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Preamble

The toxic effects of antineoplastic drugs used for cancer treatment have been well known since their introduction in the 1940s. The American society of Hospital Pharmacists in 1990, defined a drug as "hazardous" based on its qualitative toxicity including its carcinogenicity, mutagenicity, and teratogenicity, reproductive and developmental toxicity. This definition was expanded by national institute of occupational safety and health (NIOSH) (2004) and acknowledged that drugs with these toxic properties could pose a hazard to health care personnel, and these drugs are nonselective in their action by their effects on both cancerous and noncancerous cells in most organs and body tissues. The direct contact with it may cause irritation to the skin, eyes, and mucous membranes, cause ulceration and necrosis of tissue.

The toxicity of cytotoxic drugs dictates that the exposure of health-care personnel to these drugs should be minimized, and at the same time, the requirement for maintenance of aseptic conditions must be satisfied because cytotoxic chemotherapy for cancer patients is high-risk area of pharmacotherapy.

1. Design requirements pharmaceutical compounding rooms

1.1 Design criteria

Net room area briefed for cytotoxic room is 8m2. Basic design for the compounding space shall consist of ISO5 Primary Engineering Control (PEC) located within an ISO7 Buffer, IV, or chemo room. Access to these rooms shall be through an ISO7 Anteroom.

The PEC function is typically satisfied through the use of a five (5) foot or six (6) foot class II B2 biological safety cabinet (BSC) where non- hazardous and hazardous compounds are involved .PECs shall be located out of traffic patterns and away from circulating air currents.

The following minimum clearances shall be provided around individual BSCs:

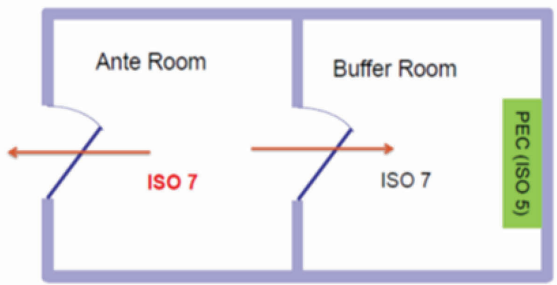
Forty (40) inches by the full length of BSC, as work space, in front.

Twelve (12) inches to nearest side wall or column.

Eighty (80) inches to opposing wall.

-Five (5) feet to opposing bench top or areas of occasional traffic.

Forty (40) inches to bench top at perpendicular walls.



Where rooms contain multiple BSCs, a staggered design arrangement is preferred. If offsetting of BSCs cannot be accomplished, the following minimum clearances shall be provided at the BSCs:

-Ten (10) feet, when facing each other.

-Forty (40) inches, when located next to each other along the same wall.

-Four (4) feet (in both directions), when located along perpendicular walls.

BSCs shall not be located near entry doors. If locating BSCs a substantial distance from in-use door is not possible, a minimum distance of forty (40) inches at the side and five (5) feet at the front of the BSC to the nearest door jamb shall be provided.

The following pressure relationships shall be maintained:

Hazardous clean (chemo) rooms: 0. 01- inch to 0.03 inch minimum negative air pressure with respect to their anterooms, with an operational design objective of 0.02- inch air pressure.

Anterooms: 0.02- inch minimum positive air pressure with respect to adjoining circulation/workroom spaces.

-Pressure gauges shall be provided to continuously monitor the differential air pressure between the compounding rooms, Anteroom, and general environment outside the compounding area.

Where swing type doors are provided, doors at negative pressure hazardous clean (chemo) rooms shall swing into the room, and doors at positive pressure non-hazardous clean (Buffer and IV) rooms and Anterooms shall swing outward from the space.

Non-hazardous and hazardous clean rooms and Anterooms shall be designed for thirty (30) air changes/hour. If recirculating BSCs are used, they may provide up to fifteen (15) of the total air changes/hour required in a room.

A storage area separate from compounding rooms shall be provided for storage of selected hazardous pharmaceuticals. The space shall be designed with negative air pressure with respect to adjacent spaces, and with twelve (12) air changes/hour.

Anteroom provide a hands-free hand washing sink of adequate dimensions to allow for washing up to the elbow. Hot and cold water volume shall be adjustable, with hot water provided at a consistent one hundred (100) degrees Fahrenheit maximum. Locate the skin near the entry door when possible.

-An eye wash located at the sink or an eye wash station shall be provided.

-A bench and storage facilities for personnel garbing shall be provided.

-Two distinct colors shall be provided at the floor to form a demarcation line between "clean" and "dirty" areas of the space. Also rectilinear footprint, without offsets, is preferred for its relative design advantage in achieving uniformity of air flow. Space for package handling and storage shall be provided unless separate rooms are provided for these functions. Space for a large container for dirty personal protective equipment shall be provided in the receiving/break-down room or dirty-storage room, if provided. The rooms/suites shall be designed to operate twenty four (24) hours/day, seven (7) days/week, and provide a minimum of two BSCs in each compounding room. Overall design shall enable one or more BSCs to remain in use should the other(s) become inoperable. Provide emergency power, where available, to storage space and equipment as required to maintain proper temperature and humidity of critical pharmaceuticals. Confirm requirements with the facility program.

1.2 Architectural requirements

Hazardous clean rooms (Buffer, IV, Chemo) and Anterooms:

-Walls: Gypsum board with epoxy paint finish .Provide integral cove trim (with approximately one inch radius) at intersection with the ceiling and at inside corners of walls.

-Ceiling: Suspended, epoxy painted gypsum board. Provide gasketed access doors, as required, for all above-ceiling items requiring access.

-Floor: Seamless sheet vinyl flooring with heat welded seams and smooth surface. Avoid flooring with hard-to-clean textured surfaces.

-Base: Coved (radiuses), seamless sheet vinyl integral with floor finish and flush with wall surface. Use of projecting trim at top of base is to be avoided.

-Light fixtures shall be designed specifically for clean room application. Light fixtures shall be flush with the surface of the ceiling and have smooth lenses. Fixture perimeter and any opening shall be sealed.

-All fixed work surfaces shall be stainless steel.

Buffer, IV, and Chemotherapy preparation rooms shall not contain sinks or floor drains.

-Doors shall be forty two (42) inches wide with vision panel, and have stainless steel hardware.

-Doors between the Anteroom and Chemo, IV, and Buffer room(s) shall be power-operated, provided with emergency power, and be activated by a touch-free "hand wave" type sensor.

-Aluminum sliding glass doors with seals/gaskets appropriate for maintaining air pressure differentials shall typically be provided.

-Use of fiberglass swing doors may be considered in lieu of sliding type doors if it can be confirmed that the design (room shape, door separation, air device placement, etc.) will allow the room(s) to maintain proper air segregation/pressure differentials when doors are opened and closed.
-Doors to Anterooms shall be designed to interlock such that no two doors in the room can be open at the same time.
-Provide widows set stainless steel
Frames in the rooms for vision between each other, and from the adjacent Work/support spaces.
Typically provide pass-through chambers to minimize the need for movement between working areas and Chemo, IV, and Buffer rooms. Chambers shall be a minimum of eighteen (18) inches by eighteen (18) inches by eighteen (18) inches in size and have double interlocked doors to maintain air pressure differentials.

1.3 Security

Access to the pharmacy suite, which includes compounding areas and their support spaces, shall be through secured doors with keyed entry and card access control
Hardware. Provide video coverage at locations where pharmaceuticals are mixed, dispensed, and distributed and at locations approved by manager for additional information by referring to the guideline.

1.4 Equipment and furnishings

-Provide standard refrigerators, ultra-low refrigerators, rolling shelving units, and movable work stations as required by the facility program and all refrigerators and freezers shall be provided with emergency power.

Fitting and Furniture (FF)

ID	Description	Category	Group	Qty	Selection/Remarks
1050	Bench: Laminate	Furniture/Fitting	1	1	
4360	Cupboard: door ht adj shelves	Furniture/Fitting	1	1	Lockable
4410	Cupboard : under bench	Furniture/Fitting	1	1	With adjustable shelf
4470	Cupboard: wall mounted, lockable	Furniture/Fitting	1	2	Over bench, optional
12900	Louvred panel: for storage-bins	Metalwork	1	2	Above bench, optional
19700	Sharp bin	Furniture/Fitting	3	1	Cytotoxic sharp

Fixtures, equipment and associated services (FE)

ID	Description	Group	Qty	Ele	Data	Selection/Remarks
43800	Refregerator:under bench,120 liter	3	1	yes	----	Optional
54510°	Telephone: handset, standard	3	1	-----	Yes	Optional ,on bench

Services

ID	Description	Service category	Qty	Selection/Remarks
1006	Voice/Data outlet: double	Communications	١	Optional
5000	air conditioning	HVAC		
6000	General fluorescent	Lighting		
6055	Special task light, built in	Lighting		Under O/H cupboards
9000	GPO single	power	1	Refrigerator, under bench
9000	GPO single	power	4	
	Computer ,Printer , Scanner	Registration	1	

2. Facilities for sterile cytotoxic reconstitution and personal protective equipment

Facilities for the sterile reconstitution of cytotoxic agent need to ensure both the protection of the product and the protection of the drug handlers.

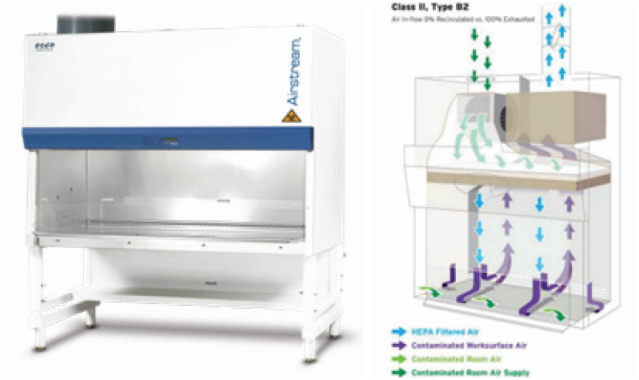
Aseptic drug manipulation must take place in a controlled enviroment to ensure the sterility of the end product. Additional protective measures are required to guarantee the safety of the operators.

2.1 BSCs

When compounding IV sterile preparations containing hazardous medications:

-An appropriate biological safety cabinet(BSC) or compounding aseptic containment isolator(CACI) should be utilized. The BSC or isolator must be capable of maintaining an ISO5 air quality environment under normal operating conditions and should be 100% vented to the outside, and this contaminated air exhaust vent should be situated at least 12 feet from ground level and should not be in close proximity to any doors, windows,or air-intake vent.

Hazardous drugs should be compounded in a controlled area where access is limited to authorized personnel trained in handling requirements,also contained environment where air pressure is negative to the surrounding areas, protected by an airlock or anteroom is preferred.



A best practice recommendation for BSC use would be a class II B2 units for the following reasons:

-They have an inflow air velocity of 100 feet/minute.

-The cotaminated down flow drown from external air and exhausted to the atmosphere without recirculation.

-All contaminated ducts are undre negative pressure.

-The use of horizontal laminar fiow BSCs is contra indicated in the preparation of hazardous drugs

-For maximum safety, the isolator should be situated in the ISO7 negative pressure cleanroom.if this is not possible, at a minimum, it should be situated in a separate negative pressure room capable of at least 12 air exchanges per hour.

2.2 Temperature and humidity

In order to prevent microbiological contamination and ensure comfort of the personnel working in the area, the temperature of the preparation rooms must be controlled. A temperature in the range of 18-22 0 C is acceptable. The humidity must be controlled in order to prevent corrosion and condensation on any work surfaces and also to provide operator comfort.The human comfort zone is generally in the range of 30% to 70% relative humidity . For isolatos sterilized by hydrogen peroxide a 50% relative humidity level must be reached and controlled between 40% and 60%.

2.3 PPE

The correct selection and use of personal protective equipment (PPE) is required to both ensure the sterility of the end product and protect the operator.PPE must be worn to protect personnel during cytotoxic reconstitution and during other activities

where they may come into contact with hazardous drugs. Activities may include opening drug packaging ,handling vials or finished product, labelling drug containers, or disposing of waste.PPE includes gloves, gowns or coveralls, boots or overshoes, respirators,head covering and protective eyewear(safety glasses with side shields) are not necessary during preparation but must be used during cleaning and decontamination procedures, and during the clean up of any spills, or when there is a risk for splashes or sprays

Gowns

The use of disposable coveralls or gowns made of non-linting and non-absorbent polyethylene-coated polypropylene material is recommended. The gown used should have the following characteristics:

-Long and closed at the neck

-Long sleeves with cuffs gripped at the wrist

-Disposable sleeve covers to protect the wrist and lower arm

-Waterproof material for the front and sleeves

Sterile-

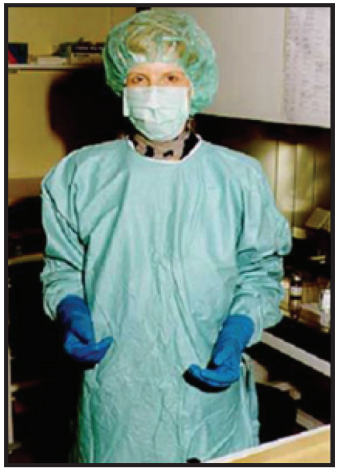
-Non-linting

Integrated coveralls which include head and foot covering are very suitable in term of both microbiological and chemical contamination.

Overshoes should be worn:

-If shoes are worn in the production zone,Dedicated shoes should be used for this purpose.

-In the event of any accidental contamination



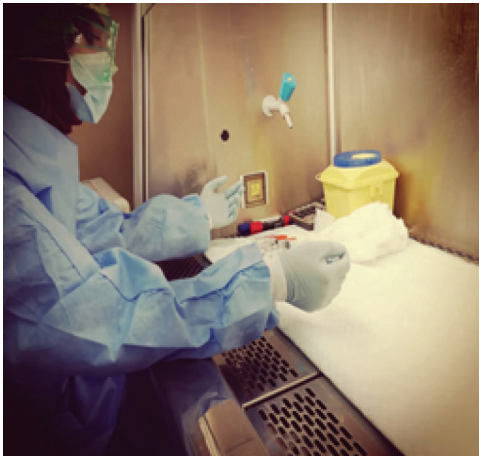
Respirator:

N95 mask that is impregnated with charcoal should be used during production in cleanroom

Protective Goggles:

Goggels are recommended when any projection risk is present.

In most cases the glass screen of BSC should offer adequat protection against any possible spray of solution during cytotoxic reconstitution .Goggles must be worn when cleaning a spill.



Gloves:

Gloves used must be proven to be resistant to chemotherapy And labelled as chemotherapy gloves.

Gloves used should have the following characteristics:

--Sterile, non-powdered

--Latex (consider latex-sensitive workers)

A double pair of gloves may be used. The outer glove must extend over the cuff of the gownnn.Gloves should be changed at least every 30 minutes or whenever damage or obvious contamination occurs.

Gloves should not be decontaminated with alcohol.

--Hair covering

The hair must be covered with a separate head covering or an integrated hood of a coverall.men with beards may need to wear a separate covering for this purpose.

2.4. Equipment for drug preparation

Certain cancer chemotherapy drugs are not administered in equipment that contains polyvinyl chloride(PVC) for these drugs (e.g. paclitaxel,docetaxel, etoposide), non-PVC equipment is used for drug administration and, if possible, drug preparation according to manufacturs' guidelines.

All aevices for transfer and parenteral delivery of cancer chemotherapy drugs are equipped with Luer-Lock connections, to reduce the potential for spillage subsequent to accidental disconnection.

A closed-system may offer additional protection benefits to workers for both preparation and administration of cancer chemotherapy drugs.It may be used in conjunction with a BSC, but is not be used as a substitute for a BSC and should be used whenever possible for transfer of cancer chemotherapy drugs from primary packaging(e.g. vials) to dosing equipment(e.g. infusion bags, bottles, pumps or syringes).

Closed-system devices have been demonstrated to limit potential aerosol generation and reduce potential worker exposure to sharps.

3. Policy

Cytotoxic chemotherapy drugs are not prepared on patient care wards or other areas outside the central chemotherapy preparation area. Each chemotherapy drug will be prepared with the proper diluent(s) for reconstitution and/or admixture, and given the appropriate expiry date and time, as indicated in the chemotherapy preparation and stability chart.

All cancer chemotherapy drugs used for treatment of cancer patients are prepared by Pharmacy Personnel with Chemotherapy Preparation Training and dispensed by the oncology pharmacy service, optimizing safety, efficiency and economical use of chemotherapeutic agents.

All staff involved with handling cancer chemotherapy drugs regularly review local procedures for the safe handling of these agents. All cancer chemotherapy are ordered on approved pre-printed orders (PPOs).

The Hospital Pharmacist with Oncology Training (or designate pharmacist) his job is:

1-Verifies the medication order against the treatment protocol, the patient's medication profile and the patient's health record prior to dispensing cancer chemotherapy drugs.

2- Prepare computer-generated labels, using a standardized format, terminology and generic nomenclature. The labels are verified prior to dispensing cancer chemotherapy drugs.

3-Perform an independent check of the final product against the product label and a copy of the verified physician's order. The product check is performed at the time the product is prepared or using a system that ensures correct product selection and dosage volume.

Safe handling of cancer chemotherapy drugs 3.1.

The National Institute for Occupational Safety and Health (NIOSH) , the American Society of Health- System Pharmacists, the Oncology Nursing Society, and the International Society of Oncology Pharmacy Practitioners (ISOPP) have current guidelines for safe receiving hazardous chemotherapy drugs from the manufacturer or distributer, storage these drugs, handling ,preparing and labeling , packaging for transporting ,administering , handling the waste products ,cleaning and decontamination of hazardous chemotherapy drug equipment and work surface and cleanup of hazardous drug spills .Cytotoxic agents are handled in a manner to ensure:

A .Protection of patient (using aseptic technique) regarding sterility of the parenteral agent accuracy and appropriateness of the drug and dose.

B. Safety of personnel (using personal protective equipment). Minimization of exposure and undue hazardous to other including pharmacy personnel, nursing staff, allied health staff and patients.

C. Protection of the environment (using class II B2 biological safety cabinet (BSC). A horizontal laminar flow isolated cabinet is not used to prepare cytotoxic chemotherapy. Buffer zone or room should be ventilated into the ante room /area to maintain a negative air pressure gradient difference (isolating biological and chemical contaminants within the clean room and buffer zone/room). Due to possibility of cross contamination biological (e.g. BCG) and cytotoxic drugs should not be prepared in the same BSC, There will be procedure for disinfection and Decontamination of the BSC after each session where biologic agents are prepared in the BSC.

Parenteral cancer chemotherapy drugs are prepared using appropriate equipment to ensure product sterility and protection for the health care worker by wearing PPE, Luer -Lock devices are used where available and closed system devices should be used for preparation and administration of cancer chemotherapy and other occupationally hazardous drugs.

Employees who are pregnant, attempting to conceive or father a child, or are breast feeding may opt to be transferred to comparable duties, that do not involve handling cytotoxic drugs. There is a departmental policy to provide direction with this issue.

All personnel involved in any aspect of handling of cytotoxic drugs are informed about the risks of occupational exposure to hazardous dugs and the personnel with upper respiratory infections or cutaneous infections are excluded from preparing cytotoxic whenever possible.

Personal follow best practice procedures for identification, containment, collection, segregated storage, and disposal or removal of cytotoxic waste materials, also trained personnel follow established policies and procedures immediately for spill management and clean up procedures by using spill kits which containing all materials and equipment necessary to clean a spill.

4. Medical surveillance of health care worker handling cytotoxic drugs and waste

According to Occupational Safety and Health Administration (OSHA, USA), safe levels of occupational exposure to cytotoxic agents cannot be determined. No reliable method of monitoring exposure exists. It is imperative that those who work with cytotoxic agents adhere to practices, as outline above, to eliminate or reduce occupational exposure. While there are no direct measurements to indicate total exposure to cytotoxic drugs, individual staff members may opt to follow selected surveillance components by their own means, which may include:

1-Reproductive and general health questionnaires by the individual's family physician completed at the time of hire and annually.

2-Blood work, including complete blood count, liver function tests and urinalysis completed by the individual's family physician at the time of hire and annually.

3-Physical examination by the individual's family physician at the time of hire and then annually as needed.

4-Follow up by the individual's family physician for those workers who have shown health changes and/or have been exposed to hazardous drugs (e.g. through spills or during routine handling).

Documentation is maintained by the Occupational Health and Safety department on:

1-Any personal contamination from a spill

2-Results from any visits to occupational health related to chemotherapy administration activities.

5. GUIDING PREINCIPLES

Preparation of cancer chemotherapy drugs is more complex than many other drugs given in the hospital due to risk and safety concerns. Educational programs for health professionals involved in the care of cancer patients are under development, including the chemotherapy preparation course for pharmacy technicians (and others). These education programs are important to developing the competencies needed to comply with the Level of Care for Cancer Chemotherapy and the related policies and procedures.

Three basic principles must be considered at all times when handling, transporting or administering cancer chemotherapy drugs:

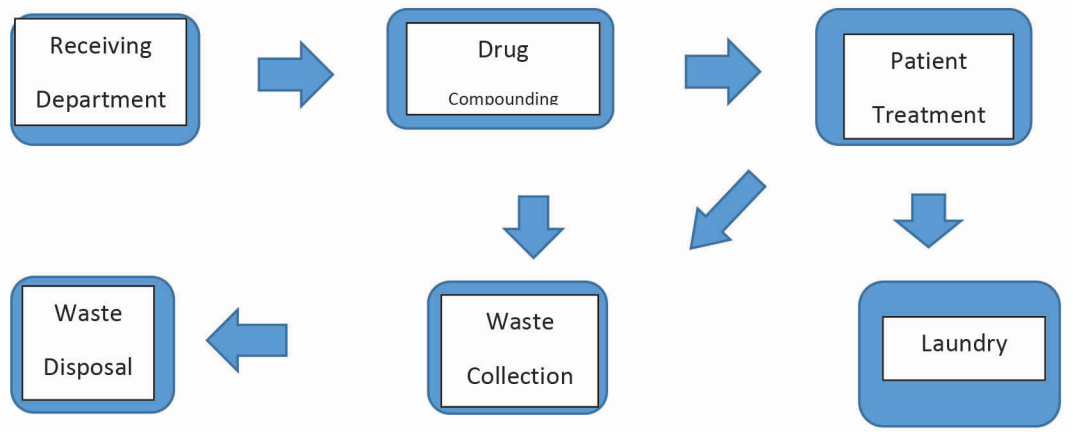
A .Protection of the patient (i.e. using good aseptic technique, prevention extravasation event)

B. Protection of personnel (i.e. using PPE and specialized techniques, and education of all personnel involved at each step that cancer chemotherapy is handled, such as nurses, housekeeping staff, and porters.

C. Protection of the environment (I.e. drug administration techniques to avoid leakage, aerosolization or spillage, management of waste materials to minimize environmental contamination).

Cancer Care Nova Scotia (CCNS) is the provincial cancer program, with a mandate to develop standards of cancer care across Nova Scotia. CCNS has developed a "Systemic Therapy Manual for Cancer Patients", cataloging the drugs and regimens used for the systemic therapy of cancer (including cytotoxic chemotherapy drugs).

Receiving hazardous chemotherapy drugs from the manufacturer or distributor and storage of hazardous drugs:



Hospital and clinics receive medications in shipments from manufacturer and/ or distributor, then distributed through the facility use in patient care. The transport of medications from the manufacturer can sometimes lead to broken or cracked vials or packages. It is therefore important for each employee involved in receiving the medications to inspect the packages to determine whether any are broken. Gloves should be worn when inspecting any hazardous drug package. If a hazardous drug package is damaged, the employee must assess the extent of the damage and select and put on appropriate PPE, as unprotected skin should not come into contact with the drug. Also hazardous drug spill kits must be readily available in the receiving area, and receiving personnel must be trained to perform spill cleanup.

All cancer chemotherapy products are stored in closed containers (0e.g. zip-lock bags), on shelves that are not above eye level and have a ledge to prevent potential spill and breakage. This area is separate from other drug products and has sufficient external air ventilation (minimum 12 air exchanges per hour).

Storage areas must be cleaned at least every 30 days with detergent solution. Diluted bleach solution may also be used if the container is resistant to damage from bleach. Wipe don't spray, HD storage bins.

6 .preparation of cytotoxic drugs:

Compounding sterile doses of hazardous drugs (HDs) requires precautions to ensure that sterility is not compromised by adding any non-sterile substance into the drug vial and that no drug residue as aerosol or spill is allowed out of the drug vial.

Ampoules must be handled carefully to avoid either form of contamination and to prevent cuts or scrapes resulting from the sharp edges of the open ampoule. These procedures assume a working knowledge of standard aseptic technique and are specific to the stringent techniques used to compound HDs.

a. Compound in a suitable primary engineering control (PEC) if available, clean and disinfect the interior surface of the BSC daily as described in procedure. Disinfection will be done prior to start of shift or before a new dose is prepared.

b. Wash hands before donning personal protective equipment (PPE).

c. Wear appropriate PPE for compounding in a PEC or in the open (outside a containment cabinet).Full PPE including a coated gown, double HD-tested gloves, eye protection, and an N95 respirator plus face shield should be worn for compounding in the open.

d. Assemble source products and diluents for each dose or batch and check prior to dose preparation, if multiple dose vials are used, then leftover solution should then be kept in a dedicated, visually marked location in the chemotherapy preparation area, for later use. Whenever possible, prepare doses for a single patient at a time; alternately, prepare all doses of the same medication at one time.

e. Sanitize gloves routinely by wiping with a sterile cloth saturated with alcohol, do not spray alcohol on contaminated gloves as that will transfer contamination to the environment and other surfaces. Take care to avoid puncturing of gloves and possible self-inoculation, use only Luer-Lock syringes at all times.

F. Place all the necessary items for manipulation in the hood to minimize moving in and out the BSC, do not overload the working area, and work 6 inches away from the grill and sides of the BSC.

g. Wipe off all vials or ampoules of HD with a moist wiper to remove HD residue. Discard wiper in containment bag for appropriate disposal.

h. Select needles of appropriate gauge and length for the vial and final container, no needle should be used to make more than 3 punctures during preparation of a drug dosage (the needle becomes dull with each use and coring can occur),no needle will be used for more than a single drug.

I. Use syringes larger enough so that they are never more than 75% full (or 50 ml in 60 ml syringe), but are small enough to measure the contents with acceptable accuracy, as follows:

1 ml syringe no more than 0.75 ml

3 m syringe no more than 2.3 ml

5 ml syringe no more than 3.8 ml

10 ml syringe no more than 7.5 ml

j. Adjust volume and/or eliminate any air bubbles in the syringe before taking the needle out of the vial. Use great care when replacing the needle cap or attaching a Luer tip.

k. Attached intravenous sets are closed and secure from any cytotoxic drug leakage. Reconstituted solution are checked to ensure complete dissolution before withdrawal from the vial or ampoule, the final product is visually inspected for particulate matter or physical incompatibility.

Check source product, diluent, equipment/supplies and dosage for each dose during preparation or immediately after each dose is prepared. Any solution to be admixed into a large volume parenteral (LVP) is visually checked for correct medication, quantity and quality before admixture into the LVP, then collect all of the completed doses for each patient and place them together on a tray or plastic tub(s) and removed from the BSC to an adjacent counter for final check and preparation for dispensing.

l. Remove source products and diluents from work area to permanent or temporary storage area, to reduce clutter inside work area, all waste materials are placed in a hard cytotoxic waste container within the BSC.

m. Separate institutional procedures are employed for preparation of any Intrathecal doses.

6.1. Handling and reconstitution 0f drug in vials:

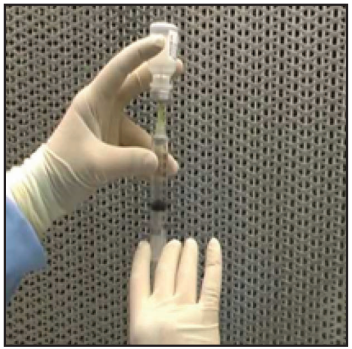
UN punctured vials may have positive or negative pressure in relation to the work area. Use a chemotherapy dispensing pin with hydrophobic filter to maintain equal pressure inside and outside the vial, and to minimize the risk of aerosol spray or leakage at the needle-vial juncture that can be caused by over pressure in the vial.

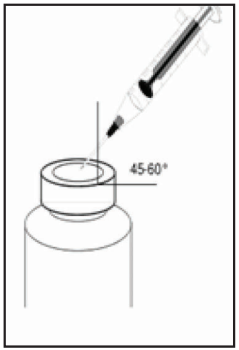
To reconstitute a powdered drug in vial, calculate the amount of diluent needed to achieve the desired concentration, remove plastic protector cap from the HD vial and the diluent vial, expose rubber stopper and wip by using a sterile swab of 70% isopropyl alcohol, swab each vial three times in the same direction, using a new swab for each vial; allow to fully air dry. Using standard aseptic technique, draw up the exact amount of diluent in a syringe large enough to be no more than 75% full when containing the entire dose, with attached needle, insert the needle at a 45-degree angle into the closure of the vial until the bevel is half covered.

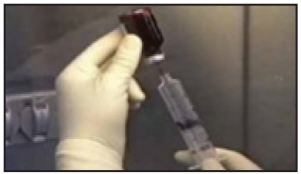
Bring the needle and syringe perpendicular to the vial closure and insert the needle through the closure into the vial. Be sure the needle is in the vial and no part of this critical site is exposed during reconstitution. Push the pin directly into and through the rubber stopper of the drug vial. Do not twist the pin during insertion, to avoid creation of rubber particles. Make sure the pin is fully inserted.

Slowly inject the diluent into the drug vial. Use a carful rotating motion to dislodge any powder from the inside surfaces of the vial. Keep the vial on the work surface to maintain stability. Take care to keep the protector device facing upward and avoid wetting the filter. Air cannot escape if the filter is wet. The protector device will inflate to capture any air displaced during the reconstitution procedure.

If the syringe will be reused for dispensing, hold in a clear area of the BSC, otherwise discard it in the chemotherapy waste container. After removal of the solution aliquot, always wipe the top of the vial with an alcohol swab to remove any droplets of drug and discard the swab into the cytotoxic waste container within the BSC.



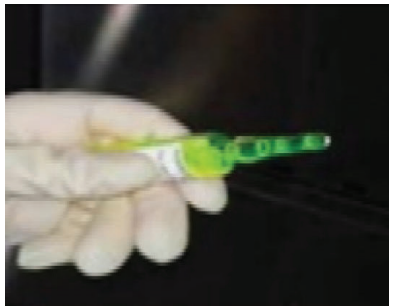
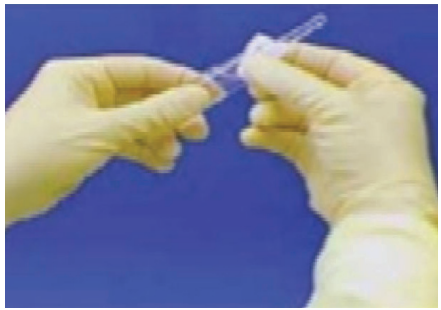




6.2. Handling ampoules:

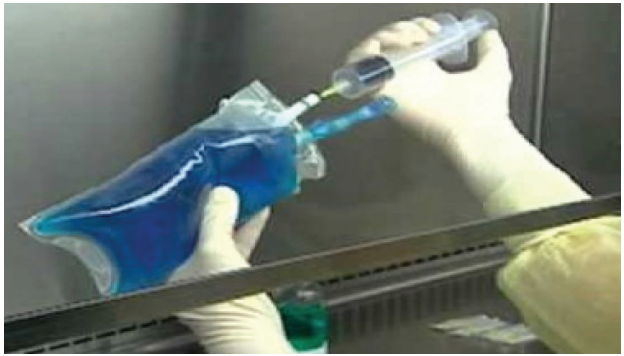
Ampoules are difficult to manipulate, as once opened there is no barrier to the sterile liquid. Precautions must be taken to avoid microbial contamination as well as HD escaping into the environment. Working with ampoules in the open (outside a containment cabinet) is a particular risk for respiratory and eye contamination.

Ensure contents of ampoule are below neck of ampoule before opening.
Tap ampoule with finger to remove fluid from upper section.
Wipe neck of ampoule with sterile alcohol swab before breaking the top.
For dry ampoule, slowly add diluent down inside ampoule wall. Tilt and rotate the ampoule to ensure wetting of all powder, then agitate slowly to dissolve

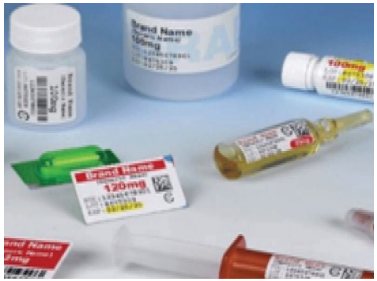




6.3. Priming the intravenous tubing:

Cancer chemotherapy agents are mixed into intravenous parenteral solutions inside the BSC, rather than by nursing staff in patient care areas. Prudent practice dictates that drug administration sets be attached and primed within the BSC, prior to addition of the drug. This eliminates the need to prime the set in a less well-controlled environment and ensures that any fluid that escapes during priming contains no drug.



Priming the intravenous (IV) tubing in the BSC is one recommendation that becomes more problematic if the surface of the BSC is contaminated. This contamination. Could be transferred to the outside of the tubing and become a source of exposure. A more reasonable approach, especially when using the newer infusion adaptors, is to use a secondary set for chemotherapy infusions and prime this set by allowing non- chemotherapy IV fluid to backflow into the secondary tubing from the primary IV line.



6.4. Labeling:

In addition to standard pharmacy labeling practices, all syringes and IV bags containing HD's should be labeled with a distinctive warning label, such as:

"Caution-chemotherapy, Dispose of Properly"

6.5. Preparation of Non- sterile cancer chemotherapy products:

Non-sterile preparations may include oral cytotoxic drugs (tablet, capsules or syrup) or the topical application of cytotoxic drug for topical application. PPE, including eye protection and masks is worn during preparation and discarded at the end of the procedures as contaminated equipment. All equipment used for extemporaneous preparation is either non-porous or disposable. The crushing of tablets or the opening of capsules in an open mortar and the mixing of powders is avoided if possible, if tablets must be crushed outside the pharmacy, techniques are used to minimize exposure:

a. Choose area near sink away from drafts and high traffic .Alternately, the procedure could be done inside the BSC, with the blower turned OFF. The BSC blower can cause drug powder to be suspended in the air and inhaled by workers. The BSC may be tuned back on once the procedure and subsequent cleanup is completed.

Pull plunger back and forth to crush tablets (place thumb on syringe cap, fingers around barrel and hit plunger on counter while holding cap on with thumb).

c. Gently knock powder away from syringe cap, remove from re-sealable zipper bag. Remove syringe cap. Draw up diluting liquid into syringe from med cup. (Not: hold syringe at angle to avoid powder from spilling into med cup), re-cap syringe, place back in re-sealable zipper bag, and then shake until dissolved

d. Clean area with detergent and water and wipe dry, dispose of waste in a chemotherapy waste container. Wash hands thoroughly, wear new gloves to deliver and administer agent to patient.

All materials and equipment used (such as mortar, pestle, glass plate, spatulas, mixing devices, tube fillers) for the preparation of oral/external use cytotoxic drugs are identified for that use and reserved solely for these activities. This equipment is not used for non-cytotoxic preparations and cleaned separately from all non-cytotoxic equipment. Tablets and capsules are handled in a manner that avoids skin contact, spread of drug into the air and chemical cross contamination with other drugs. ALL equipment used in the dispensing of cytotoxic solid dosage forms are dedicated to this purpose and clearly labeled as such.

6.6. Packaging HD's for transport:

The outside of bags or bottles containing the prepared drug should be wiped with moist gauze, and the entry ports should be wiped with moist alcohol pads and capped.

Special precautions will be followed to prevent breakage, minimize exposure and contain spills when transporting cytotoxic drugs within the health care facility.

Cytotoxic drugs are placed in a sealable plastic bag. The bagged contents are then transported inside a closed container that will minimize the possibility of drug products falling during delivery. Closed containers have a disposable absorbent pad to contain any spillage and to cushion the contents if dropped. Luer-Lock syringe caps are used when transporting syringes containing cytotoxic solutions.

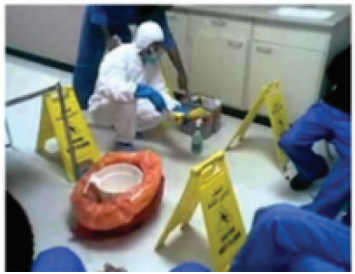
All individuals involved in the transportation of cytotoxic agents have quick and reasonable access to a spill kit and are trained in methods to handle cytotoxic spills.

6.7. Spill management:

Chemotherapy spills may occur during preparation, transport, or administration of chemotherapy. Spill kits should be located in all areas where chemotherapy is prepared and administered.

Chemotherapy Spill Kit

- 2 caution spill signs
- 1 chemotherapy gown
- 1 pair overshoes
- 1 Plastic safety glasses
- 1 Respirator mask
- 2 pairs heavy duty rubber gloves
- 2 absorbent pads
- 4 absorbent towels
- 1 waste bag
- 2 cable ties
- 1 small scoop to collect glass fragments
- 1 bottle of water



In the event of cytotoxic spill in any area other than safety cabinet the following clean up procedure is followed:

a. Alert other staff in the area of the potential hazard; limit access to the area by placing the warning sign in a prominent position. Obtain a spill kit and remove the contents. Don PPE in this order; the mask/face shield, the safety glasses, one pair of gloves (PVC-under the gown cuff), gown, boots, and the second pair of gloves (Latex-over the gown cuff).

b. For a liquid spill, carefully place an absorbent pad over the spilled liquid, absorb as much liquid as possible into the pad. If the liquid spill is greater than 5 ml, it is generally best practice to call environmental services to handle the spill.

c. If the spill involves powder, carefully place a damp disposable pad over the powder and then carefully pat the spill area to adsorb as much powder as possible.

d. If there is broken glass in the spill, carefully pick up the glass pieces using the disposable scoop and place all glass in the puncture-proof container.

e. Gather up the contaminated pads and discard all of this waste into cytotoxic waste container.

f. Repeat steps until the entire spill has been cleaned then use the cleaning solution to wash the area of the spill thoroughly, discarding all waste generated into waste container, rinse the area well with clean water and dry it completely to prevent accidental slippage on wet floor.

g. Discard all used items into the cytotoxic waste container, remove gloves, mask, gown and dispose in the cytotoxic waste container.

h. Wash hands thoroughly with soap and water, arrange for hospital cleaning staff to reclean the area.

I. Health care personnel exposed during spill management should complete an incident report as per institutional policy.

In the event of a cytotoxic spill inside the safety cabinet, the following clean up procedure is followed:

a. Obtain a spill kit if the volume of the spill exceeds 30 ml or the contents of a full vial or ampoule. Spill less than 30 ml inside the BSC may be managed using a spill kit or as a more routine BSC decontamination clean up.

b. If there is broken glass in the spill, carefully pick up the glass pieces using the disposable scoop and place all glass in the puncture-proof container.

c. For a liquid spill, carefully place an absorbent pad over the spilled liquid. Absorb as much liquid as possible into the pad.

d. If the spill involves a powder, carefully place a damp disposable pad over the powder and then carefully pat the spill area to adsorb as much powder as possible.

e. Gather up the contaminated pads. Discard all of this waste into the cytotoxic waste container, repeat steps until the entire spill has been cleared. Thoroughly clean and decontaminate the BSC, including the drain trough/sump, the BSC should not be used until a complete decontamination.

f. Health care personnel exposed during spill management document the incident using an incident report as soon as possible

In the event that a staff member or patient/family member is contaminated with a cytotoxic agent, the following procedure is followed:

a. All overtly contaminated protective clothing is removed and placed in the cytotoxic waste container.

b. Eyes that have been exposed to a cytotoxic agent are thoroughly irrigated with water or an isotonic eyewash for as long as possible (e.g. up to 15 minutes). Contact lenses, if not flushed from eye, are removed as soon as possible and discarded. An eyewash station is used , if available(including eyewash stations attached to faucet), or water splashed by hand into the eye from a faucet .It is Not recommended to irrigate the eye directly with running water from a faucet because of the potential for water pressure damage to the eye. In all cases where the eye is contaminated by cytotoxic agent, ophthalmologic advice should be sought.

c. An emergency shower or equivalent (e.g. hand-held spray device) is used if appropriate. If this is not available, then the contaminated area of skin is washed with soap and rinsed with large amounts of water.

d. If the skin is broken or there is a needle-stick injury, the affected area is irrigated with plenty of water and blood expressed from the wound (until the bleeding is controlled).

e. Health care personnel exposed during spill management will complete an incident report as soon as possible.

6.8. Cytotoxic waste handling:

Cytotoxic waste includes all materials that have come into contact with cytotoxic drugs during the process of reconstitution and administration. This includes syringes, needles, empty or partially used vials, gloves, single use PPE, disposable respirator masks, and materials from the cleanup of cytotoxic spills. The packaging in direct contact with received chemotherapy products is also cytotoxic waste. Air filters from BSCs are included.. In addition, hazardous drugs that have expired, or for any other reason must be destroyed, are also treated as cytotoxic waste

Breakable contaminated needles, syringes, ampoules, broken glass, vials, intravenous sets and tubing, intravenous and intravesical catheters etc. Are placed into designated leak-proof, puncture proof sharps containers that clearly and visibly display the cytotoxic hazard symbol. Sharps containers for chemotherapy waste are placed in the BSC as needed and full sharps containers are transferred to the oncology waste container.

Non –breakable contaminated materials including disposable gowns gloves, gauzes, masks, intravenous bags etc. are placed in thick, sealed plastic bags, hard plastic or cytotoxic containers that clearly and visibly display the cytotoxic hazard symbol. When full, the bags and containers are placed in the oncology waste container, clearly marked chemotherapy waste receptacles are kept in all areas where cytotoxic drugs are prepared or administered, all cytotoxic drug waste is separated from general waste. Cytotoxic waste is not mechanically or manually compacted, it is destroyed in an incinerator (1200 degree cent egret) approved for the destruction of cytotoxic drugs.

If access to an appropriately licensed incinerator is not available, transport to and burial in a licensed hazardous waste dump is an acceptable alternative.

Table 1. Group 1 and Group2 a Carcinogens

Group 1: Human Carcinogens	Group 2A:Probable Human Carcinogens
Arsenic trioxide	Azacitidine
Azathioprine	BCNU
Busulfan	CCNU
Chlorabucil	Chlorozotocin
Chloranaphazine	Cisplatin
Cyclophosphamide	Doxorubicin HCL
Etoposide	N-Ethyl-N-nitrosourea
ECB[2]	Mechlorethamine HCL
Melphalan	N-Methyl-nitrosourea
MOPP[1]	Procarbazine HCL
Semustine	Teniposide
Tamoxifen	
Thiotepa	
Treosulfan	

Source: Adapted from the International Agency for Research on Cancer,http://monographs.iarc.fr/ENG/Classification/index.php.

1 Mustargen-oncovin-Procarbazine-prednisone

2 Etoposide-Cisplatin-bleomycin

TABLE 2. Antineoplastic Agents Classified by the FDA as pregnancy Category D or X

Drug	Pregnancy Category	Drug	Pregnancy Category
Arsenic trioxide	D	Interferon alfa-2b	X
Azathioprine	D	IrinotecanHCL	D
Bleomycin	D	Leflunomide	X
Capecitabine	D	Lomustine	D
Carboplatin	D	Mechlorethamine HCL	D
Carmustine	D	Melphalan	D
Chlorambucil	D	Mercaptopurine	D
Cisplatin	D	Methotrexate	X
Cladribine	D	Mitoxantrone HCL	D
Cyclophosphamide	D	Oxaliplatin	D
Cytarabine	D	Paclitaxel	D
Dactinomycin	D	Pipobroman	D
Daunorubicin HCL	D	Procarbazine	D
Docetaxel	D	Tamoxifen	D
Doxorubicin HCL	D	Temozolomide	D
Epirubicin	D	Teniposide	D
Etoposide	D	Talidomide	X

Drug	Pregnancy Category	Drug	Pregnancy Category
Floxuridine	D	Thioguanine	D
Fludarabine	D	Thiotepa	D
Florouracil	D	Topotecan	D
Gemcitabine	D	Tositumomab	X
Hydroxyurea	D		
Ibritumomab tiuxetan	D	Vinblastine sulfate	D
Idarubicin	D	Vinicristine sulfate	D
Ifosfamide	D	Vinorelbine	D
Imatinib mesylate	D		

Source: **Adapted from the U.S. Food and drug Administration, Center for Drug Evaluation and Research, http://www. Accessdata. fda.gov/scripts/cder/drugsatfda/index.cfm**

Note: Category D definition: There is clear evidence of risk to the human fetus, but the benefits may outweigh the risk for pregnant women who have a serious condition that cannot be treated effectively with a safer drug. Category X definition: There is clear evidence that the medication causes abnormalities in the fetus. The risk outweigh any potential benefits for women who are (or may become) pregnant.

Glossary

Antineoplastic drug: A chemotherapeutic agent that control or kills cancer cells. Drugs used in the treatment of cancer are cytotoxic but generally more damaging to dividing cells than to resting cells.

Aseptic technique: Is carrying out a procedure under controlled conditions in a manner that minimizes the chance of contamination.

Carcinogenic: The ability or tendency to produce cancer.

Cancer chemotherapy: A single drug or combination of drug used for the treatment of cancer. The cancer chemotherapy drugs may or may not be cytotoxic (see Systemic Therapy Manual). Supportive treatments, used to help ameliorate adverse effects of the cancer treatment or the disease, and hormone agents are not included in this definition.

Cancer chemotherapy regimen: A drug or combination of chemotherapy drugs, with predetermined relative or absolute doses, schedule of administration, and often with recommended supportive therapy (e.g. antiemetic, hydration).

Chemotherapy preparation and stability chart: A list of all chemotherapy drugs, with information on reconstitution, vial stability and expiry dating, final product stability and expiry dating and other information for each drug/drug product. This chart is located in the Systemic Therapy Manual and updated as necessary.

Chemotherapy administration unit: A facility (usually hospital) unit dedicated for the local preparation and delivery of chemotherapy.

A chemotherapy administration area, a dedicated drug preparation area (which may be located in the hospital pharmacy department), dedicated registered nurses with chemotherapy certification, and on-site medical supervision. It is desirable that a chemotherapy administration unit has access to a hospital pharmacist with oncology training.

Chemotherapy preparation area: A designated area in the hospital designed for safe preparation of cancer chemotherapy drugs .This area may be located in the hospital pharmacy area, or adjacent to the chemotherapy administration unit. The chemotherapy preparation area will include a designated room with the Biological Safety Cabinet and associated facilities (e. g. drug storage, refrigeration unit, drug preparation staging area). There will be sufficient space and environmental controls to ensure occupational safety in this area. If possible, the chemotherapy preparation area will be a proper cleanroom.

Class II biosafety cabinet (class II BSC): A ventilated biological safety cabinet that protect personnel, product, and the work environment. A class II biosafety cabinet has an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow producing an ISO 5 environment for product protection, and HEPA-filtered exhausted air for environmental protection. The class II biosafety cabinet is further defined by the method of handling contaminated air in the cabinet. Outdoor exhaust of contaminated air is preferred, as some hazardous chemotherapy drugs are not trapped by HEPA –filters.

Cleaning: The removal of all visible dust, soil, and other foreign material, usually done using water and soaps, detergents or enzymatic products along with physical action such as brushing.
Closed system device: A drug transfer device which mechanically prohibits the transfer of environmental contaminants in to the system and the escape of hazardous drug or vapor concentrations outside the system.

Cytotoxic: A drug possessing a specific destructive action on certain cells. Used commonly in referring to antineoplastic drugs that selectively kill dividing cells. Cytotoxic drugs are associated with specific occupational risk concerns.

Decontamination: Inactivation, neutralization, or removal of toxic, non-infectious agents, usually by chemical means. Cleaning a non-disposable surface with a detergent and disposable wipers may also be an effective method of decontamination (removal) of non -infectious agents.

Disinfection: A process that kills or destroys nearly all disease-producing micro-organisms.

Genotoxicity: The ability to damage or mutate DNA. Genotoxic substances are not necessarily carcinogenic.

Health care worker: Any worker who is involved in the care of patients. The category includes pharmacists, pharmacy technicians, nurses (registered nurses, licensed practical nurses, nurses ' aides, etc.), physicians, home health care workers, and environmental services workers (housekeeping, laundry, and waste disposal).

HEPA filter: High-efficiency particulate air filter rated 99.97% efficient in capturing 0.3-micro diameter particles.

Hazardous drug: Any drug meeting at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, genotoxicity, or new drugs that mimic existing hazardous chemotherapy drugs in structure or toxicity.

Horizontal laminar flow isolated cabinet: A device (horizontal laminar flow clean bench or hood) that protects the sterile work product by supplying HEPA-filtered air to the rear of the cabinet and producing a horizontal flow across the work area and out toward the worker. This device provides no containment properties and is not appropriate for hazardous chemotherapy drugs.

Hospital pharmacist with Oncology Training: A hospital pharmacist, with oncology-specific training, competency assessment and practice privileges in the local treatment facility, designated to verify cancer chemotherapy treatment orders within a scope of practice, defined by the District Health Authority in consultation with Cancer Care Nova Scotia.

ISO5: Classification of air cleanliness e.g. 3520 particles of 0.5 µ m per m_2 or larger is equivalent to 100 particles per ft_2.

ISO7: Classification of air cleanliness e.g. 352000 particles of 0.5 µ m per m2 or larger is equivalent to 10000 particles per ft2.

List of hazardous agents: A list of drugs used for the systemic therapy of cancer, identifying which agents must be handled as hazardous drugs, and which do not necessarily require the precautions of handling hazardous agents. This chart is located in the Systemic Therapy Manual and updated as necessary.

Mutagenicity: The ability to increase the spontaneous mutation rate by causing changes in DNA.

Oncology pharmacist: A pharmacist trained and assigned to a clinical practice in the Cancer Care Program by the Pharmacy Department. An oncology pharmacist is certified through an educational program offered in consultation with Cancer Care Nova Scotia or an equivalent pediatric program. An oncology pharmacist will also meet the full criteria for hospital pharmacist with oncology training.

Oncology pharmacist service: A component of the hospital pharmacy department that supports the local cancer care program/services. The oncology pharmacy service is responsible for chemotherapy preparation and other related services.

Personal included in the oncology pharmacy service may include: pharmacy personnel with chemotherapy preparation training; hospital pharmacist(s) with oncology training; and oncology pharmacist(s) as appropriate for level of care designation. The oncology pharmacy service meet the criteria established by these policies and procedures, and by the systemic therapy levels of care.

Ordering cancer chemotherapy policies: Provincial policies and procedures for ordering cancer chemotherapy have been approved by Cancer Care Nova Scotia, and are standards for development of district health authority policies and procedures. The ordering cancer chemotherapy policies and procedures integrate with the preparation of cancer chemotherapy policies and procedures.

Parenteral: A drug administered to a patient by a route other than enteral (via the gut). This may include intravenous, subcutaneous, intramuscular, intradermal, Intrathecal, intra vesicular, or intrahepatic. Since the integuemental barrier will be breached in administration, precaution is required to ensure the product is aseptic.

Personal protective equipment (PPE): Equipment designated for personnel to wear during administration of cancer chemotherapy, and other activities where physical exposure to cytotoxic agents and/or waste is a risk. PPE may include a gown, gloves, goggles and/or a respirator.

Gloves that meet ASTM testing standards are designated as chemotherapy gloves and are defined as «sterile disposable, powder-free non-latex gloves designed and validated for chemotherapy preparation.

Pharmacy personnel with chemotherapy preparation training: A pharmacist, pharmacy technician (or, in selected circumstances, a nurse) who has completed training and (when available) certification to prepare cancer chemotherapy.

Pre- Printed Order (PPO) Form: A preprinted order sheet approved by the appropriate Cancer Site Team and the local DHA Forms Committee (for format). For pediatric oncology, the chemotherapy order forms approved IWK will be considered as PPO for this document.

Primary engineering controls (PEC): Devices such as laminar airflow workbenches, class II biosafety cabinets, compounding aseptic isolators, and compounding aseptic containment isolator utilized specifically for compounding sterile preparations.

Reproductive toxicity: The ability to cause adverse effects to the male and/or female reproductive systems.

Respirator: A type of PPE that prevents harmful materials from entering the respiratory system, usually by filtering hazardous agents from workplace air such as N-95. A surgical mask does not offer respiratory protection.

Systemic therapy: The use of drugs for the treatment or support of cancer patients. Systemic therapy includes cancer chemotherapy, hormone therapy, immunotherapy and supportive care drugs, and includes drugs given by any route, including oral. These drugs are also used for non-cancer treatment.

Systemic therapy manual for cancer treatment: A manual listing all drugs and treatment regimens typically used within Nova Scotia. The systemic therapy manual is published and updated by the systemic therapy program of cancer care Nova Scotia.

Teratogenicity: The ability to produce fetal malformation.

Appendix 1

List of hazardous agents

List of drugs which must be handled as hazardous agents

Parenteral agents

Amsacrine	Fludarabine	Oxaliplatin
Arsenic trioxide	Fluorouracil	Paclitaxel
Azacytidine	Ganciclovir	Paclitaxel NAB
Azathioprine	Gemcitabine	Pemetrexed
Bleomycin	Ibritumomab tiuxetan	Pentostatin
Bortezomib	Y-90	Raltitrexed
Busulfan	Idarubicin	Streptozocin
Carboplatin	Ifosfamide	Strontium-89
Carmustine	Irinotecan HCL	Temsirolimus
Cisplatin	Liposomal Cytarabine	Teniposide
Cladribine	Liposomal Daunorubicin	Thiooootepa
Cyclophosphamide	Liposomao doxorubicin	Topotecan
Cytarabine	Liposomal doxorubicin	Tositumomab with I-131
Daunorubicin HCL	(pegylated)	Valrubicin

Diethylstilbestrol
Docetaxel
Doxorubicin
Epirubicin
Etoposide
Floxuridine
Mechlorethamine
Melphalan
Methotrexate
Mitomycin
Mitotane
Mitoxantrone HCL
Vinblastine sulfate
Vincristine sulfate
Vinorelbine tartrate
Zoledronic acid

Oral and non-parenteral/commercial products

Alitretinoin
Altretamine
Bexarotene
Bicalutamide
Buserelin
Capecitabine
Chlorambucil
Cyclophosphamide
Dasatinib
Fludarabine
Fulvestrant
Goserelin
Histrelin
Hydroxyurea
Lapatinib
Lenalidomide
Letrozole
Leuprolide acetate
Mercaptopurine
Methotrexate
Procarbazine
Raloxifene
Sorafenib
Tamoxifen
Temozolomide
Thalidomide
Thioguanine

Erlotinib	Lomustine	Thyrotropin
Estramustine	Medroxyprogesterone	Toremifine
Etoposide	Megestrol	Tretinoin
Exemestane	Melphalan	Triptorelin

List of drugs which are not necessary to be handled as hazardous agents

Parenteral agents

Aldesleukin	Dacarbazine	Palifermin
Alemtuzumab	Dactinomycin	Pamidronate
Amifostine	Dexamethasone	Panitumumab
Ancestim	Dexrazoxane	Pegaspargase
Asparaginase	Gemtuzumab ozogamicin	Porfimer
Asparaginase erwinia	Infliximab	Rituximab
Bacillus calmette-Guerin	Interferon alfa	Trastuzumab
Bevacizumab	Leucovorin	
Cetuximab	Mycophenolate mofetil	

Oral and non-parenteral/commercial products

Aprepitant
Anastrozole
Cyproterone
Darbepoietin
Dexamethasone
Dronabinol
Epoietin
Estramuustine
Filgrastim
Flutamide
Gefitinib
Interferon alfa
Leucovorin
Levamisole
Mitotane
Nabilone
Nilutamide
Palifermin
Pamidronate
Pegfilgrastim
Pilocarpine
Prochlorperazine

APPENDIX 2 **CHEMOTHERAPY PREPARATION AND STABILITY CHART- *Cancer Care Nova Scotia***

	To Give:	Vial Expiry ⁂		Product Expiry	Auxiliary Labels
Aldesleukin 22 million IU (1.3 mg) (Chiron) (F)(PFL) no preservative‡	1.2 mL **SWI only** do not shake; roll to reconstitute	48 h **FT**, RT‡	30–70 mcg/mL‡ 50 mL **D5W only** < 30 mcg/mL: dilute only in D5W that contains human albumin 0.1%	48 h **FT**, RT‡	- non-cytotoxic§ - do not filter - nonvesicant - latex** content not determined
	18 million IU/mL (1.1 mg/mL)	48 h **FT**, RT‡			
Alemtuzumab 30 mg/3 mL (Schering/Ilex) (F)(PFL) do not shake no preservative†	N/A- Solution source product - low protein binding filters use 5 micron filter to withdraw drug from ampoule	discard unused portion†	SC syringe 100 mL NS or D5W†	8 h **FT** or RT†	- non-cytotoxic§ - nonvesicant - latex-free - non-formulary drug
	10 mg/mL	Single use vial†			Do not shake Protect from light Refrigerate
Amifostine 500 mg (MedImmune) (RT) no preservative†	9.7 mL **NS only**	24 h FT, 5 h RT†	25–50 mL* **NS only**†	5–40 mg/mL: 24 h FT†, 5 h RT	- non-cytotoxic - discard cloudy solution - nonvesicant - latex** content not determined - non-formulary drug
	50 mg/mL	24 h FT, 5 h RT†			
Amsacrine 75 mg/1.5 mL (Pfizer) (RT) no preservative	13.5 mL supplied diluent - transfer 1.5mL from ampoule into the diluent vial	48 h RT	500 mL **D5W only**‡ glass container NOT compatible with NS solutions	7 d FT	- do NOT dilute in chloride-containing solutions; do NOT flush line with NS - contains latex - non-formulary drug
	5 mg/mL - glass syringes preferred during reconstitution - max time in plastic syringe: 15 min	24 h RT‡		72 h FT, 24 h RT‡ PVC Syringe: 15 min RT	Cytotoxic Vesicant Protect from light

Codes: ‡ Data from † § Data from Manufacturer's Product RT = room FT = SWI = sterile water for
⁂ Expiry date limited to 14 d FT for unpreserved low-risk level compounded sterile product per USP 797 water for injection
NS = normal D5W = dextrose BWI =
PFL = protect from

DRUG & STRENGTH (Storage Prior to Use, Manufacturer, Presevative Status)	Reconstitute With: To Give:	Vial Stability Vial Expiry ⁂	Product	Product Stability Product Expiry	Special Precautions/Notes Auxiliary Labels
Arsenic Trioxide 10mg/10mL ampoule Through SAP (RT) no preservative§	N/A- Solution source product	Single use ampoule	100 to 250mL D5W, NS	48 h **FT**, 24 h RT	- non-vesicant - non-formulary drug - do NOT save unused portion
	1 mg/mL	Single use ampoule			Cytotoxic
Asparaginase (asparaginase E. coli) 10,000 units (OPi) (F) no preservative†	4 mL SWI (IV doses) 0.5 to 4 mL NS (IM doses) - do not shake; roll to reconstitute Rotate gently. Discard if turbid. Use 5 µm filter to remove gelatinous fibres. Withdraw reconstituted sol within 15 min to minimize protein denaturization. Maximum IM vol/site = 2 mL. Not given SC	14 d FT, 7 d FT	syringe† 100 mL* NS or D5W†	Syringe: 14 d FT† IV: 14 d FT, 2 d RT†	- non-cytotoxic§ - nonvesicant - latex-free - Use for high dose only - 25,000 IU/m² or if vol of 12,500 IU/m² is >2 mL make 20,000 IU/mL rather than split Syringes
		48 h FT, RT†			Do not shake
	4 mL- 2500 units/mL 2 mL- 5000 units/mL 1 mL- 10000 units/mL 0.5 mL- 20000 units/mL (high dose protocol only)	**Intradermal test:** ♦ Reconstitute with 5 mL SWI to give 2000 units/mL ♦ Transfer 0.1 mL to 10 mL vial (or 12 mL syringe) ♦ Add 9.9 mL SWI roll to dissolve to give 20 units/mL ♦ 2 unit test dose = 0.1 mL (Note: the rest of the reconstituted vial has a concentration of 2000 units/mL)			
Erwinia asparaginase (asparaginase Erwinia chrysanthemi) 10,000 units (OPi) (F) no preservative†	1-2 mL NS - do not shake; roll to reconstitute	15 minutes in the original container; 8 h in glass or polypropylene syringe†	glass or polypropylene syringe	8 h in a glass or polypropylene syringe†	- non-cytotoxic§ - nonvesicant - latex** content not determined
	10,000-5,000 units/mL				

Codes: ‡ Data from † § Data from Manufacturer's Product RT = room FT = SWI = sterile water for
⁂ Expiry date limited to 14 d FT for unpreserved low-risk level compounded sterile product per USP 797 water for injection
NS = normal D5W = dextrose BWI =
PFL = protect from

DRUG & STRENGTH (Storage Prior to Use, Manufacturer, Presevative Status)	Reconstitute With: To Give:	Vial Stability Vial Expiry ⁂	Product	Product Stability Product Expiry	Special Precautions/Notes Auxiliary Labels
Asparaginase Pegylated- see **Pegaspargase**					
Azacytidine 100 mg (RT) No preservative§	4 mL SWI (SC dose) 19.9 mL SWI (IV dose)	1 h RT, 8 h FT after reconstitution†	Syringe for SC use† Lactated ringers (or D5W, NS)	Use within 1 h of reconstitution; or warm to RT for 30 min†	- non-vesicant - best freshly prepared. Increased stability in glass. Concentration <2 mg/mL not recommended. - non-formulary drug
	25 mg/mL	1 h RT, 8 h FT			Cytotoxic
BCG 81 mg (Aventis Pasteur) (F)(PFL) preservative‡	3 mL supplied diluent - do not shake; roll to reconstitute - record time of reconstitution	2 h FT, RT‡	50 mL NS‡	2 h FT or RT after reconstitution‡	- non-cytotoxic§ - nonvesicant - latex** content not determined
	10.5 ± 8.7×10^8 CFU/vial (Connaught strain)	2 h FT, RT‡			Protect from light
BCG (Organon) (F)(PFL) no preservative†	1 mL NS - do not shake; roll to reconstitute - record time of reconstitution	2 h FT†	transfer from vial to 50 mL syringe, rinse vial with another 1 mL NS. Add rinse to 50 mL syinge. QS syringe to 50 mL with NS†	2 h FT after reconstitution†	--non-cytotoxic§ - do not filter - nonvesicant - latex-free**
	1-8×10^8 CFU/vial (TICE strain)	2 h FT†			Protect from light
Bevacizumab 100 mg/4 mL 400 mg/16 mL (Roche) (F)(PFL) no preservative†	N/A- Solution source product	discard unused portion†	100 mL NS only†	48 h **FT**, RT†	- non-cytotoxic§ - nonvesicant - latex** content not determined - non-formulary drug
	25 mg/mL	Single use vial†			Do not shake

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Bleomycin 15 IU (NB: dose in units only) (BMS) (F) no preservative† (Mayne) (F)(PFL) no preservative†	7.5 mL* NS (Bristol) 7.5 mL* **NS** or SWI (Mayne) - Can be filtered through a 5 micron filter.	14 d RT, 28 d FT (or 48 h FT‡ [BMS]; 48 h FT, 24 h RT [Mayne]†)	50-100 mL* NS‡ (Bristol) 50 mL* **NS**, SWI† (Mayne) Max Conc: 3U/mL Do NOT dilute further in	NS: 24 h RT‡ (Bristol) 24 h RT (Mayne)	- nonvesicant - latex-free (Mayne); latex** content not determined (BMS) - Test dose = 1 IU in 50 mL NS, wait 2h & monitor q30min. - 1 IU = 1mg reference standard
	2 IU/mL	14 d RT, 14 d FT ⁂	D5W or ⅔-⅓	24 h RT	Cytotoxic Refrigerate
Bortezomib 3.5 mg (Millennium) (RT)(PFL) no preservative	3.5 mL NS	30 d FT, 2d RT	syringe†	5 d FT (or 8 h RT†)	- latex** content not determined - Provincial funding for specific indication
	1 mg/mL	14 d FT ⁂			Cytotoxic Irritant
Busulfan 60 mg/10 mL (Orphan Medical) (F) no preservative	N/A- Solution source product	discard unused portion†	NS or D5W (dilute in volume 10 times the busulfan volume to ~0.5 mg/mL)†	Complete administration within 12 h FT, 8 h RT: NS†, D5W	- latex** content not determined - non-formulary drug
	6 mg/mL use 5-micron nylon filter provided with ampoule to withdraw drug	Single use vial†			Cytotoxic Vesicant
Carboplatin 50 mg/5 mL 150 mg/15 mL 450 mg/45 mL (Mayne, Novopharm) (RT)(PFL) no preservative	N/A- Solution source product	7 d RT (or: discard unused portion† (Mayne); 8 h RT † (Novopharm)	D5W (IV): 250-500 mL Conc Range (0.5-4 mg/mL) (NS not recommended as diluent) <125 mg -100mL D5W 125-750 mg –250mL D5W >750 mg -500mL D5W	21 d FT, 7 d RT (or 24 h RT, 48 h FT† [Mayne]; 8 h RT † [Novopharm])	- nonvesicant - latex** content not determined (Mayne) - do not use aluminum needles - latex-free** (Novopharm)
	10 mg/mL	7 d RT		14 d FT ⁂, 7 d RT	Cytotoxic Protect from light

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Carmustine 100 mg (Bristol Labs) (F) no preservative	3 mL diluent (supplied) - diluent to reach RT, then dissolve drug with 3 mL diluent; add 27 mL SWI - discard if oily film in vial	24 h FT, 8 h RT†	glass†, or polyolefin container 500 mL D5W	24 h FT: in glass† or polyolefin container use within 6 hours of reconstitution: RT	- do not use if product has oily droplets - latex** in diluent stopper[9] - no latex** in product stopper or drug product - best fresh prepared - administer through polyethylene-lined (non-PVC) nitro tubing set.
	3.3 mg/mL in 10% ethanol†	24 h FT, 8 h RT†			Cytotoxic Vesicant Protect from light
Cetuximab 100 mg/50 mL (BMS) (F) do not dilute no preservative†	N/A- Solution source product	discard unused portion†	syringe† sterile evacuated container (e.g., glass bottle, polyolefin bag, ethylene vinyl acetate bag, DEHP plasticized PVC bag, or PVC bag)†	12 h FT, 8 h RT†	- non-cytotoxic§ - use 0.22 micron in-line filter to administer - nonvesicant - latex** content not determined - non-formulary drug
	2 mg/mL†	Single use vial†			Do not shake
Cisplatin 1 mg/10 mL 50 mg/50 mL 100 mg/100mL (Mayne) (RT)(PFL) no preservative† continued…	N/A- Solution source product	28 d RT (or 48 h RT‡)	NS, (IV): 250 mL or 500 mL (1000 mL for BMT-Max Conc: 1 mg/mL) (DHAP protocol- divide dose in 3L NS with mannitol 20g/L [total volume]): ⅔-½, 3% NaCl, D5-NS, D5-1/2S; D5-NS with mannitol; D5-1/2S with mannitol†; D5W-1/3S with mannitol†	14 d RT, 14 d FT (if concentration < 0.5 mg/mL)	- must be diluted in chloride-containing solutions - latex stoppers - do not use aluminum needles - IV sol must contain ≥0.2% NaCl. - do not refrigerate. - may be filtered from viaflex bag into a bottle using 5 µm filter - advance mixing with mannitol increases risk of complex forming.
	1 mg/mL	48 h RT‡		48 h RT‡ Cisplatin + Mannitol: 48 h RT Cisplatin + KCl: 24 h RT	Cytotoxic Irritant

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DRUG & STRENGTH (Storage Prior to Use, Manufacturer, Presevative Status)	Reconstitute With: / To Give:	Vial Stability / Vial Expiry ⁂	Product	Product Stability / Product Expiry	Special Precautions/Notes / Auxiliary Labels
Cladribine 10 mg/10 mL (Janssen-Ortho) (F)(PFL) no preservative	N/A- Solution source product	30 d FT, 7 d RT (or- discard unused portion†)	500 mL **NS only**† Maximum concentration 0.1 mg/mL For Pharmacia cassette or Aim pump, dilute with BSI and filter with 0.22µ hydrophilic filter	7 d RT 14 d RT (BSI diluent, conc. 0.15-0.3 mg/mL using Infusor) (or- 24 h **RT**†)	- shake vigorously to dissolve any precipitates from refrigeration - use 0.22µ hydrophilic filter for drug and diluent when preparing cassette - nonvesicant - latex-free** - formulary: Restricted drug
	1 mg/mL	14 d FT ⁂ after vial punctred			Cytotoxic Protect from light
Cyclophosphamide non-lyophilized 1000 mg, 2000 mg (BMS) (RT) 200 mg, 500 mg, 1000 mg, 2000 mg (Baxter) (RT)(PFL) no preservative	SWI (BMS) 1000 mg: 50 mL 2000 mg: 100 mL **NS** (Baxter) 200 mg: 10 mL 500 mg: 25 mL 1000 mg: 50 mL 2000 mg: 100 mL	28 d FT, 4 d RT	< 1 g: 100 NS* > 1 g: 250 NS* high dose in BMT: may need 500 NS* **NS**, D5W, ⅔-⅓, D5NS, D5, Ringer's, Lactated Ringer's, Sodium Chloride 0.45%, Sodium Lactate† (BMS)	30 h RT, 30 d FT in NS, 6 d FT in D5W (or- 6 d FT, 24 h RT [BMS]†; 72 h FT, 24 h RT [Baxter] †)	- nonvesicant - latex-free** (BMS); latex** content not determined (Baxter) - best if administered in a.m. with proper hydration - if present, remove small black particles from reconstituted solution with 5 µm filter - may be used to prepare oral liquids.
	20 mg/mL	6 d FT, 24 h RT (or- 48 h FT†)		30 h RT, 14 d FT ⁂	Cytotoxic
Cytarabine 100 mg/1 mL 500 mg/5mL 1000 mg/10mL 2000 mg/20mL (Mayne) (RT) no preservative†	N/A- Solution source product record time of puncture - can be filtered through a 5 µm filter	7 d RT	0.1-0.8 mg/mL 100-1000 mL* **NS**, Water for Injection, D5W, Lactated Ringer's <150mg in 250mL ≥150mg in 500mL	14 d FT, 14 d RT	- nonvesicant - latex stopper** - discard if solution is hazy
	100 mg/mL	72 h FT, 24 h RT from initial vial puncture†			Cytotoxic

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Cytarabine IT injection: 100 mg/1 mL 500 mg/5 mL (Mayne) (RT) no preservative†	N/A- Solution source product	24 h RT†	diluents containing preservatives should **NOT** be used for Intrathecal administration† qs to 6 mL with preservative free NS	use within 4 hours of initial puncture	- auxiliary label to include route in full (i.e., INTRATHECAL injection) attached to both syringe and outer ziplock bag - nonvesicant - latex stopper**
	100 mg/mL	24 h RT†			Cytotoxic INTRATHECAL injection
Cytarabine SC injection: 100 mg, 1000 mg vial (Pfizer) (RT)(PFL)	BWI 100 mg: 5 mL 500 mg: 10 mL 1000 mg: 10 mL 2000 mg: 20 mL	30 d FT, 7 d RT (or 14 d FT ⁂) (or- 48 h RT†)	syringe	14 d FT, 48 h RT	- for high dose use, do not use diluent containing benzyl alcohol - nonvesicant - latex-free**(Pfizer); latex** content not determined (Novopharm)
100 mg, 500 mg, 1000 mg, 2000 mg vial (Novopharm) (RT)(PFL) no preservative‡	100 mg: 20 mg/mL 500 mg: 50 mg/mL 1000 mg: 100 mg/mL 2000 mg: 100 mg/mL	14 d FT ⁂			Cytotoxic
Dacarbazine 200 mg 600 mg (Mayne) (F)(PFL) no preservatives†	200 mg: 19.7 mL SWI 600 mg: 59.1 mL SWI (may use reconstitution device)	96 h FT, 8-24 h RT	0.19–3.0 mg/mL 250-500 mL* **NS** or D5W ≤750mg in 250mL >750ml in 500mL	24 h FT, 8 h RT	- latex stopper** - discard if solution turns pink-orange color, indicating drug decomposition
	10 mg/mL	48 h FT†, 8 h RT†			Cytotoxic Irritant Protect from light
Dactinomycin 0.5 mg (Merck Frost) (RT)(PFL) no preservative†	1.1 mL SWI	48 h **FT**, 24 h RT	syringe infusion: 50 mL* D5W, NS	Syringe: 48 h FT IV: 24 h **FT**, RT	- do not filter - latex-free
	0.5 mg/mL (500 mcg/mL)	48 h **FT**, 24 h RT			Cytotoxic Vesicant Protect from light

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Daunorubicin 20 mg (Novopharm) (RT)(PFL) no preservative†	4 mL SWI - can be filtered through a 5 µm filter	7 d RT	50-250 mL **NS** or D5W† Max concentration 5 mg/mL	Syringe: 43 d RT IV: 4 wk RT	- latex-free - discard if reconstituted solution changes color from red to blue - may cause red discoloration of urine for 1-2 days
	5 mg/mL	24 h RT, 48 h FT†		24 h RT, 48 h FT†	Cytotoxic Vesicant Protect from light
Daunorubicin Liposomal- see **Liposomal Daunorubicin**					
Dexrazoxane 250 mg 500 mg (Pfizer) (RT) no preservative†	supplied diluent : 250 mg: 25 mL 500 mg: 50 mL (may use Reconstitution device)	6 h FT, RT†	empty viaflex bag†	6 h FT, RT†	- non-cytotoxic § - nonvesicant - latex-free** - do not filter - use chemo precautions - administer in a window 30 mins prior to and 15 mins post doxorubicin. - formulary: Restricted drug
	10 mg/mL†	6 h FT, RT†			
Docetaxel 20 mg/0.5 mL 80 mg/2 mL (Aventis) (PFL) no preservative†	supplied diluent (13% ethanol): - if vials were refrigerated, allow to warm for 5 min at RT. Withdraw entire contents of the diluent and mix by repeated inversions for 45 sec – DO NOT SHAKE. - Let sit for 5 minutes.		**NS** or D5W 250 mL (concentration should be between 0.3-0.74 mg/mL) † -use Excel bags -max dose in 250 mL is 185 mg; for larger doses use larger bag -add to IV bag and manually rotate	28 d RT	- non-PVC bag and tubing only - latex-free** syringe - use nitroglycerin tubing. - do not use in-line filter. DO NOT FILTER - formulary: Restricted drug
	10 mg/mL	8 h **FT**, RT†		complete administration within 4 h **FT,** RT†	Cytotoxic Irritant Protect from light

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Doxorubicin 10 mg, 50 mg, 150 mg (Mayne) (RT)(PFL) 10 mg/5 mL, 20 mg/10 mL, 50 mg/25 mL 200 mg/100 mL (Novopharm) (F)(PFL) no preservative†	NS, SWI, D5W (NS reconstitution takes longer) 10 mg: 5 mL 50 mg: 25 mL 150 mg: 75 mL	30 d FT, 7 d RT (or- 48 h FT, 24 h RT [Mayne]; 8 h RT [Novopharm])	syringe† (Mayne, Novopharm) IV: Conc 0.2–2 mg/mL 100 mL* NS (Mayne) Max Conc 5 mg/mL	24 d RT, 43 d FT Syringe: 30 d FT, 7 d RT IV: 30 d FT, 7 d RT	- latex stopper** (Mayne); latex** content not determined (Novopharm) - may cause red discoloration of urine for 1-2 days
	2 mg/mL	7 d RT, 14 d FT ⁂		Syringe: 48 h FT, 24 h RT† IV: 48 h FT, 24 h RT	Cytotoxic Vesicant Protect from light
Doxorubicin Liposomal- see **Liposomal Doxorubicin** **Doxorubicin Pegylated Liposomal-** see **Liposomal Doxorubicin (Pegylated)**					
Epirubicin 10 mg/5 mL 50 mg/25 mL 200 mg/100 mL (Pfizer) (F)(PFL) no preservative†	N/A- Solution source product - record time of puncture	150 d FT,RT (or- 30 d FT, 24 h RT) (or- 8 h **FT**, RT†)	syringe† 50-100 mL* **NS** or D5W	Syringe: 150 d FT,RT (or- 30 d FT, 24 h RT) IV: 20 d RT, 43 d FT	- latex-free** - may cause red discoloration of urine for 1-2 days
	2 mg/mL	14 d FT ⁂, 24 h RT		Syringe: 48 h FT, 24 h RT† IV: 2 d **FT**, RT: NS or D5W	Cytotoxic Vesicant Protect from light
Etoposide 100 mg/5 mL 200 mg/10 mL 500 mg/25 mL 1000 mg/50 mL (BMS) (RT) (Novopharm) (RT)(PFL) preservative†	N/A- Solution source product	30 d RT (or- 14 h RT [BMS]; discard unused portion [Novopharm]†)	**NS**, D5W, ⅔-⅓ (IV): Excel bag ≤200 mg in 500 mL 201-235 mg in 600 mL Max Conc 0.4 mg/mL [larger doses may be prepared in an	4 h RT† [Novopharm]	- use non-PVC bag and tubing only - latex** content not determined - Discard cloudy solution. Check sol periodically for precipitate. Use 22 micron filter if needed. - Do not refrigerate - USE EXCEL BAGS
	20 mg/mL	14 d FT ⁂, 14 h RT	appropriate volume to maintain a concentration ≤0.4 mg/mL]	0.2 mg/mL: 96 h 0.4 mg/mL: 24 h 0.6 mg/mL: 8 h 1.0 mg/mL: 2 h RT† (BMS)	Cytotoxic Irritant

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Fludarabine 50 mg (Berlex) (F) no preservative†	2 mL SWI	16 d **FT**, RT (or- 48 h **FT** or RT†)	may be further diluted to 1 mg/mL† 50-100 mL* **NS** or D5W	16 d **FT**, RT	- nonvesicant - latex-free** - do not filter
	25 mg/mL	14 d FT ⁂, 24 h RT		48 h **FT** or RT†	Cytotoxic
Fluorouracil 5000 mg/100 mL (Mayne) (RT)(PFL) no preservative†	N/A- Solution source product	7 d RT	Syringe May be further diluted to 2 mg/mL in D5W† NS, D5W, ⅔-⅓ (IV): 50-1000mL CIVI Infusors - 1.5 mL/h TV 275 mL 5 mL/h-TV 240 mL and 10 mL/h-TV 240 mL or 275 mL. Use D5W only for Infusors.	Syringe: 7 d RT IV: 123 d FT, 38 d RT (Conc. Range 0.1 to 50 mg/mL)	- latex-free** - heat or shake gently if precipitate forms - slight discoloration does not alter potency - may be filtered - do not refrigerate/freeze - stable in cassettes, Infusors (latex free)
	50 mg/mL	8 h RT†		Syringe: 48 h RT 24 h RT† IV: 14 d RT CIVI: complete within 8 d RT	Cytotoxic Irritant Protect From Light
Gemcitabine 200 mg 1000 mg (Eli-Lilly) (RT) no preservative†	200 mg: 5 mL NS 1000 mg: 25 mL NS (may use Reconstitution device)	35 d RT, 7 d FT (or-48 h RT†)	syringe† 0.1–10 mg/mL† 250 mL NS	35 d RT, 7 d FT IV: 30d FT, 7 d RT	- non-vesicant - latex-free** - formulary: Restricted drug
	38 mg/mL	7 d RT		Syringe: 48 h RT IV: 48 h **FT**, RT†	Cytotoxic
Gemtuzumab ozogamicin 5 mg (F) no preservative§	5 mL SWI - Reconstitute with fluorescent lights turned off	8 h **FT**	100 mL NS	Administer over 2 h immediately after dilution	- dispense and administer inside UV protection overwrap bag - use 1.2 micron terminal filter/low protein binding - non-formulary drug
	1 mg/mL				Cytotoxic Protect from light

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Ibritumomab tiuxetan - Kit with: 3.2 mg Ibritumomab tiuxetan in 2 mL NS vial; sodium acetate vial; buffer vial; empty reaction vial (Berlex) (F) no preservative§	Prepare according to mfgr instructions; use radionuclide protection ---	Use immediately after reconstitution and radioisotope labelling		N/A	- radiation hazard - prepared and handled by nuclear medicine dep't. - non-formulary drug Vesicant
Idarubicin 5 mg 10 mg (Pfizer) (RT)(PFL) no preservative†	vial under negative pressure 5 mg: 5 mL SWI 10 mg: 10 mL SWI	7 d **FT** (or- 48 h FT, 24 h RT†)	Syringe 50 mL NS, D5W	Syringe: 48 h FT, 24 h RT†	- latex-free** - do not use bacteriostatic diluent - do not filter - may cause red discoloration of the urine for 1-2 days.
	1 mg/mL	72 h **FT**, RT		Syringe: 24h RT IV: 72h RT	Cytotoxic Vesicant Protect From Light
Ifosfamide 1000 m g 3000 mg (Baxter) (RT) no preservative†	1000 mg: 20 mL SWI 3000 mg: 60 mL SWI shake well (may use reconstitution device)	42 d FT, 7 d RT (or- 72 h **FT**†)	NS, D5W (IV): ≤2000 mg in 250 mL >2000 mg in 500 mL Conc. Range 0.6–20 mg/mL†	30 d FT, 7 d RT (or- 24 h **FT,** RT when mixed with mesna)	- nonvesicant - latex-free* - solution strength should not exceed 4% - administration of mesna is mandatory for all patients receiving ifosfamide
	50 mg/mL	14 d FT ⁂, 24 h RT		72 h **FT**† Mixed with mesna in same IV solution- Give 30h expiry.	Cytotoxic

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Interferon Alfa -2b 18 million IU/3 mL 25 million IU/2.5 mL (Schering) (F)(or up to 7 days at RT before use) no preservative†	N/A- Solution source product	48 h FT†	syringe† IV: ≥ 0.3 million IU/mL† 50 mL NS† (Note: different volume of diluent than powder, due to different stabilizers in each product formulation)	Syringe: 14 d RT, 42 d FT IV: 24 h **FT**, RT	- non-cytotoxic§ - nonvesicant - latex-free** - formulary: Restricted drug
	6 million IU/mL 10 million IU/mL	48 h FT†		Syringe: 2 d FT IV: 24 h **FT**, RT	
Interferon Alfa -2b 10 million IU 18 million IU (Schering) (F) no preservative†	1 mL supplied diluent (SWI) or 1 mL BWI do not shake; roll to reconstitute	SWI Diluent: 24 h **FT**, RT† BWI Diluent: 30 d FT, 14 d RT (or- 48 h **FT**, RT†)	SWI Diluent: syringe†, > 0.1 million IU/mL 100 mL NS (preferred for IV doses) BWI Diluent: syringe, (100 mL NS- not recommended for IV doses)	SWI Diluent: 24 h **FT**, RT- syringe, IV BWI Diluent: 7 d FT- syringes (or- 14 d F, 48 h RT†)	- non-cytotoxic§ - formulary: Restricted drug
	10 million IU/mL 18 million IU/mL				
Interferon Alfa -2b for Bladder Instillation 10 million IU/3 mL (Schering) (F)(or up to 7 days at RT before use) no preservative†	1 mL supplied diluent (SWI) or 1 mL BWI do not shake; roll to reconstitute	14 d RT, 30 d FT	5 or 10 vials drawn into 60 mL syringe, qs to 50 mL with NS	24 h FT	- non-cytotoxic§ - formulary: Restricted drug
	10 million IU/mL	48 h FT			Bladder Instillation only- Do NOT use IV
Irinotecan 40 mg/2 mL 100 mg/5 mL 500 mg/25 mL (Mayne) (RT)(PFL) (Pfizer) (RT)(PFL) no preservative†	N/A- Solution source product	30 d FT,RT after puncture (or- 2 days RT [Mayne]; discard unused portion [Pfizer]†)	500 mL **D5W** (preferred), NS† Conc range= 0.12– 2.8 mg/mL†	24 h RT: D5W, NS† 48 h FT: D5W†	- do NOT refrigerate if in NS - nonvesicant - latex** content not determined (Mayne); latex-free (Pfizer) - formulary: Restricted drug
	20 mg/mL	14 d FT ⁂, 7 d RT			Cytotoxic Protect From Light

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Leucovorin 50 mg/5 mL 500 mg/50 mL (Mayne) (F)(PFL) no preservative†	N/A- Solution source product	5 mL vial: discard unused portion† 50 mL vial: 8 h **FT,** RT	syringe may be further diluted to 0.05 mg/mL† 50-250 mL* NS, D5W, Lactated Ringer's, Ringer's, D10W, D5-NS	Syringe: 48 h FT 24 h RT†: **NS**, D5W, Lactated Ringer's, Ringer's 8 h RT†: D10W, D5-NS	- non-cytotoxic - non-vesicant - latex-free**
	10 mg/mL	8 h **FT,** RT			
Liposomal Cytarabine 50 mg/5 mL (F) no preservative§	N/A- Solution source product Warm to RT, then gently agitate to re-suspend liposomes	Single use vial		4 h RT	- do not filter - for intrathecal administration - label to include route in full (i.e., INTRATHECAL injection) attached to both syringe and outer ziplock bag - non-vesicant - non-formulary drug
	10 mg/mL			Use immediately after withdrawal from vial	Cytotoxic INTRATHECAL injection
Liposomal Daunorubicin 20 mg/10 mL (F) no preservative§	N/A- Solution source product Warm to RT, then gently agitate to re-suspend liposomes	Single use vial	D5W 1 to 1 with liposomal daunorubicin dose	6 h RT	- do not filter - non-formulary drug
	2 mg/mL				Cytotoxic Protect from light
Liposomal Doxorubicin 50 mg; 2 mL liposomes vial; 3.1 mL buffer vial (Sopherion) (F) no preservative§	20 mL NS Shake well and heat in water bath (55-60°C) for 10-15 min; admix 1.9 mL liposomes into buffer vial,shake well and withdraw contents to admix into warm doxorubicin solution; shake vigorously then wait 10 minutes	Single use vial	250 mL (doses < 90 mg) or 500 mL (doses ≥ 90 mg) D5W	8 h RT; 72 h FT	- do not filter - non-formulary drug
	2 mg/mL				Cytotoxic Irritant

Codes: ‡ Data from † § Data from Manufacturer's Product RT = room FT = SWI = sterile water for
⁂ Expiry date limited to 14 d FT for unpreserved low-risk level compounded sterile NS = normal D5W = dextrose BWI =
product per USP 797 water for injection PFL = protect from

DRUG & STRENGTH (Storage Prior to Use, Manufacturer, Presevative Status)	Reconstitute With: To Give:	Vial Stability Vial Expiry ᵡ	Product	Product Stability Product Expiry	Special Precautions/Notes Auxiliary Labels
Liposomal Doxorubicin (Pegylated) 20 mg/10 mL 50 mg/25 mL (Schering) (F) no preservative†	N/A- Solution source product 2 mg/mL	Single use vial discard unused portion†	Doses up to 90 mg: 250 mL **D5W only**† Doses over 90 mg: 500mL **D5W only**	24 h F†	- do not filter - latex-free** syringe - formulary: Restricted drug Cytotoxic Vesicant
Mechlorethamine 10 mg (Merck) no preservative†	10 mL SWI or NS - do NOT use if discoloured or water droplets form in vial before reconstitution 1 mg/mL	1 h RT, 6 h FT use immediately, or within 4 hours of reconstitution	syringe† (100 mL NS- not recommended)	1 h RT, 6 h FT complete administration within 4 hours of reconstitution†	- latex** content not determined - do not refrigerate - prepare immediately before use - neutralize all excess solution with sodium thiosulfate solution Cytotoxic Vesicant
Melphalan 50 mg (GSK) (RT)(PFL) no preservative†	10mL supplied diluent - immediately after adding diluent, shake vigorously†, or use centrifuge to mix 5 mg/mL	2 h RT† do NOT refrigerate	IV: NS 100 mL Conc range= 0.1– 0.45 mg/mL (e.g., >45 mg and <110 mg in 250 mL NS)*	90 min RT from time of initial reconstitution	- latex-free** - reduced stability and increased degradation with rise in temperature - do not dilute with dextrose solutions - do not refrigerate - can be filtered through a 5 µm filter. Cytotoxic Vesicant Protect From Light
Mesna 400 mg/4 mL 1000 mg/10 mL (PPC) (RT) preservative†	N/A- Solution source product 100 mg/mL	14 d FT, RT† 14 d FT, RT†	> 1mg/mL† NS or D5W	48 h FT, 24 h RT†	- non-cytotoxic - nonvesicant (diluted) - irritant (undiluted) - latex** content not determined

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NS = normal D5W = dextrose BWI = PFL = protect from

DRUG & STRENGTH (Storage Prior to Use, Manufacturer, Presevative Status)	Reconstitute With: / To Give:	Vial Stability / Vial Expiry ⁂	Product	Product Stability / Product Expiry	Special Precautions/Notes / Auxiliary Labels
Methotrexate 50 mg/2mL 500 mg/20mL 1 g/40mL 5 g/200mL (Mayne) (RT)(PFL) no preservative†	N/A- Solution source product	PFL vials: discard unused portion† 500mg, 1 g mL, 5 g mL: 8 h **FT,** RT†	syringe IV: **NS**, D5W 1-20 mg/mL ≤100 mg in 50 mL 101-200 mg in 100 mL 201-500 mg in 250 mL 501-1000 mg in 500 mL continuous infusion in 1000 mL x 3 doses high dose (e.g., 1-8 g/m²): 500–1000 mL	Syringe: 2 d **FT**, RT IV: 24 h RT† Methotrexate high dose (3.5g/m²) + NAHCO3 50 mEq/L in D5W 500 mL or 1L. Stable 24h at RT	- for high-dose regimens (e.g., 1-8 g/m² as a single dose) use preservative-free methotrexate - nonvesicant - latex-free** - do not refrigerate - can be filtered through a 5 µm filter.
	25 mg/mL				Cytotoxic Protect From Light
Methotrexate 50 mg/2mL 500 mg/20mL (Mayne) (RT)(PFL) preservative†	N/A- Solution source product	30 d RT (preserved vials), 24 h FT	syringe 0.4–2 mg/mL† e.g., 100 mL* **NS**, D5W†	Syringe: 30 d RT (or- 7 d **FT**†) IV: 5 d RT, 14 d FT (or- 24 h RT†)	- non-vesicant - latex-free** - do not refrigerate - can be filtered through a 5 µm filter
	25 mg/mL			Syringe: 7 d **FT**† IV: 24 h RT†	Cytotoxic Protect From Light
Methotrexate IT Injection: Only preservative free methotrexate may be administered by the intrathecal route 20 mg/2mL (Mayne) (RT)(PFL) no preservative†	N/A- Solution source product	Single use vial discard unused portion†	preservative free NS, SWI or CSF (volume as per protocol)	use within 4 hours of initial puncture	- auxiliary label: "IT" - label to include route in full (i.e., INTRATHECAL injection) attached to both syringe and outer ziplock bag - nonvesicant - latex-free**
	10 mg/mL				Cytotoxic INTRATHECAL injection

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NS = normal D5W = dextrose BWI =
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DRUG & STRENGTH (Storage Prior to Use, Manufacturer, Presevative Status)	Reconstitute With: To Give:	Vial Stability Vial Expiry ⁂	Product	Product Stability Product Expiry	Special Precautions/Notes Auxiliary Labels
Mitomycin 5 mg, 20 mg (Novopharm) (RT)(PFL) 5 mg, 20 mg (BMS) (RT)(PFL) no preservative†	SWI 5 mg: 10 mL 20 mg: 40 mL Mild agitation to dissolve (may use reconstitution device) (BMS)	14 d FT, 7 d RT (or- 48 h FT, RT†)	syringe 50-100 mL* **NS**, D5W, sodium lactate† Conc range= 0.02-0.04 mg/mL;	4 d RT, 14 d FT	- can be filtered through a 5 µm filter - latex-free** (stopper or product) (Novopharm); latex stopper**(BMS)
	0.5 mg/ mL†	14 d FT, 7 d RT	Max conc 0.6 mg/mL	Syringe: 12 h RT IV: 3 h RT: D5W 12 h RT: NS 24 h RT: sodium lactate†	Cytotoxic Vesicant Protect From Light
Mitomycin for Bladder Instillation 20 mg (Novopharm, BMS) (RT)(PFL)	20 mL SWI Mild agitation to dissolve	12 h RT (1 mg/mL solution)	Dose drawn into 60 mL syringe, qs to 50 mL with NS	Syringe: 12 h RT	- intravesicular use: mix at 1 mg/mL concentration; NOT to be used IV or refrigerated - can be filtered through a 5 µm filter
	1 mg/mL				Cytotoxic Bladder Instillation only- Do NOT use IV Protect From Light
Mitoxantrone 20 mg/10mL (Mayne) (RT)(PFL) 20 mg/10 mL 25 mg/12.5 mL (Wyeth) (RT)(PFL) no preservative†	N/A- Solution source product	30 d FT, 7 d RT in glass container (or- discard unused portion†)	Syringe IV: 50 mL **NS**, D5W† Max conc 0.4 mg/mL	Syringe: 30 d FT, 7 d RT IV: 7 d **FT**, RT (or- NS: 24 h **FT**, RT; D5W: 72 h FT, 24 h RT† [Mayne]; 24 h RT†[Wyeth])	- latex-free**(Mayne); latex** content not determined (Wyeth) - may cause a blue-green discoloration to the urine for 1-2 days - can be filtered through a 5 µm filter
	2 mg/mL	14 d FT ⁂, 7 d RT		Syringe: 7 d **FT** IV: 7 d **FT**, RT	Cytotoxic Irritant Protect from light

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NS = normal D5W = dextrose BWI =
PFL = protect from

DRUG & STRENGTH (Storage Prior to Use, Manufacturer, Presevative Status)	Reconstitute With: / To Give:	Vial Stability / Vial Expiry ⁂	Product	Product Stability / Product Expiry	Special Precautions/Notes / Auxiliary Labels
Oxaliplatin 50 mg, 100 mg (Sanofi-Aventis) (RT)† 50 mg, 100 mg (Mayne) (RT) no preservative†	SWI, D5W: 50 mg: 10 mL 100 mg: 20 mL do **NOT** use NS or other chloride-containing solutions (degrades) (may use reconstitution device) (Sanofi-Aventis)	24 h **FT** discard unused portion (Mayne)†	≥ 0.2 mg/mL 250–500 mL D5W Do **NOT** use NS or other chloride-containing solutions (degrades) †	24 h FT†, 6 h RT† 24 h FT (Mayne)†	- latex-free (Sanofi-Aventis); latex** content not determined (Mayne, Sigmacon) - non-formulary drug
50 mg, 100 mg (Sigmacon) (RT) no preservative†	5 mg/mL	24 h **FT**			Cytotoxic Irritant
Oxaliplatin 50 mg/10 mL 100 mg/20 mL (Sanofi-Aventis) (RT) no preservative†	N/A- Solution source product	Single use vial discard unused portion†	250–500 mL D5W† 0.2-2 mg/mL† Do **NOT** use NS or other chloride-containing solutions (degrades) †	24 h FT†, 6 h RT† Stable 6 more hours at RT once removed from fridge	- latex-free - non-formulary drug
	5 mg/mL				Cytotoxic Irritant
Paclitaxel 30 mg/5 mL 100 mg/16.7 mL 300 mg/50 mL (BMS) (RT)(PFL) † 30 mg/5 mL 100 mg/16.7 mL 300 mg/50 mL (Biolyse) (F) (may store at RT for 2 months) † no preservative	N/A- Solution source product Warm vial to RT if stored at FT; discard if precipitate present after warming. Do NOT use filter disk or filter needle to withdraw dose from vial	30 mg: 48 h RT† 100 mg: 48 h RT† 300 mg: 24 h RT† (BMS) 8 h RT (Biolyse)†	**NS**, D5W (IV): 500 mL Conc Range 0.3-1.2 mg/mL in **NS**, D5W, D5-NS, D5 in Ringer's (BMS)† (e.g.,100–1000 mL)* 0.3–1.2 mg/mL in **NS**, D5W (Biolyse)† (e.g.,100–1000 mL)* ☐ <75 mg in 100 mL NS ☐ 75-300 mg in 250 mL NS ☐ >300-500 mg in 500mL NS	Glass bottle 27h RT. Polyolefin bag (McGaw Excel Bags) 72h at RT (or- 24 h RT†)	- administer in a glass bottle (or polyolefin bag), through polyethylene-lined nitro tubing/Taxol infusion set and use a 0.22µm inline filter - solution may have a slight haze - contains Cremophor EL - do not use with patients with previous hypersensitivity to cyclosporin IV - latex-free** (BMS); latex** content not determined (Biolyse) - formulary: Restricted drug
	6 mg/mL	48 h RT†			Cytotoxic Irritant Protect from light

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product per USP 797 water for injection PFL = protect from

DRUG & STRENGTH (Storage Prior to Use, Manufacturer, Presevative Status)	Reconstitute With: To Give:	Vial Stability Vial Expiry ⁂	Product	Product Stability Product Expiry	Special Precautions/Notes Auxiliary Labels
Paclitaxel NAB (Nanoparticle Albumin-Bound) 100 mg (Abraxis) no preservative§	20 mL NS Slowly inject diluent down inside wall of vial, let sit for 5 min, then swirl gently for 2 minutes	8 h RT, FT	Empty sterile PVC infusion bag	8 h RT, FT	- do NOT use in-line filter - protect from blue light - non-formulary drug
	5 mg/mL	8 h RT, FT			Cytotoxic Irritant
Pamidronate 30 mg/10 mL 60 mg/10 mL 90 mg/10 mL (Mayne) (RT) no preservative†	N/A- Solution source product		0.06–0.36 mg/mL **NS**, D5W† Do **NOT** mix with calcium containing solution (e.g., Ringer's) † e.g., 250 mL NS	24 h FT followed by 24 h RT (total 48 h) †	- non-cytotoxic - non-vesicant - latex-free** - formulary: Restricted drug
	3 mg/mL 6 mg/mL 9 mg/mL				Protect from light
Pegaspargase PEG-asparaginase (pegasparagase) (pegylated asparaginase E. coli) 750 units/mL (Enzon) (F) no preservative†	N/A- Solution source product	Single use vial discard unused portion†	IM : maximum volume 2 mL; if >2 mL use multiple sites† IV: 100 mL NS or D5W (given over 1-2 h) †	syringe: 4 h† bag: 4 h†	- non-cytotoxic§ - nonvesicant - latex** content not determined - discard cloudy solution - do not use if stored out of refrigerator for >48 h - do not use if previously frozen - non-formulary drug
	750 units/mL				Do not shake
Pemetrexed 500 mg (Eli Lilly) (RT) no preservative†	20 mL NS	24 h **FT**, RT†	Dilute with NS to total volume 100 mL Do **NOT** mix with calcium containing solution (e.g., Ringer's) †	24 h **FT**, RT	- non-vesicant - latex** content not determined - non-formulary drug
	25 mg/mL	24 h **FT**, RT†			Cytotoxic

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product per USP 797 water for injection PFL = protect from

DRUG & STRENGTH (Storage Prior to Use, Manufacturer, Presevative Status)	Reconstitute With: / To Give:	Vial Stability / Vial Expiry ⁂	Product	Product Stability / Product Expiry	Special Precautions/Notes / Auxiliary Labels
Porfimer 15 mg 75 mg (Axcan) (RT)(PFL) no preservative†	6.6 mL D5W 31.8 mL D5W†	24 h FT (PFL) †	syringe†	use within 4 h of initial reconstitution	- non-cytotoxic - latex-free - non-formulary drug
	2.5 mg/mL†				Irritant
Raltitrexed 2 mg (AstraZeneca) (**F**, RT)(PFL) no preservative†	4 mL SWI	24 h **FT**, RT†	50–250 mL **NS**, D5W†	24 h **FT**, RT†	- nonvesicant - latex-free** - formulary: Restricted drug
	0.5 mg/mL	24 h **FT**, RT†			Cytotoxic
Rituximab 100 mg/10 mL 500 mg/50 mL (Roche) (F)(PFL) no preservative†	N/A- Solution source product	Single use vial discard unused portion†	1–4 mg/mL in **NS,** D5W† (e.g., 500 mg/250 mL, 1000 mg/500 mL) Gently invert to mix	24 h FT + additional 12 h RT†	- non-cytotoxic - non-vesicant - latex-free** - can be filtered through a 5 µm filter - Provincial funding for specific indications - formulary: Restricted drug (other indication)
	10 mg/mL				Protect from light Do not shake
Streptozocin 1g (Pfizer) (F)(PFL) no preservative†	9.5mL **NS**, SWI, D5W	96 h FT, 48 h RT	syringe† 100 ml (50-500 mL) **NS**, D5W†, ⅔-⅓	96 h FT, 48 h RT	- latex-free**
	100 mg/mL	48 h FT, 24 h RT†		48 h FT, 24 h RT†	Cytotoxic Vesicant

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DRUG & STRENGTH (Storage Prior to Use, Manufacturer, Presevative Status)	Reconstitute With: To Give:	Vial Stability Vial Expiry ⁂	Product	Product Stability Product Expiry	Special Precautions/Notes Auxiliary Labels
Teniposide 15 mg/1.5 mL amp (Bristol) Preservative‡	N/A- Solution source product Do NOT filter ampoule contents	Single use vial discard unused portion‡	0.1, 0.2, 0.4, or 1 mg/mL in **NS** or D5W‡	0.1, 0.2, 0.4 mg/mL: 24 h RT 0.5-1 mg/mL: complete administration within 4 h‡	- administer in a glass bottle (or polyolefin bag), through polyethylene-lined nitro tubing/Taxol infusion set - contains Cremophor EL - do not use with patients with previous hypersensitivity to cyclosporin IV - do NOT refrigerate - do not filter - do not administer through port-a-catheter - latex-free
	10 mg/mL				Cytotoxic Irritant Protect from light
Thiotepa 15 mg (Bedford) (F)(PFL) no preservative†	1.5 mL SWI†	28 d FT, 7 d RT (or 14 d FT ⁂) (or- 8 h FT†)	IV: 50 mL NS, D5W, ⅔-⅓:	24h RT: 1, 3 and 5 mg/mL in NS 0.5 mg/mL in NS unstable. Use immediately. 14d FT: 5 mg/mL in D5W 3d RT: 5 mg/mL in D5W	- solution is slightly opaque - filter through 0.22 micron filter before administration - non-vesicant - latex** content not determined
	10 mg/mL†	14 d FT ⁂, 7 d RT			Cytotoxic
Thiotepa **IT injection:** 15 mg (Bedford) (F)(PFL) no preservative†	diluents containing preservatives should NOT be used for intrathecal administration 7.5 mL NS	Use immediately†	qs to 6 mL with preservative free NS	use within 4 h of initial reconstitution†	-auxiliary label to include route in full (i.e., INTRATHECAL injection) attached to both syringe and outer ziplock bag -filter through 0.22 micron filter before administration - non-vesicant - latex** content not determined
	2 mg/mL solution				Cytotoxic INTRATHECAL injection

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DRUG & STRENGTH (Storage Prior to Use, Manufacturer, Presevative Status)	Reconstitute With: To Give:	Vial Stability Vial Expiry ⁂	Product	Product Stability Product Expiry	Special Precautions/Notes Auxiliary Labels
Thyrotropin alfa 1.1 mg (Genzyme) (F)(PFL) no preservative†	1.2 mL SWI† swirl contents†; do not shake	24 h FT†		24 h FT†	- noncytotoxic - nonvesicant - latex-free
	0.9 mg/mL†	24 h FT†			
Topotecan 4 mg (GSK) (RT)(PFL) no preservative†	4 mL SWI	28 d FT, 7 d RT (or 14 d FT ⁂) (or- 24 h **FT**, RT†)	IV: 50–100 mL **NS**, D5W† Conc range= 0.02–0.5 mg/mL	28 d FT, 7 d RT	- nonvesicant - latex-free** - formulary: Restricted drug
	1 mg/mL	14 d FT ⁂, 7 d RT		24 h **FT**, RT†	Cytotoxic Protect from light
Tositumomab (with Iodine^{131}) Kit for radiolabelling with I^{131} (GSK) no preservative§	Prepare according to mfgr instructions; use radionuclide protection	Use immediately after reconstitution and radioisotope labelling		N/A	- radiation hazard - prepared and handled by nuclear medicine dep't. - non-formulary drug
	---				Vesicant
Trastuzumab 440 mg (Roche) (F) preservative†	20 mL BWI supplied Or 20 mL SWI swirl vial gently; allow to stand undisturbed for 5 minutes†	28 d FT then discard unused portion	250mL NS† Do **NOT** use dextrose containing solutions†	24 h **FT,** RT†	- non-cytotoxic - non-vesicant - if patient sensitive to Benzyl Alcohol, reconstitute: SWI (in this case discard unused portion) - latex** in drug vial but not diluent vial - Provincial funding for specific indication - formulary: Restricted drug (other indication)
	21 mg/mL	14 d FT ⁂			Do NOT shake

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DRUG & STRENGTH (Storage Prior to Use, Manufacturer, Presevative Status)	Reconstitute With: To Give:	Vial Stability Vial Expiry ⁂	Product	Product Stability Product Expiry	Special Precautions/Notes Auxiliary Labels
Valrubicin for Bladder Instillation 200 mg/5 mL (F) preservative§	Warm 4 vials, Dilute all 4 vials with a total of 55 mL NS	Single use vial discard unused portion (or- 12 h RT)	Syringe for intravesicular (bladder) administration	12 h RT	- intravesical use only - drug must come to RT slowly before adding to NS. DO NOT SHAKE - rotate bag gently - non-PVC NS 100 mL bags supplied to make total volume 75 mL (55 mL NS + 20 mL drug) - may also use empty non-PVC bags + add NS + drug - special administration sets must also be ordered with drug - non-formulary drug
	40 mg/mL 800 mg/75 mL				Cytotoxic Bladder Instillation only- Do NOT use IV
Vinblastine 10 mg/10 mL (Mayne) (F)(PFL) no preservative†	N/A- Solution source product	30 d FT (or- 24 h **FT**, RT†)	syringe† 50 mL (up to 100–250 mL) **NS**, D5W Max Conc 0.4 mg/mL	syringe: 30 d FT IV: 7 d FT, 24 h RT (or- 14 d FT: NS)	- auxiliary label (for syringe only): "Warning: FATAL if Given intrathecally" - avoid dilution in large volumes to decrease the chance of extravasation - latex-free** - can be filtered through a 5 µm filter
	1 mg/mL	14 d FT ⁂		Syringe: 48 h FT† IV: 7 d **FT**, 24 h RT	Cytotoxic Warning: FATAL if Given intrathecally Vesicant Protect from light

Codes: ‡ Data from † § Data from Manufacturer's Product RT = room FT = SWI = sterile water for
⁂ Expiry date limited to 14 d FT for unpreserved low-risk level compounded sterile product per USP 797 NS = normal D5W = dextrose BWI = water for injection
PFL = protect from

DRUG & STRENGTH (Storage Prior to Use, Manufacturer, Presevative Status)	Reconstitute With: To Give:	Vial Stability Vial Expiry ⁂	Product	Product Stability Product Expiry	Special Precautions/Notes Auxiliary Labels
Vincristine 1 mg/1 mL 2 mg/2 mL 5 mg/5 mL (Mayne) (F)(PFL) (Novopharm) (F)(PFL) no preservative†	N/A- Solution source product	30 d FT (or- 8 h **FT**, RT†)	syringe: qs to 20 mL with NS in 30 mL syringe* IV: 50 mL* **NS**, D5W† Max conc 0.6 mg/mL	IV: 21 d FT,RT (or- 24 h FT, 6 h RT [Mayne]; 72 h FT, 24 h RT [Novopharm])	- auxiliary label (for syringe only): "Warning: FATAL if given intrathecally" - peripheral administration of a continuous infusion is not recommended - refrigerate - do not filter- latex-free**
	1 mg/mL	14 d FT ⁂		syringe: 48 h RT, 7 d FT IV: 24 h **FT**, RT VAD Infusor = 7d at 4°C followed by 4 days at 35°C	Cytotoxic Warning: FATAL if given intrathecally Vesicant Protect from light
Vinorelbine 10 mg/1 mL 50 mg/5 mL (GSK) (F)(PFL) 10 mg/1 mL 50 mg/5 mL (Mayne) (F)(PFL) no preservative†	N/A- Solution source product	7 d FT (or- discard unused portion†)	syringe: 1.5 – 3.0 mg/mL in **NS** or D5W† IV: 50 mL* **NS**, D5W, ½NS, D5½NS, Ringer's, Ringer's Lactate† Max Conc: 0.5 – 2.0 mg/mL (Mayne)† Infusion Bag: 0.5-2 mg/mL	syringe: 24 h **FT,** RT† 24 h **FT**, RT†	- auxiliary label (for syringe only): "Warning: FATAL if given intrathecally" - solution clear to pale yellow; darker yellow solutions may be used - refrigerate - latex-free** (GSK); latex** content not determined (Mayne) - formulary: Restricted drug
	10 mg/mL	7 d FT			Cytotoxic Warning: FATAL if given intrathecally Vesicant Protect From Light

Adapted from Stability and Reconstitution Chart (27 Feb 2007)- Capital District Health Authority, ACB Cytotoxic Drug Chemical Stability Chart (May 2006)- Alberta Cancer Board, and BCCA Cancer Drug Manual (2 Feb 2007)- British Columbia Cancer Agency

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LEGEND

Ж Expiry time in a vial is either the time provided in the product monograph, or 14 d F (maximum time to store a low-risk level compounded sterile product with no preservative per USP 797 to minimize risk from potential microbial contamination)

**** Latex free means the product does not contain natural rubber latex in its packaging or is packaged as plastic (e.g., Polyamps) and glass ampoules**

‡ Data from Compendium of Pharmaceuticals and Specialties (CPS), as abstracted by the BCCA Cancer Drug Manual (2 February 2007)

† Data from Manufacturer's Product Monograph, as abstracted by the BCCA Cancer Drug Manual (2 February 2007)

§ Data from Manufacturer's Product Monograph, as abstracted by the CCNS Chemo Preparation Policy Working Group

Explanatory Notes

Stability: Physicochemical stability noted as first option, where information is available.

Expiry: If the expiry time is different than stability data, this will be noted in a separate cell. Shorter expiry times may be noted from the Manufacturer's Product Monograph or limited by USP 797 regulations due to product sterility concerns.

It is the responsibility of each institution to determine the level of acceptable risk for assurance of product sterility in the local Chemotherapy Preparation Area, and to support this level through appropriate process validation data.
Vial stability: Stability of solution after first puncture or reconstituted solution
Storage temperature: If information states same stability with refrigerator and room temperature storage, then bold refrigerated as preferred
Cytotoxic: hazardous.
Discard unused portion: Unused portion from single use vials are assumed to discarded at the end of the day.
If information states same stability with refrigerator and room temperature storage, then bold refrigerated as preferred (ie, to minimize growth of micro-organisms).
PFL = protect from light RT = room temperature FT = refrigerated
SWI = sterile water for injection NS = normal saline
D5W = dextrose 5%
BWI = bacteriostatic water for injection
BSI = bacteriostatic normal saline for injection
These Policies and Best Practice Procedures are adapted from the "Standards of Practice for Oncology Pharmacy in Canada", published in October 2004 by the Canadian Association for Pharmacy in Oncology, and the "Guidelines on Handling Hazardous Drugs", published in July 2006 by the American Society of Health Systems Pharmacists.

It is the responsibility of each District to develop Policies and Procedures tailored to individual sites and practices, while adhering to these provincial standards.

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طبع بموافقة وزارة الصحة العراقية
رقم ١٥٦٣ في ٢٠١٩/١٠/٢٤