



Tamoxifen

Principal Investigator (PI) Approval is Required Prior to Performing this Procedure

Description

This standard operating procedure outlines the handling and use of tamoxifen. Review this document and supply the information required in order to make it specific to your facility. In accordance with this document, laboratories should use appropriate controls, personal protective equipment, and disposal techniques when handling tamoxifen.

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

Potential Hazards

- 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

- Use a biological safety cabinet or chemical fume hood during reconstitution and dilution of this material.
- Syringes used for tamoxifen injection must be safety engineered (self-sheathing syringes, luer-lock syringes, etc.)
- Use with animals typically requires ABSL2 containment housing.
- Animals should be appropriately restrained and/or sedated prior to administering injections and other dosing methods.
- Laboratories and other spaces where handling of tamoxifen occurs must be equipped with an eyewash station.

Work Practice Controls

- 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 (PPE)

Appropriate lab attire including long pants and closed toe shoes must be worn. Personal protective equipment includes a lab coat or disposable coveralls, eye protection and two pairs of disposable nitrile gloves. 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.

Transportation and Storage

- 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.

Waste Disposal

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 EHS 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.*** Contact Environment, Health and Safety (EHS) at (810) 766-6763 for waste containers, labels, manifests, waste collection and for any questions regarding proper waste disposal. Also refer to UM-Flint Hazardous Waste Management Program and EHS webpage <http://www.umflint.edu/ehs/environment-health-and-safety> for more information.

Exposures/Unintended Contact



If the employee is in need of emergency medical attention, call 911 immediately.



SWALLOWED

- Rinse mouth with water.
- Consult a physician.

EYE

If this product comes in contact with the eyes:

- Wash out immediately with fresh running water for a minimum of 15 minutes.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- If pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN

If skin contact occurs:

- Immediately remove all contaminated clothing, including footwear.
- Flush skin and hair with running water (and soap if available) for a minimum of 15 minutes.
- Seek medical attention in event of irritation.

INHALED

- Move person from contaminated area into fresh air.
- Move person into fresh air.
- Seek medical attention.

Contact EHS for advice on symptoms of chemical exposure, or assistance in performing an exposure assessment.

Report all work related accidents, injuries, illnesses or exposures to UM-Flint DPS. Additionally, employees and supervisors must be sure to report the injury to EHS and complete and submit the [Illness and Injury Report Form](#) to WorkConnections within 24 hours. Follow the directions on the WorkConnections website [Forms Instructions](#) to obtain proper medical treatment and follow-up.

If you were involved in or observed an incident or near miss, please complete the [EHS Laboratory Incident and Near-Miss Report Form](#). This will be valuable in improving laboratory safety on UM-Flint campus.

TREATMENT FACILITIES:

<u>MAJOR INJURIES</u>	<u>MINOR INJURIES –During Business Hours</u>	<u>MINOR INJURIES –After Business Hours</u>
Genesys Hospital One Genesys Parkway Grand Blanc, MI 48439 (810) 606-5710 Hurley Medical Center One Hurley Plaza Flint, MI 48503 (810) 262-9000 McLaren Hospital Flint 401 South Ballenger Hwy Flint, MI 48532 (810) 342-2000	Genesys Occupational Health Network 1460 Center Rd. Burton, MI 48509 (810) 715-4620 Mon. to Fri. 7:30 am to 10 pm Sat. & Sun. Noon to 8 pm McLaren Flint-Burton OCC Center 1459 S. Center Rd. Burton, MI 48509 (810) 496-0900 Mon. - Fri. 8 am to 8 pm Sat & Sun 10 am to 2 pm	Downtown Flint 420 S. Saginaw St. Flint, MI 48502 (810) 762-1550 Genesys East 1096 S. Belsay Rd, Suite F Burton, MI 48509 (810) 743-3351 Genesys North 4154 W. Vienna Rd Clio, MI 48420 (810) 686-7397 Genesys South 8447 N. Holly Rd Grand Blanc, MI 48439 (810) 603-0856 Mon. - Fri. 6 to 10pm / Sat. & Sun. 1-10pm

Click [here](#) for more information on the UM – Flint Emergency Preparedness and Response Plan.

Spill Procedure

- When a spill occurs, **personal safety should always come first.**
- Alert and clear everyone in the immediate area where the spill occurred.

A **minor (small) chemical spill** is one of a known chemical that the laboratory staff is capable of handling safely without the assistance of safety and emergency personnel, i.e., (*less than 1 Gallon or 3.5 Liters*). A **major/large chemical spill** requires active assistance from emergency personnel.

Spill Response Steps:

MINOR CHEMICAL SPILL

- Alert people in immediate area of spill.
- Open outside windows, if possible.
- Use proper personal protective equipment (PPE) as indicated above.
- Avoid breathing vapors from spill.
- Confine spill to as small an area as possible.
- **Do not wash spill down the drain.**
- Use appropriate spill kits/sorbents to absorb spill. Collect contaminated materials and residues and place in container. For powdered chemicals sweep carefully to avoid generation of dust or, if appropriate, use moist sorbent pads or wet the powder with a suitable solvent and then wipe with a dry cloth. Contact EHS at (810) 766-6763 for proper disposal.
- Clean spill area with water.

MAJOR CHEMICAL SPILL

Report large chemical spills (*greater than 1 Gallon or 3.5 Liters*) in corridors or common areas, e.g., hallways, elevators, eating areas, rest rooms, offices, etc., to UM-Flint DPS at 911.

- Attend to injured or contaminated persons and remove them from exposure.
- Alert people in the laboratory to evacuate.
- **Call University of Michigan – Flint Public Safety Department (DPS) at 911 immediately for assistance.**
- Close doors to affected area.
- Post warnings to keep people from entering the area.
- Have person available that has knowledge of incident and laboratory to assist emergency personnel.

Additional Spill Links:

- www.oseh.umich.edu/pdf/chemspil.pdf
- <http://www.oseh.umich.edu/emer-chemical.shtml>

Report all emergencies, suspicious activity, injuries, spills, and fires to the UM-Flint Department of Public Safety (DPS) at 911 from any university telephone or (810) 762-3333 from cell phone or non-university telephone. Register with the [University of Michigan-Flint Emergency Alert System](#) via Wolverine Access. Also, preprogram the UM-Flint DPS telephone number (810) 762-3333 into your cell phone for quick, easy use.

Training of personnel

All personnel are required to complete Laboratory Safety Training. Documentation of the training is required. This training can be accomplished by completing the ***Comprehensive Laboratory Safety*** session (**BLS009** or equivalent) via [MyLINC](#), or UM-Flint EHS on-line training or other equivalent approved by EHS. Furthermore, all personnel shall read and fully adhere to this SOP when handling tamoxifen.

Certification

I have read and understand the above SOP. I agree to contact my Supervisor or Lab Manager if I plan to modify this procedure.

Name	Signature	UM ID #	Date

Principal Investigator _____

Revision Date _____