOP. I have received prior approval from my Lab Director to perform this procedure. I agree to contact my Lab Director if I plan to modify this procedure.

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### Major Revisions (Tracking purposes only -- Do not print as part of SOP)

03-23-2018 Put into EHS format, changed department name, and fixed links.
 Revised Spill Procedure section (AKJ).

04-09-18 Revised formatting (AKJ).

04-24-18 Changed injury type and action from paragraph to table format (AKJ).

05-17-23 Reviewed and updated (IWT).

02-13-24 Reviewed and updated (IWT)