

Safe Operating Procedure of using Tamoxifen for Animal Research

NOTE: You must read this entire document and both you and the Principal Investigator must sign it before commencing any work.

Project Number (e.g. Tick@Lab): ____ { University SOP} _____

Principal Investigator/Supervisor: ____ { University SOP} _____

Room and Building where SOP is used: Wet labs, LAF labs _____

Summary of How the Material/Equipment/Process will be Used

Tamoxifen is a chemotherapy drug which is commonly used to treat breast cancer and is classified as a Group 1 known human carcinogen by WHO International Agency for Research on Cancer (IARC). It is also a known mutagen and teratogen which may impair fertility and cause harm to fetus.

In animal research, Tamoxifen is administered into animals to trigger tissue-specific gene expression. The use of Tamoxifen may involve the following processes:

- 1) Preparation of Tamoxifen solution
- 2) Transport of Tamoxifen from research lab to LAF for administration
- 3) Administration of Tamoxifen into animals
- 4) Housing and handling of Tamoxifen administered animals
- 5) Cage changing and washing of Tamoxifen contaminated cages
- 6) Disposal of Tamoxifen contaminated waste

Potential Hazards

Human Carcinogen, Mutagen and Teratogen Exposure (Process 1-6)

- Group 1 known human carcinogen (hazard statement H350)
- May damage fertility (hazard statement H360)
- Cause harm to unborn child (hazard statement H360)

Note: Pregnant women should not prepare or handle Tamoxifen or Tamoxifen contaminated materials

Sickness or Irritation due to Ingestion, Inhalation or Skin Contact (Process 1-6)

- Accidental ingestion may be harmful (hazard statement H280)
- May cause eye or skin or respiratory tract irritation (hazard statement H280)
- May cause harmful systemic effects if absorbed via bloodstream through open wounds (hazard statement P280)

Needle Stick Injury due to Injection (Process 3)

- May cause harmful systemic effects if absorbed via bloodstream (hazard statement P280)

Animal Bite (Process 3-5)

Environmental pollutant (Process 6)

- Very toxic to aquatic life with long lasting effects (hazard statement H410)
- Avoid release to environment (hazard statement P273)

Tamoxifen SDS weblink: <https://www.sigmaaldrich.com/HK/zh/product/sigma/t5648>

Safety Installations

Engineering Control Measures

- Certified fume hood (FH) for Tamoxifen preparation (e.g. open, weight, reconstitute and dilute)
- Certified Class II Biosafety cabinet (BSC) for injection, animal handling and cage changing
- Secondary container for transport
- Luer lock syringes for administration
- Animal restraint devices for administration (if applicable)
- Forceps for animal handling
- Animal cage changing station for cage changing
- Individually ventilated cage (IVC) and air handling unit for housing
- Cage liners for housing
- Cage washing machine for washing
- Tamoxifen waste bin for disposal of contaminated wastes
- Tamoxifen sharp box for disposal of contaminated syringes
- Eye wash station for emergency use
- Availability of Tamoxifen Safety Data Sheet (SDS) in handling areas

Work Practices

LAF Notification

- Inform LAF prior to using Tamoxifen in LAF for better arrangement

Medical Surveillance Program

- Enroll in medical surveillance program and indicate “toxic chemicals injected ”

Training

- Complete Tamoxifen specific safety training which provided by the PI
- Complete HSEO MC03 Chemical I, MC07 Chemical II, MC06 Biological Safety Training
- Complete general animal user training and animal handling training provided by LAF

SOP

- Establish and follow in-house SOPs for specific process (e.g. Tamoxifen administration, waste collection, cage washing, etc.)

Labelling and Warning Sign

- Complete LAF blue cage card “Health Hazard Card” with administration information and place in each tamoxifen administrated animal cage until post-administration of 72 hours.
- Affix a tamoxifen warning sign with hazard information on each of the tamoxifen administrated animal holding room
- Label all Tamoxifen tubes, containers, waste bin, waste bag with appropriate hazard warnings and chemical identification.
- Post a “Tamoxifen Hazard” sign on the FH and BSC which used for tamoxifen preparation and administration

Proper Storage

- Store Tamoxifen in a lockable secondary container, away from light and avoid strong oxidizing agents
- Use zipper bags and secondary containers during transport to avoid spillage

Good Hygiene Practice

- Minimize exposure by implementing control measures and wear adequate PPE
- Clean work surfaces with detergent and water, followed by sodium hypochlorite and rinse thoroughly.
- Wash hands immediately after handling Tamoxifen and Tamoxifen-contaminated waste

Specific Experimental Procedures

Preparation, Transportation and Administration of Tamoxifen (process 1-3)

- Purchase only the necessary quantity of Tamoxifen
- Wear adequate PPE when handling Tamoxifen
- Inspect the outer package of Tamoxifen to make sure it is intact
- Open, weigh and prepare Tamoxifen solution inside a certified FH
- A plastic-backed absorbent pad should be placed under the work surface during preparation and administration process to avoid contamination
- Place a waste bag on the work surface for collection of contaminated wastes
- Aliquot the Tamoxifen solution into leak-proof, screw cap tubes and place inside a secondary container labelled with chemical name and hazard warning labels. Store the container in a fridge.
- During transportation, Tamoxifen solution tubes must be stored in a zipper bag inside a secondary container (only bring the required amount to LAF)
- Conduct the administration inside a certified BSC
- Do not recap the syringes. Dispose of used syringes into Tamoxifen sharp box inside BSC
- Dispose of all contaminated wastes (e.g. tubes, tips, absorbent pad, syringes, etc.) into a waste bag inside FH/BSC and then discard into designated Tamoxifen chemical waste bin
- Clean work surfaces with detergent and water, followed by sodium hypochlorite and rinse thoroughly.

Housing and Handling of Tamoxifen-Administrated Animals (process 4)

- Complete LAF blue cage card “Health Hazard Card” with administration information and place in each tamoxifen administrated animal cage
- Conduct cage changes within a BSC or Cage Changing Station (CCS)
- Each Tamoxifen administrated animal should return to a cage with cage liner and “Health Hazard Card”, then house in designated animal holding room

Cage Changing and Washing of Tamoxifen-Contaminated Cages (process 5)

- After 72 hours (3 days) of last administration, the contaminated cage/water/feed can be changed inside a BSC or CCS
- Dispose all contaminated disposable waste into the cage liner inside BSC/CCS, and bag the cage liners into chemical waste bag (refer to waste disposal for more details)
- After disposing wastes, the “Health Hazard Card” can be removed and considered free of Tamoxifen
- Bag the non-disposable cage accessories’ (e.g. lid, cage base, wire bar, etc.) in a bag for LAF collection
- LAF staff collect the bagged cage accessories to cage washing area for normal washing process

Personal Protective Equipment

Skin Protection, Eye Protection, Face Protection and Respiratory Protection

- Wear double layer of gloves. One glove should be placed under the coat / coveralls and one over.
- Lab coat or coveralls
- Sleeve covers if wrist is exposed
- Safety glasses or chemical goggles or face shield
- N95 mask or PAPR if work is not conducted in BSC or fume hood

Waste Disposal

Tamoxifen-Contaminated Waste Disposal (Process 6)

- Discard all contaminated wastes during preparation and administration into waste bags.

Double bags all wastes.

- Tie up the waste bags and place in designated Tamoxifen chemical waste bin for HSEO collection
- The waste bin should be kept closed at all times
- For contaminated sharps waste box, place the sharp box in designated Tamoxifen chemical waste bin for HSEO collection
- For Tamoxifen-administrated animal carcasses, **double bags** before placing in clinical waste fridge for contractor collection

Bedding and Cage Liner Disposal (Process 6)

- Place the bedding and cage liners in a chemical waste bag, and tie up the bag
- Place the waste bag in designated Tamoxifen chemical waste bin for HSEO collection

Spills and Incidents

Minor Spill of Tamoxifen

- Absorb the spill with absorbent pad or paper towel with adequate PPE
- Cover, clean work surfaces with detergent and water, followed by sodium hypochlorite and rinse thoroughly.
- Collect the wastes in a plastic bag and dispose in a Tamoxifen contaminated waste bin

Major Spill of Tamoxifen

- Avoid inhalation and generating dust
- Remove contaminated clothing with gloved hands, remove gloves and place near the spill
- Evacuate other workers within the laboratory and activate emergency ventilation (EV) system
- Call CCS Ext 8999 for assistance and do not allow anyone to enter the affected area
- HSEO will be notified by CCS to clean up the spill

Bites by Animals Treated with Tamoxifen

- Wash bite area with running water for 15 minutes
- Seek medical attention. Bring SDS to the clinic / doctor.

Emergency Procedures

Exposure

- If Tamoxifen comes into contact with the eye, face and skin, wash the area with running water for 15 mins using the nearest emergency facilities and seek medical advice immediately.
- Notify HSEO of any exposure.

Emergency Response

- Notify the Security Control Center by dialing ext. 8999 and provide information on the incident, including the chemical involved, the location, and any injuries.

References

- Tamoxifen Safety Data Sheet (SDS). Sigma-Aldrich. Retrieved February 20, 2025 from <https://www.sigmaaldrich.com/HK/en/sds/sigma/t5648>
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- National Center for Biotechnology Information (2025). PubChem Annotation Record for TAMOXIFEN, Source: Hazardous Substances Data Bank (HSDB). Retrieved February 20, 2025 from <https://pubchem.ncbi.nlm.nih.gov>.
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