

BACKGROUND

Hazardous drugs are drugs that pose a potential health risk to workers who may be exposed to them during receipt, transport, preparation, administration, or disposal. These drugs require special handling because of their potential to cause toxicity.

At Children's and Women's Hospitals hazardous drugs are further classified in the following categories:

- Hazardous Drug – **HIGH** – includes injectable antineoplastic and carcinogenic drugs
- Hazardous Drug – **MEDIUM** – includes oral and topical antineoplastic and carcinogenic drugs
- Hazardous Drug – **LOW** – includes other than antineoplastic and carcinogenic agents

For a complete listing of hazardous drugs, see **Hazardous Drugs List**.

There are 2 levels of precautions when handling hazardous drugs:

- **Cytotoxic precautions** are used when handling hazardous drugs – high and medium categories
- **Hazardous precautions** are used when handling hazardous drugs – low category

PURPOSE

The purpose of this policy is to outline safe handling precautions and standard processes for health care providers (HCPs), to minimize exposure when handling hazardous drugs and blood and body fluids contaminated with hazardous drugs.

POLICY STATEMENTS

- 1.1 Pharmacy Services will maintain a comprehensive list of drugs considered to be hazardous. See Hazardous Drugs List.
- 1.2 HCPs handling hazardous drugs will receive appropriate training, including spill management procedures.
- 1.3 HCPs will adhere to safe handling precautions, when handling hazardous drugs and when handling body waste contaminated with hazardous drugs (within the 48 hour precautionary period), as outlined in Appendix B: "Hazardous Drug Handling Precautions – Health Care Providers".
 - Note that the handling precautions are specific to the C&W Hazard Categories (high/medium or low).
- 1.4 Eating, drinking, application of cosmetics and storage of food/drink are prohibited in any area where hazardous drugs are stored, prepared, or handled.
- 1.5 Hazardous drugs will be provided by Pharmacy Services in a ready to use format, where applicable, so that further manipulation at the patient care unit is minimized.
 - 1.5.1 Pharmacy Services will prepare parenteral hazardous drugs in the high category, including reconstituting medication, diluting medication to the proper concentration, drawing medication up into a syringe and adding medication to infusion solution.
 - 1.5.2 Pharmacy Services will provide oral tablets and capsules in unit dose packages, including partial tablets, so that splitting tablets on the patient care unit is not required.
 - 1.5.3 Pharmacy Services will provide oral doses in liquid format whenever possible, so that crushing tablets and opening capsules on the patient care unit is avoided.
- 1.6 Pharmacy Services will include standard warnings as indicated below on all medication labels, Medication Administration Record (MAR) entries, and medication containers to alert HCPs.

- 1.6.1 Pharmacy Services will include standard warnings on all MAR entries and patient medication labels, where indicated, to alert HCPs.
High and Medium: *Cytotoxic Precautions*
Low: *Hazardous Precautions*
- 1.6.2 Pharmacy Services will affix standard auxiliary labels on outer packaging (e.g. zip lock bags), medication containers, and storage bins (including wardstock) where indicated, to alert HCPs:
 - High: universal "Cytotoxic" auxiliary label
 - Medium: universal "Cytotoxic" auxiliary label
 - Low: yellow "Hazardous Drug" auxiliary label
- 1.6.3 HCPs will adhere to safe handling precautions, when handling hazardous drugs and when handling body waste contaminated with hazardous drugs for patients identified as having taken hazardous drugs in the 48 hours prior to presenting to C&W.
- 1.7 HCPs who regularly handle hazardous drugs (high/medium category) have the option to request protective reassignment to another unit after consultation with the Program Manager or supervisor if they are pregnant, breastfeeding, or intending to conceive.
- 1.8 HCPs who administer hazardous drugs - high category via the parenteral route will document each drug administered (handled) on a record entitled "Handling Record – Hazardous Drugs" indicating drug name, date the drug was administered, and number of times the drug was administered on the indicated date.
 - 1.8.1 Handling Records will be maintained on the unit for the duration of the employee's employment plus 10 years.
- 1.9 Spills of hazardous drugs (high/medium category) or body fluids containing hazardous drugs (high/medium category) will be cleaned up immediately by nursing staff trained in safe handling of hazardous drugs, following procedures as outlined in the Workplace Health "Cytotoxic – Spill Cleanup Procedure – Prepared medication or body fluids" and "Cytotoxic – Spill Cleanup – undiluted Medication".
 - 1.9.1 Hazardous Drug Spill Kits will be readily available in areas where a spill may occur.
- 1.10 Acute exposure (e.g. skin puncture, splash to eye/nose/mouth/skin) to hazardous drugs (high/medium category) or blood and body fluid contaminated with hazardous drugs (high/medium category) will be reported immediately to the supervisor.
 - 1.10.1 If injury or adverse effects occur upon exposure, HCPs will seek a medical assessment at the nearest adult emergency department within 2 hours of exposure.
 - 1.10.2 All acute exposures to hazardous drugs (high/medium category) or blood and body fluid contaminated with hazardous drugs (high/medium category) will be reported to the Workplace Health Call Centre, where the details of the injury/exposure are documented.
 - 1.10.3 Exposure to hazardous drugs (low category) that results in injury or adverse effects will be reported to the Workplace Health Call Centre.

SITE APPLICABILITY

The special requirements by Pharmacy Services relating to distributing and labeling hazardous drugs apply to medications dispensed to inpatients and outpatients at BC Children's Hospital and BC Women's Hospital.

These safe handling precautions are applicable to all areas within BC Children's Hospital and BC Women's Hospital where hazardous drugs are handled.

PRACTICE LEVEL/COMPETENCIES

Safe Handling procedures are a foundational competency for HCPs who may handle these drugs.

Hazardous drug spill clean-up procedures are done by registered nurses who have received additional education and training on spill clean-up procedures.

DEFINITIONS

Also see Appendix A: Hazardous Drugs – Definitions

Hazardous drugs: Pharmacologic compounds that are detrimental or destructive to cells within the body, human or animal. Hazardous drugs include antineoplastics, antiviral drugs, hormones, some bioengineered drugs, and other miscellaneous drugs.

Antineoplastic: A chemotherapeutic agent that controls or kills cancer cells

Carcinogenic: Drugs that can cause cells to become cancerous

Cytotoxic: A pharmacologic compound that is detrimental or destructive to cells within the body

Approved Nitrile Gloves: Gloves that have been chemotherapy drug resistant tested and results provided to and reviewed by Workplace Health.

HAZARDOUS DRUG CRITERIA

Hazardous drugs exhibit one or more of the following characteristics in humans or animals:

1. Carcinogenicity
2. Teratogenicity or other developmental toxicity
3. Reproductive toxicity
4. Organ toxicity at low doses
5. Genotoxicity
6. Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria

Adapted from:

National Institute for Occupational Safety and Health (NIOSH) – NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2010

B.C. Cancer Agency (BCCA) Pharmacy Directive – Hazardous Drug List, May 2011

PROCEDURE

Personal Protective Equipment

2.1 **WEAR** personal protective equipment, appropriate to hazardous drug category, as indicated in Appendix B:

2.1.1 High and Medium Category:

- **Eye / Facial Protection:** If risk of splash, ensure eye/facial protection by wearing, fluid resistant mask, goggles, protective glasses with side shields, or transparent full faceshield.
- **Gloves:** wear 2 pairs of approved nitrile gloves*; change both pairs of gloves every 30 minutes or if visibly damaged. Wash hands thoroughly after removing personal protective equipment.
- **Gowns:** If risk of splash, wear fluid resistant gowns with closed front, long sleeves, and elasticized cuffs.
- **Respiratory Protection:** Use N95 respirators (to which you have been fit-tested within the past year) if cleaning up a spill.

2.1.2 Low Category:

- **Gloves:** wear 1 pair of approved nitrile gloves; change gloves every 30 minutes or if visibly damaged. Wash hands thoroughly after removing personal protective equipment.
- **Additional Protection:** If crushing tablets or manipulating capsules, wear 2 pairs of gloves, protective gown and N95 respirator (to which you have been fit-tested within the past year) as described in Appendix C.

*Approved nitrile gloves are defined in Definition section.

Medication Administration

2.2 **PRIME** the IV line with infusion solution that does not contain hazardous drug OR use a back-flow closed system.

2.3 **WHENEVER POSSIBLE, DO NOT CRUSH OR SPLIT** oral tablets, or open oral capsules on the patient care unit

- 2.3.1 These functions are performed by Pharmacy staff using appropriate handling precautions in a Class II Biological Safety Cabinet
- 2.3.2 If manipulation of tablets or capsules cannot be avoided, follow recommendations described in Appendix C

Cytotoxic Precautions Labels and Signage

2.4 For patients receiving hazardous drugs (high/medium category), **APPLY** the “**Cytotoxic Precautions Required – Chart Label**” on the cover of the patient’s health record, upon administration of the medication and for 48 hours following the last administered dose.

Cytotoxic Precautions Required Start Date: _____ Time: _____ Finish Date: _____ Time: _____ Patient: _____

2.4.1 For intravenous infusions place a chemotherapy sticker on the IV tubing.

- 2.5 For patients receiving hazardous drugs (high/medium category), **POST** a sign “**Cytotoxic Precautions Required – Signage for Patient Room/Area**” in the patient area (e.g. on the door to patient’s room), during administration of the medication and for 48 hours following the last administered dose.

Patient Education

- 2.6 **INFORM** the patient that they are receiving a hazardous drug (high/medium category) and that cytotoxic precautions will be practiced during administration of the medication and for 48 hours following the last administered dose
- 2.6.1 **REFER** to BCCH Patient/Family Information pamphlet: “Chemotherapy: Safety at home” or the BC Cancer Agency Patient Information Handout “Safe Disposal of Waste at Home After Chemotherapy”.

Handling Records

- 2.7 **DOCUMENT** administration of hazardous drugs – high category (via parenteral route) on a record entitled “**Handling Record – Hazardous Drugs**” indicating drug name, date the drug was administered, and number of times the drug was administered on the indicated date
- 2.7.1 At year end, forward all Handling Records for that year to your unit leader.

Disposal of Drugs and Disposable Equipment

- 2.8 Where indicated in Appendix B, (high/medium categories) **DISPOSE** drugs and disposable equipment in a cytotoxic waste container.

Handling Body Waste

- 2.9 Where indicated in Appendix B (high/medium categories), during the 48 hour precautionary period, **DISPOSE** body wastes including urine, stool, emesis, and blood via macerator, toilet, or hopper.
- 2.9.1 When disposing via toilet, cover the toilet opening with a disposable pad, double flush the toilet, and place the disposable pad in a cytotoxic waste container.
- 2.10 **DISPOSE** contaminated diapers in a cytotoxic waste container.

Cleaning Re-usable Equipment

- 2.11 Where indicated in Appendix B (high/medium categories):
- 2.11.1 **RINSE** contaminated items (e.g. bedpans, urinals, commodes) using the lowest water pressure possible (to minimize the risk of splash) and return to Sterile Processing Department in a leak-proof container every 24 hours.
- OR**
- 2.11.2 **STERILIZE** via established procedures when using a bedpan washer/disinfector on the Nursing Unit

Handling Laundry

- 2.12 Where indicated in Appendix B (high/medium categories), **DISCARD** linens that are heavily soaked or contaminated with blood or body fluid in a cytotoxic waste container.

Handling Spills

- 2.13 Where indicated in Appendix B (high/medium categories), trained nursing staff **CLEAN** spills immediately using Cytotoxic Spill Kits and following procedures as outlined in the Workplace Health “Cytotoxic – Spill Cleanup Procedure – Prepared medication or body fluids” and “Cytotoxic – Spill Cleanup – undiluted Medication”.

Exposure to Hazardous Drugs

- 2.14 **REPORT** acute exposures to hazardous drugs (high/medium category) and to blood and body fluids contaminated with hazardous drugs (high/medium category) immediately to supervisor:
- 2.13.1 Acute exposures include skin puncture, splash to eye/nose/mouth/skin
- 2.15 **TREAT** appropriately as soon as possible:
- 2.14.1 Flush the eye for 15 minutes with tepid water or normal saline
 - 2.14.2 Wash the affected areas with soap and water for 15 minutes
 - 2.14.3 Allow puncture wounds to bleed freely
- 2.16 **SEEK** a medical assessment at the nearest emergency department within 2 hours of exposure:
- 2.16.1 For all exposures to hazardous drugs via skin puncture with patient contaminated sharps (e.g. needle, scalpel, or other sharp instrument)
 - 2.16.2 For all exposures to hazardous drugs via contaminated blood or body fluids to non-intact skin, eyes, nose, or mouth
 - 2.16.3 For all other exposures to hazardous drugs if exposure causes injury or adverse effects
- 2.17 **REPORT** all exposures to hazardous drugs (high/medium category) and to blood and body fluids contaminated with hazardous drugs (high/medium category) by contacting the Workplace Health Call Centre (1 866 922 9464)
- 2.17.1 Leave a voice message after hours
- 2.18 **REPORT** exposures to hazardous drugs (low category) that result in injury or adverse effects to the Workplace Health Call Centre (1 866 922 9464)
- 2.18.1 Leave a voice message after hours

REFERENCES

- ASHP Guidelines on Handling Hazardous Drugs, January 2006
- BC Cancer Agency, Pharmacy Practice Standards for Hazardous Drugs, May 2014
- Fraser Health – Handling Precautions – Nursing Staff, April 2012
- International Agency for Research on Cancer (IARC) Monographs on Evaluation of Carcinogenic Risks to Humans, June 2015
- NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2014, National Institute for Occupational Safety and Health
- OSHA Technical Manual, Section VI, Chapter 2 – Controlling Occupational Exposure to Hazardous Drugs
- WorkSafe BC Occupational Health and Safety Regulations, sections 6.42 – 6.58.

APPENDIX A

HAZARDOUS DRUGS – DEFINITION

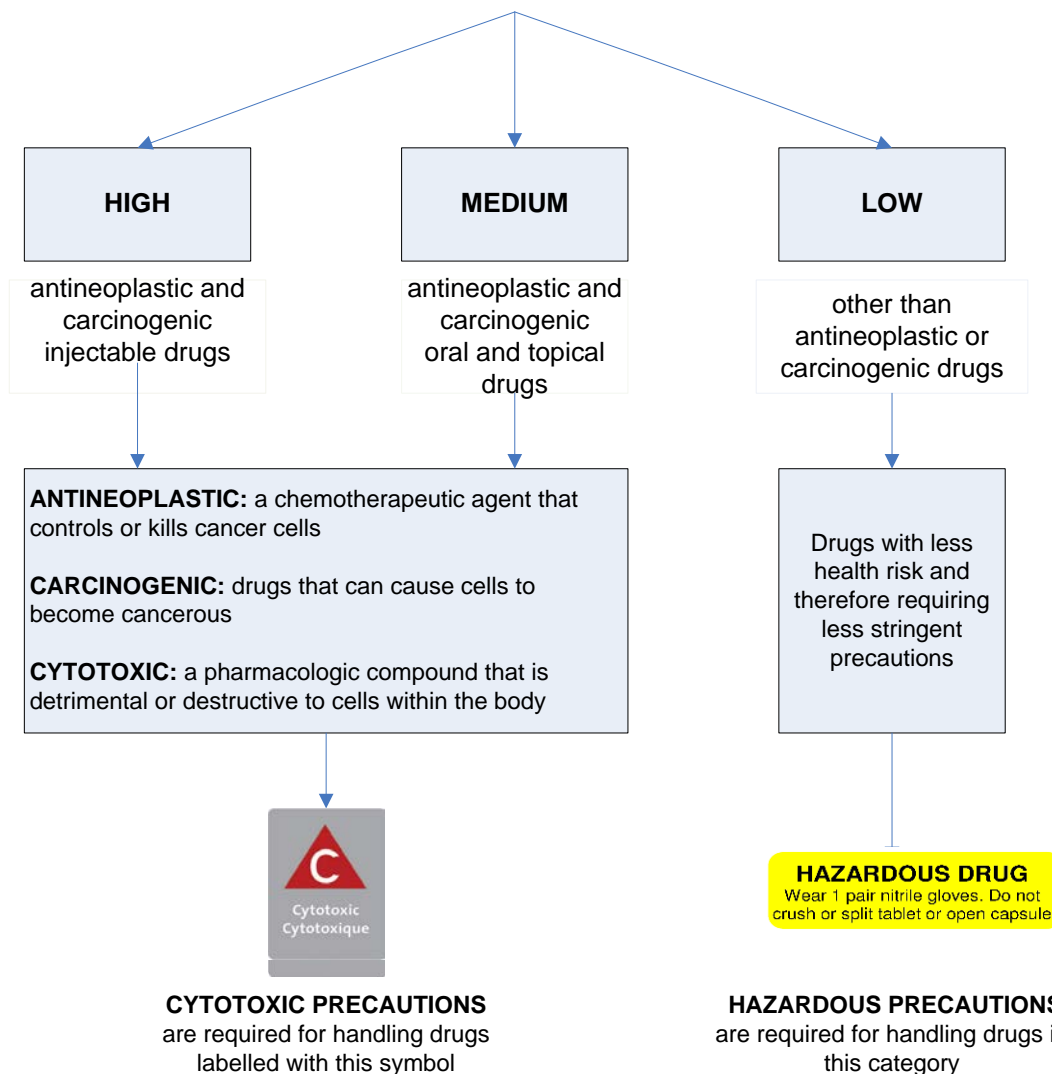
HAZARDOUS DRUGS: HANDLING PRECAUTIONS

HAZARDOUS DRUGS

Hazardous Drugs are pharmacologic compounds that are detrimental or destructive to cells within the body, human or animal.

Hazardous Drugs include: antineoplastics, antiviral drugs, hormones, some bioengineered drugs, and other miscellaneous drugs.



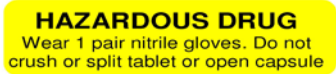
Hazard Categories



APPENDIX B

HAZARDOUS DRUGS HANDLING PRECAUTIONS – Health Care Providers (by C&W Hazard Category)

HAZARDOUS DRUGS: HANDLING PRECAUTIONS

HAZARD CATEGORIES	HIGH (antineoplastic and carcinogenic injectables)	MEDIUM (antineoplastic and carcinogenic oral and topical drugs)	LOW (drugs other than antineoplastics and carcinogenics)
PERSONAL PROTECTIVE EQUIPMENT (PPE) for administering drugs Wash hands thoroughly after removing PPE	<ul style="list-style-type: none"> ▪ Eye and Facial Protection: If risk of splash, use eye and facial protection by wearing fluid resistant mask, goggles, protective glasses with side shields, or transparent full face shield ▪ Gloves: wear 2 pairs of approved nitrile gloves; change both pairs of gloves every 30 minutes or if visibly damaged ▪ Gowns: If risk of splash, wear fluid resistant gowns with closed front, long sleeves, and elasticized cuffs 	<ul style="list-style-type: none"> ▪ Eye and Facial Protection: If risk of splash, use eye and facial protection by wearing fluid resistant mask, goggles, protective glasses with side shields, or transparent full face shield ▪ Gloves: wear 2 pairs of approved nitrile gloves; change both pairs of gloves every 30 minutes or if visibly damaged ▪ Gowns: If risk of splash, wear fluid resistant gowns with closed front, long sleeves, and elasticized cuffs 	<ul style="list-style-type: none"> ▪ Gloves: wear 1 pair of approved nitrile gloves; change gloves every 30 minutes or if visibly damaged
MAR ENTRIES AND PATIENT MEDICATION LABELS	On MAR and patient medication label: "Cytotoxic Precautions"	On MAR and patient medication label: "Cytotoxic Precautions"	On MAR and patient medication label: "Hazardous Precautions"
AUXILIARY LABELS	On outer packaging, medication container, storage bin: Universal "Cytotoxic" Label: 	On outer packaging, medication container, storage bin: Universal "Cytotoxic" Label: 	On outer packaging, medication container, storage bin: Yellow "Hazardous Drug" Label: 
MEDICATION ADMINISTRATION	If required to prime IV lines, use IV solution not containing drug OR use a back-flow closed system	Do NOT crush or split tablets, or open capsules	Do NOT crush or split tablets, or open capsules unless clinically required (e.g. phenytoin) If crushing or manipulating capsules, wear: <ul style="list-style-type: none"> ○ 2 pairs of approved nitrile gloves ○ protective gown ○ N95 respirator ○ eye protective glasses with side shields or goggles if risk of splash
CYTOTOXIC PRECAUTIONS LABEL/SIGNAGE	Affix "Cytotoxic Precautions Required" label on patient's health record Post "Cytotoxic Precautions Required" sign in the patient's area (e.g. on door)	Affix "Cytotoxic Precautions Required" label on patient's health record Post "Cytotoxic Precautions Required" sign in the patient's area (e.g. on door)	No label or signage required
HANDLING RECORDS	Document administration on Handling Records	No handling records maintained	No handling records maintained
DISPOSAL	Discard drugs and disposable equipment in cytotoxic waste	Discard drugs and disposable equipment in cytotoxic waste	No special precautions required

HAZARDOUS DRUGS: HANDLING PRECAUTIONS

HAZARD CATEGORIES	HIGH (antineoplastic and carcinogenic injectables)	MEDIUM (antineoplastic and carcinogenic oral and topical drugs)	LOW (drugs other than antineoplastics and carcinogenics)
	container	container	
HANDLING BODY WASTE (48 hour precautionary period)	<ul style="list-style-type: none"> ▪ Wear personal protective equipment as indicated above for medication administration including eye/facial protection, gloves, gown ▪ Dispose body waste via toilet, hopper, or macerator. When using toilet, cover with a disposable pad, double-flush, and discard pad in cytotoxic waste container ▪ Dispose diapers in a cytotoxic waste container 	<ul style="list-style-type: none"> ▪ Wear personal protective equipment as indicated above for medication administration including eye/facial protection, gloves, gown ▪ Dispose body waste via toilet, hopper, or macerator. When using toilet, cover with a disposable pad, double-flush, and discard pad in cytotoxic waste container ▪ Dispose diapers in a cytotoxic waste container 	No special precautions required
CLEANING REUSABLE EQUIPMENT	Carefully rinse reusable equipment, minimizing the risk of splash by using the lowest water pressure possible and return equipment in a leak proof container to Sterile Processing OR Sterilize via established procedures when using bedpan washer / disinfector	Carefully rinse reusable equipment, minimizing the risk of splash by using the lowest water pressure possible and return equipment in a leak proof container to Sterile Processing OR Sterilize via established procedures when using bedpan washer / disinfector	No special precautions for cleaning equipment
HANDLING LAUNDRY	<ul style="list-style-type: none"> ▪ Discard heavily contaminated linen in cytotoxic waste container ▪ Place all other linen in regular laundry 	<ul style="list-style-type: none"> ▪ Discard heavily contaminated linen in cytotoxic waste container ▪ Place all other linen in regular laundry 	Place in regular laundry
HANDLING SPILLS (Medications or body fluids)	Clean spills using Cytotoxic Spill Kits. as per procedures outlined by Workplace Health "Cytotoxic - Spill Cleanup Procedures - Prepared medication or body fluids" and Cytotoxic - Spill Cleanup-undiluted Medication"	Clean spills using Cytotoxic Spill Kits. as per procedures outlined by Workplace Health "Cytotoxic - Spill Cleanup Procedures - Prepared medication or body fluids" and Cytotoxic - Spill Cleanup-undiluted Medication"	Wear one pair of approved nitrile gloves to clean medication spills
EXPOSURE	<p>Report exposures to drug or contaminated blood and body fluids immediately to supervisor</p> <ul style="list-style-type: none"> ▪ Treat appropriately: Flush eye for 15 minutes with tepid water or normal saline; wash affected areas with soap and water for 15 minutes; allow puncture wounds to bleed freely ▪ Seek medical assessment at BCCH ER within 2 hours if needed ▪ Report exposure to Workplace Health Call Centre (1 866 922 9464) <p>• Leave message after hours</p>	<p>Report exposures to drug or contaminated blood and body fluids immediately to supervisor</p> <ul style="list-style-type: none"> ▪ Treat appropriately: Flush eye for 15 minutes with tepid water or normal saline; wash affected areas with soap and water for 15 minutes; allow puncture wounds to bleed freely ▪ Seek medical assessment at BCCH ER within 2 hours if needed ▪ Report exposure to Workplace Health Call Centre (1 866 922 9464) <p>▪ Leave message after hours</p>	<ul style="list-style-type: none"> ▪ Treat appropriately ▪ Report exposures that result in <u>injury or adverse effects</u> to Workplace Health Call Centre (1 866 922 9464) <p>Leave message after hours</p>

APPENDIX C

MANIPULATING TABLETS AND CAPSULES ON NURSING UNITS

Crushing tablets, dispersing tablets in water or opening capsules on nursing units should be performed only under the following circumstances:

- Medication is in the Low Hazard category, **and**
- Patient is unable to swallow solid dosage forms or drug is administered by feeding tube, **and**
- Medication is not available in a liquid form (commercially or prepared by Pharmacy) or medication is therapeutically unsuitable in liquid form (e.g. phenytoin)

Preparation location and Personal Protective Equipment (PPE):

- Where possible, hazardous drugs will be prepared in a pre-determined designated area of the Med Room, away from general circulation. Staff in the area will be alerted about the compounding of a hazardous drug taking place.
- The following PPE will be used when manipulating tablets and capsules of hazardous drugs:
 - 2 pairs of approved nitrile gloves
 - protective gown
 - N95 respirator fit-tested within the past year
 - eye protective glasses with side shields or goggles if risk of splash
- After the drug preparation is completed, the work surface will be cleaned with aqueous detergent solution.
- Hands will be washed with soap and water before donning protective gloves and immediately after removal.

Preparation Methods:

Depending on the size of tablets or capsules, type of tablet coating and type of food to be administered with, one of the following methods are recommended:

- Use of water
Tablets can be dispersed in water by using an oral syringe or small cup. For this initial dispersion, only water should be used and the resulting suspension should be administered immediately after preparation.
 - Place tablet(s) without crushing in a 10 mL oral syringe or small cup
 - Draw 2-5 mL water and 4 mL air into the syringe and cap the syringe (alternatively, add 2-5 mL water to the cup)
 - Allow to sit until tablet(s) is in suspension (3-5 minutes)
 - Gently invert syringe a few times or stir in the cup immediately before administration
 - After administration, add 2-5 mL water, swirl to suspend remaining particles and administer entire contents
- Use of pill crushers (Silent Knight recommended)
Pill crushers must have a cover for containing the dispersion of powder, must be dedicated for hazardous drugs and must be cleaned after each use.
- Use of plastic bags
Tablets can be crushed inside a double set of zip-lock bags. Bags should be opened with caution to minimize the spread of the powder.