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 administrated 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 administrated 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 Azoxymethane
•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 Security Control Center Ext 8999 for assistance and do not allow anyone to enter the affected area
- HSEO will be notified by Security Control Center 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
- National Center for Biotechnology Information (2025). PubChem Compound Summary for CID 2733526, Tamoxifen. Retrieved February 20, 2025 from https://pubchem.ncbi.nlm.nih.gov/compound/tamoxifen

Prepared by: ___ _____ Date: _____

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