# Summary of BCCA Pharmacy Practice Standards for Hazardous Drugs

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Pharmacy Oncology Certification

All pharmacy staff involved in the preparation and delivery of hazardous drugs must demonstrate knowledge and competency for the duties that they are required to undertake. Re-evaluation of competency and knowledge must take place on a regular basis with documentation of results.1-5

Module 1 – Safe Handling of Hazardous Drugs

Section A

A.1 Potential Hazards of Handling Hazardous Drugs

Hazardous Drug (HD) safe handling policies and procedures must be developed to address the following activities:1,6

- Receipt and storage4
- Preparation
- Labelling
- Use of safety equipment and Personal Protective Equipment (PPE)
- Emergency procedures for treating accidental contact and spills
- Packaging and transport4
- Disposal

All pharmacy staff must be informed of HD policies and procedures, and receive training for handling hazardous drugs safely, cleaning up spills, and using all equipment and PPE properly.3-5,7-9 There must be established work practices related to both drug manipulation techniques and to general hygiene practices.7 Workplace procedures must be developed for using and maintaining all equipment that functions to reduce hazardous drug exposure.2,4,9

Warning signs, which are clearly visible and clearly state the identified hazards, must be posted in all areas where hazardous drugs are received,7 stored,9 prepared7,9 and administered.7

A.2 Hazardous Drug List

Each facility must develop and maintain a hazardous drug list to ensure that healthcare staff working in the facility is made aware of which drugs are hazardous.1,2,4,7,9

A.2.1 BCCA Hazardous Drug Evaluation Criteria

The facility’s hazardous drug list must be posted in all areas where these drugs are received,4,7 stored,4,9 prepared4,7,9 and administered.4,7

A.3 Medical Surveillance, Personal Exposure Records, and Work Re-Assignment

WorkSafe BC Occupational Health and Safety (OH&S) Regulation 6.52 states: “the employer must maintain a record of all workers who prepare or administer cytotoxic (hazardous) drugs, including the name of the drugs handled, and when practicable, the number of preparations or administrations per week. Exposure records must be maintained for the duration of employment plus 10 years, and training records for 3 years from the date that the training occurred.”

Employees must be fully informed of the potential for reproductive hazards that may occur if they are exposed to hazardous drugs.1,5,7,9
Section B

B.1 Hazardous Drug Cleanroom and Anteroom

Access to the hazardous drug cleanroom must be limited to authorized personnel who are assigned to work there. A warning sign must clearly identify the hazard and state that access to the cleanroom is controlled and limited to authorized personnel only.

Door(s) leading into the cleanroom must not be left open. Appropriate personal protective equipment must be donned by all personnel prior to entering the cleanroom as the first major step in preventing microbial contamination of compounded sterile preparations and to minimize healthcare workers’ exposure to hazardous drugs.

B.2 Biological Safety Cabinets

WorkSafe BC Occupational Health and Safety (OH&S) Regulation 6.53(1) states:

“All mixing, preparation and priming of administration sets with a cytotoxic (hazardous) drug must be performed in one centralized area in a specially designated Class II Type B biological safety cabinet that:

- is exhausted to the outside atmosphere in a manner that prevents recirculation into any work area;
- has exhaust and ventilation systems that remain in operation for a sufficient period of time to ensure that no contaminants escape from the biological safety cabinet into the workplace; and
- is equipped with a continuous monitoring device to permit confirmation of adequate airflow and cabinet performance.”

B.2.1 Class I BSC

Class I BSCs are used when there is a need for containment, but not aseptic product protection and therefore must not be used for sterile hazardous drug preparations.

B.2.2 Class II BSC

Class II Type A cabinets must not be used for preparing hazardous drugs. A minimum Class II Type B BSC must be used for the preparation of sterile hazardous drugs.

B.2.5 HEPA Filter

HEPA filters must be present in BSCs used for the preparation of hazardous drug sterile admixtures. Air that flows towards the work surface inside the cabinet and air that is expelled out to the environment must first pass through at least one HEPA filter.

B.2.6 Airflow

Manipulations must be performed at least six inches in from the front opening of the cabinet, behind the air ‘split’. Contaminated air must be able to escape via the rear grill, not via the front opening.

In order for the BSC to help protect the operator, paths of airflow must remain clear.

Note:

- Horizontal laminar airflow hoods must not be used for the preparation of hazardous drugs

B.2.7 Ultraviolet Lights

The ultraviolet light may cause eye damage and must not be turned on when personnel are working in or near the BSC, or in the cleanroom.
B.2.8 Viewing Window

To protect the upper body and face from any splashes or aerosols produced inside a BSC, the viewing window must be kept at the manufacturers’ recommended height during hazardous drug preparation.1,4,13,14

B.2.9 Location

A biological safety cabinet used for hazardous drug preparations must be located away from doorways, traffic corridors, and air conditioning and heating vents1,5,6,14 inside a restricted access ISO Class 7 cleanroom.5

B.2.10 BSC Monitoring

The BSC must be operated continuously with the blower turned on 24 hours a day, seven days a week4,6-8 unless being serviced3,4,6-8. It must be equipped with a continuous monitoring device to allow confirmation of adequate airflow and cabinet performance.2,4,7,9

For the safety of the patient and the operator, hazardous drug compounding must not take place when a BSC alarm is sounding or the lights and/or gauges indicate the cabinet is not functioning within the manufacturer’s specifications.7,14

Site specific procedures must be created and posted for workers so that when the gauges, lights or alarms indicate that the BSC is not working properly or there is a power interruption, the safety of personnel, the environment and the aseptic condition of the product (if possible) will be maintained.4

B.2.11 Testing and Certifying Biological Safety Cabinets

Testing and certifying the biological safety cabinet must be completed by a qualified National Sanitation Foundation (NSF) certified technician when installed2,4,15. The BSC must be re-certified to industry standards every six months2,3,5,8,16 and when the cabinet is altered, repaired or moved2-5,9,14. Testing and certifying the biological safety cabinet must occur during simulated operating conditions.5 Certification procedures used must meet the requirements of the NSF2,15 and American National Standards Institute (ANSI) NSF/ANSI 49-2002, Class II (Laminar Flow) Biohazard Cabinetry.2

Prior to servicing a biological safety cabinet, service technicians or maintenance workers must be informed that the BSC may be contaminated with hazardous drugs. Appropriate personal protective equipment must be worn when testing, certifying or servicing the BSC.2,8

After field certification, the BSC must have certification information posted on the front of the cabinet housing in a readily visible location2,9

B.2.12 Replacing HEPA Filters

Only NSF certified technicians informed of the hazardous nature of the admixtures prepared in the biological safety cabinet shall replace HEPA and charcoal (if present) filters.2,6,8 Appropriate personal protective equipment must be worn when replacing HEPA filters and the contaminated filters must be handled and disposed of as hazardous waste.1,7

B.2.13 Turning off a Biological Safety Cabinet

If it is necessary to turn off a BSC for testing and certifying or for maintenance, the entire inner cabinet must be decontaminated first2,3,8,8

If the internal blower and external exhaust fan of a BSC are both turned off, the work-access opening and the HEPA exhaust area must be covered with impermeable plastic and sealed with tape to prevent any remaining hazardous drug contamination from inadvertently escaping from the BSC until maintenance work begins. The BSC must be sealed with plastic whenever it is moved or left inoperative for a period of time.8,12
B.2.14 Cleaning Biological Safety Cabinets

To maintain an aseptic environment and to protect against possible contact with hazardous drug particles, surfaces of the BSC must be cleaned and disinfected regularly throughout the day using aqueous antibacterial solution (e.g., chlorhexidine 0.05%)\textsuperscript{1,4,5,7} followed by 70% alcohol\textsuperscript{4,7,10}.

Prior to cleaning a BSC, proper hand washing procedures must be followed and full personal protective equipment (PPE) must be donned\textsuperscript{2,4,7,8}.

B.2.14.1 Cleaning All Interior Biological Safety Cabinet Surfaces

Prior to commencing daily compounding, all interior surfaces of the biological safety cabinet (except under the work surface) must be cleaned and disinfected with an aqueous antibacterial solution followed by 70% alcohol\textsuperscript{4,7}. If the viewing window has been raised during cleaning and disinfecting, it must be lowered to the manufacturers recommended operating level and the BSC must purge for at least fifteen minutes\textsuperscript{4} afterwards.

Following hazardous drug compounding, the BSC must purge for five minutes\textsuperscript{14} and then all interior surfaces (except under the work surface) must be cleaned and disinfected:

- after preparations within the BSC are completed for the day\textsuperscript{1,4}
- prior to compounding ‘latex-free’ preparations\textsuperscript{17}
- prior to compounding sterile HD preparations in a BSC once it has been used to compound non-sterile HD preparations\textsuperscript{1}
- prior to resuming compounding in a BSC that is turned off between aseptic processes for any reason (e.g., power interruption, maintenance)\textsuperscript{7}

If cleaning interior surfaces of a BSC with the viewing window raised, additional PPE is required including a NIOSH-approved respirator (e.g., N95) appropriately fit-tested for the operator and safety goggles with side shields\textsuperscript{2,4,7,8} to prevent splashing into the eyes.

To protect others from potential exposure to hazardous drugs, pharmacy personnel who must be present in the cleanroom or in the area of the biological safety cabinet\textsuperscript{18} must wear an N95 or better respirator mask in addition to all other PPE if the viewing window is raised.

B.2.14.2 Cleaning the Work Surface of the BSC

The work surface of the BSC must be cleaned and disinfected using an aqueous antibacterial solution (e.g., chlorhexidine\textsuperscript{10} or Wet Ones\textsuperscript{8}) followed by 70% alcohol:\textsuperscript{1,5,10,14}

- after a completed preparation has been cleaned and removed from the BSC
- before leaving the BSC for an extended period of time (e.g., for a break)
- upon returning to the BSC after an extended period of time
- after a minor spill involving the working surface

At least 30 seconds of surface contact time must be allowed for the alcohol to act before beginning the next sterile preparation\textsuperscript{5}.

B.2.15 Decontaminating Biological Safety Cabinets

Decontamination of the BSC must occur once a week, after a HD spill in the BSC, and before maintenance/certification/servicing if shutdown of the BSC is required\textsuperscript{4}.

Prior to decontaminating the BSC, proper hand washing procedures must be followed and full personal protective equipment (PPE) must be donned\textsuperscript{2,4,7,8}.

When decontaminating interior surfaces of the BSC with the viewing window raised, additional PPE is required, including a NIOSH-approved respirator (e.g., N95) appropriately fit-tested for the operator and safety goggles with side shields\textsuperscript{2,4,7,8} to prevent splashing into the eyes.
To protect others from potential exposure to hazardous drugs, pharmacy personnel who must be present in the cleanroom or in the area of the biological safety cabinet must wear an N95 or better respirator mask in addition to all other PPE when the viewing window has been raised.

After decontamination is completed, the viewing window is lowered to the manufacturers recommended operating level and the BSC must purge for at least thirty minutes prior to sterile preparation.

Section C

C.1 General Protective Guidelines

Workers must follow protective guidelines to minimize the release of particles into the aseptic preparation environment leading to possible contamination of the final product(s) and to decrease the possibility of personal exposure to hazardous drugs.4,5

There must be procedures and directives available for safe and aseptic handling of hazardous drugs. There must be strict adherence to safe handling procedures and directives.6,7

C.2 Personal Protective Equipment (PPE) and Clothing

Protective equipment and clothing must be provided and used to minimize or prevent healthcare workers exposure to hazardous drugs.1,2,6,9

Prior to entering the cleanroom, proper ‘gowning’ of the healthcare worker is required (e.g., hair cover, mask, gown, chemotherapy gloves, and shoe covers).3,9,19

C.2.1 Scrubs

A buttoned lab coat must be donned over scrubs upon exiting the cleanroom/anteroom.3,10

C.2.2 Footwear

Each facility must be in compliance with WorkSafe BC regulations to help reduce preventable injuries due to inappropriate footwear.20

WorkSafe BC Regulation 8.22 states:
1. “A worker’s footwear must be of a design, construction and material appropriate to the protection required.”
2. “To determine appropriate protection, the following factors must be considered; slipping, uneven terrain, abrasion, ankle protection and foot support, crushing potential, temperature extremes, corrosive substances, puncture hazards, electrical shock and any other recognizable hazard.”

C.2.3 Shoe Covers

Shoe covers must be put on by all workers before stepping inside the cleanroom and must be removed with gloved hands at the doorway/demarcation line upon exiting.1,4,7,19 Shoe covers worn inside the HD cleanroom must be disposed of in hazardous waste containers and not saved for re-entry into the cleanroom.1

C.2.4 Hair Covers

A disposable hair cover (covering hair and ears completely) must be worn by all personnel working in the BSC and/or present in the cleanroom.1,4,7,10,19

C.2.5 Masks

Surgical masks must be worn by all personnel working in the BSC and/or present in the cleanroom.4,5,7,19 Masks worn in the cleanroom must cover from the bridge of the nose down to include the chin.5
C.2.6 Respirators

A NIOSH-approved respirator must be worn when cleaning up HD spills outside of the BSC and when decontaminating or cleaning the BSC.3,4,7

Staff wearing a NIOSH-approved respirator (e.g., N95, P100) must be fit-tested3 prior to initial use and retested at least once a year, when there is a change in the respirator face piece, or when a user’s physical condition changes affecting the fit.20

WorkSafe BC Regulation 8.41 states:

“Before each use of a respirator which requires an effective seal with the face for proper functioning, a worker must perform a positive or negative pressure user seal check in accordance with CSA Standard CAN/CSA-Z94.4-02, Selection, Use, and Care of Respirators.”

C.2.7 Chemotherapy Gowns

To decrease particulate levels in the preparation area and to decrease the risk of direct skin contact with the hazardous drugs, workers must wear non-linting, impermeable, disposable chemotherapy gowns with long sleeves and tightly-fitting cuffs, a closed front, and tied in the back.1,4,10 Chemotherapy gowns must be worn for all activities that may result in the worker’s direct exposure to hazardous drugs.1,2

Chemotherapy gowns worn in the HD cleanroom must be removed for storage or disposal while still in the cleanroom to prevent the spread of HD contamination from one area to another.9,10

Lab coats or isolation gowns must not be worn in the hazardous drug cleanroom by staff working in the biological safety cabinet in place of chemotherapy gowns.5

C.2.8 Chemotherapy Gloves

Chemotherapy approved gloves must pass permeation testing with nine chemotherapy agents as required by the American Society for Testing and Materials (ASTM) Standard 6978-05 (Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Gloves).21

Gloves worn to handle hazardous drugs must be made of made of latex, nitrile, neoprene, or polyurethane, powder-free,1,4,5,7 and long enough to cover the cuff of the chemotherapy gown.2,4,7 If powder-free gloves are not available, powdered gloves must be wiped with a towel moistened with 70% alcohol1,6 prior to entering the cleanroom. Alcohol must not be sprayed to remove powder.

Gloves made of material other than latex, nitrile, neoprene or polyurethane may be used if documentation of approved testing for impermeability to chemotherapy can be provided.21

Latex-free ‘chemotherapy-approved’ gloves must be made available to staff.9

Two pairs of disposable chemotherapy gloves must be worn for all activities that may result in hazardous drug exposure22 including handling all hazardous drugs and hazardous drug waste and must be disposed of as hazardous waste.1,2,5,7 Two pairs of disposable chemotherapy gloves must be worn at all times by all personnel working in the HD cleanroom.3,7,19

Both pairs of disposable chemotherapy gloves must be changed every 30 minutes or immediately if a tear, puncture or contamination is known or suspected.1,2,4,7 Hands must be washed with soap and water every time gloves are removed.1,2,4,7

C.2.9 Eye Protection

Eye shields or safety goggles with side shields must be worn for splash protection when cleaning or decontaminating a BSC with the viewing window raised or when cleaning up a hazardous drug spill outside the BSC.4,7
C.3 Hand Hygiene

Hand hygiene must be performed by all staff prior to entry into the clean room to minimize microbial contamination of sterile products. After handling hazardous drugs and removing chemotherapy gloves, hand washing is performed to remove possible drug contamination.\textsuperscript{10}

C.3.2.1 Compounding personnel

Personnel handling hazardous drugs, performing activities other than compounding, must wash their hands immediately after removal of chemotherapy gloves.\textsuperscript{1,2}

Personnel compounding sterile HD preparations must wash their hands before donning chemotherapy glove.\textsuperscript{1,2,4,7,10} Prior to hand washing, all jewellery including bracelets, rings and watches must be removed to prevent material from being trapped around or underneath them.\textsuperscript{10,11} Hands must be dried with a clean, low lint towel.\textsuperscript{5,11}

Personnel compounding sterile hazardous drugs must wash their hands immediately after removal of chemotherapy gloves\textsuperscript{1,2,4,7,10} with soap and water.

C.3.2.2 Non-compounding personnel

Non-compounding personnel working in the clean room may apply ABHR prior to donning chemotherapy gloves in place of washing hands with soap and water. All personnel must wash hands with soap and water immediately after removal of chemotherapy gloves.

All personnel handling hazardous drugs, performing activities other than compounding outside the SPR are not required to wash their hands before donning chemotherapy gloves, but must wash their hands immediately after removal of chemotherapy gloves using soap and water.

C.3.3 Nails and Nail Polish

Wearing of artificial nails or nail extenders is prohibited while working in the sterile compounding environment.\textsuperscript{5} Natural nails should be kept neat and trimmed\textsuperscript{5,11,23} and must be free of nail polish.\textsuperscript{11,19}

C.4 Safety Stations

Eyewash stations and emergency showers must be easily accessible.\textsuperscript{4,6,24} The location of each emergency shower or eyewash station must be identified with a highly visible sign.\textsuperscript{9}

For potential exposure to high risk materials: WorkSafe BC Occupational Health and Safety (OHS) Regulation 5.89 states:

“Eye Equipment: Tempered continuous flow eyewash facility with a minimum duration of 15 minutes (or more if required by the nature of the material)

Location: Within 5 seconds walking distance of the hazard area, but no further than 6 meters (20 feet).

Skin Equipment: Tempered, continuous flow emergency shower facility with a minimum duration of 15 minutes (or more if required by the nature of the material)

Location: Same location criteria as for high risk eyewash facility except that the shower may be located further than 6 meters, and

(a) a supplementary emergency washing facility such as a non-tempered drench hose is located within 5 seconds walking distance of the hazard area but no further than 6 meters, and

(b) a tempered shower facility is available within the building to start emergency washing within 5 minutes of the contact”
C.4.1 Eyewash Stations

C.4.1.2 Hand Held Portable

Portable eyewash stations must be capable of delivering a minimum flush duration of 15 minutes.24

C.4.2 Emergency Showers

Emergency showers must not be used to flush the user's eyes because the high rate or pressure of water flow could possibly damage the eye.25

C.4.3 Safety Stations Maintenance

Inspecting and operating (activating) the emergency shower and mounted eyewash station must be performed and documented by an employee monthly.24

Hand held portable eyewash equipment must be inspected and maintained according to the manufacturer's instructions.25

Section D

D.1 Supplies

D.1.3 Alcohol Swabs and Solutions

Single use11, individually packaged sterile5 70% isopropyl alcohol swabs must be used to disinfect a critical site prior to accessing. 70% alcohol-soaked gauze pads or other particle-generating material must not be used to disinfect critical sites of containers5 prior to accessing.

Partially emptied containers of alcohol (including spray bottles) must not be topped up.7

D.2 Devices

Devices used in the safe and accurate reconstitution and withdrawal of hazardous drug in a vial must support minimizing the production and release of HD aerosols and vapours, maintaining the sterility of hazardous drugs, and preventing HD leaks/spills.6,10

Staff must be trained to use the proper aseptic technique required with each device utilized in the safe preparation of hazardous drugs.3

The following criteria may be considered when deciding which devices are most suitable for the preparation of hazardous drugs.

- Venting devices must have filters1,7
- Luer-lock fittings must be used for all hazardous drug connections made during manipulation and dispensing1,4,8,16

D.2.1 Syringes

An appropriate size syringe must be selected so that no more than three-quarters (75%) of the syringe’s maximum calibrated volume is filled with hazardous drug solution at any time during the compounding process.14,6,10

A syringe must not be used more than five times for a single compounding procedure (e.g., reconstitution).3
D.2.2 Syringe Tip Caps

Care must be taken to avoid touch-contaminating the end of the multi-function tip cap that will be luer-locked to either the syringe or the chemotherapy dispensing pin (critical site).5,10

D.2.3 Needles

All parts of a needle are critical sites. Needles must be manipulated by handling their paper over-wrap and/or needle caps. Paper-covered needles must be unwrapped by peeling apart the sides of the package just enough to expose the needle’s luer-lock hub. Airflow to the hub must be maintained as the needle is un-wrapped and luer-locked onto a syringe. The needle cap must be left in place until the needle is ready to be used.11

Aluminum-free needles and devices must be used in the preparation and administration of CISplatin, CARBOplatin and oxaliplatin.26

Safety Engineered Needles (SEN) must not be used in the preparation of hazardous drugs. There is a risk that the HD will spray droplets off of the needle point when the SEN cap is engaged.27

D.2.4 Needle Caps

Placing the open end of the needle cap directly on the work surface of the BSC must be avoided.5

D.2.7 Filters

Solutions prepared for parenteral administration must be filtered when there is a possibility that glass particles3 or particulate matter (e.g., core from a vial stopper) may be present and the solution is filterable.

D.2.7.1 Filter Needles

The same filter needle must not be used for both withdrawing and expelling solution.10,11

D.2.7.2 Filter Discs

A filter disc used for hazardous drugs must be equipped with proximal and distal luer-locking connections.1,4,9

D.2.8 Filter Venting Devices

Negative pressure technique must not be used for hazardous drug reconstitution or withdrawal if filter venting devices7 or closed system drug transfer devices2,7 are available.

D.2.8.1 Chemotherapy Dispensing Pins

Chemotherapy dispensing pins or similar devices with spikes must not be used with vials of TAXOL® since they can cause the stopper to collapse resulting in loss of the sterile integrity28 and the possible release of hazardous drug.

Note:

- Chemotherapy dispensing pins must be inspected for cracks prior to use. A cracked chemotherapy dispensing pin must be replaced prior to manipulation of HD solution27
- Chemotherapy dispensing pins must be disposed of in a HD sharps waste container if removed from a HD vial27
- A new chemotherapy dispensing pin must be used for each vial. Spraying of the solution or touch contamination can occur upon removal of the pin29
D.2.8.2 Chemotherapy Vents

A new chemotherapy vent must be inserted prior to removal of a plugged venting device.12

A HD vial stopper must be disinfected with sterile 70% IPA prior to each puncture when multiple punctures are necessary.5

D.2.9 Syringe Fluid Dispensing Connectors/Syringe Tip Connectors

Both ends of the individually packaged fluid dispensing connector used with hazardous drugs must have luer-lock connections1,4,9 which allow transfer of solution from one syringe to another without leakage.

D.2.14 Closed System Drug Transfer Devices

Closed System Drug Transfer Devices must be used within the ISO Class 5 environment of a biological safety cabinet.4,5 Protective clothing must be worn and best practice safety measures must be adhered to when using a Closed System Drug Transfer Device to prepare, administer and dispose of hazardous drugs.2

D.3 Containers

D.3.1 Ampoules

The length of time between opening the ampoule and transferring the solution into a closed-system (e.g., syringe) must be minimized.10

The neck of the ampoule must be wiped with an alcohol swab before breaking and must not be touch-contaminated after being swabbed.1,10

Glass particles in solutions must be filtered prior to administration30 unless the manufacturer indicates the solution cannot be filtered. Solution must not be withdrawn and injected using the same filtration equipment.10,11

All parts of an opened ampoule must be discarded into a sharps container.3

D.3.2 Vials

Removal of a flip top cap from a hazardous drug vial must be performed carefully inside the BSC to ‘contain’ and avoid spreading HD contamination to areas outside of the BSC.12

Hazardous drug vials must be wiped to disinfect (not sprayed) using a low-lint towel or gauze moistened with 70% alcohol prior to placement inside the BSC.1,12

The date and time of puncture or the expiry date and time must be written directly onto reconstituted and partial vials that will be saved for future use with ink that will not smudge or wipe off.10

D.3.4 Non-Polyvinyl Chloride (Non-PVC) Bags

PACLitaxel, DOCEtaxel, temsirolimus, teniposide, etoposide, cycloSPORINE and ixabepilone must be prepared in non-PVC containers and administered using non-PVC tubing.26

D.3.5 Empty Sterile Infusion Bags

Infusion bags used for HD solution waste must be disposed of as hazardous drug waste.1,6,7

D.4 Ambulatory Drug Delivery Infusion Devices

D.4.1 Elastomeric Infusion Devices
D.4.1.2 INFUSOR™ Flow Rates

The correct size of elastomeric INFUSOR™ with the correct infusion rate must be selected when preparing hazardous drug medication. To decrease the risk of accidental exposure to HD, the delivery tubing of the INFUSOR™ must be primed with HD-free solution.

D.4.1.4 Hazardous Drug Medication Infusion Device Labels

The intended infusion rate must be stated in millilitres per hour (mL/hour) on the medication label when hazardous drug is administrated via an infusion device.

D.4.2 Computerized Ambulatory Drug Delivery (CADD®) Pump and Medication Cassette Reservoir

To decrease the risk of exposure to HD, the tubing of a CADD® medication cassette reservoir must be primed with hazardous drug-free solution.

Section E

E.1 Operational Standards for Sterile Hazardous Drug Preparation

Hazardous drugs shall be prepared only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas.

Operational standards must be adhered to when preparing sterile HD admixtures.

E.1.1 Personnel Hygiene in the Cleanroom and BSC

- Eating, drinking, smoking, chewing gum, storing food, or applying cosmetics in the vicinity of the BSC, in the cleanroom and in the anteroom are strictly prohibited.
- Personnel with rashes, severe sunburn, weeping sores, conjunctivitis, cold sores, active respiratory infection and wearing cosmetics are prohibited from preparing sterile admixtures.
- The wearing of artificial nails or extenders is prohibited while working in the BSC.
- Natural nails shall be kept neat and trimmed and must be free of nail polish.
- Compounding personnel must remove cosmetics and all jewellery including any visible body piercing above the neck before entering the cleanroom.
- Before entering the cleanroom, compounding personnel must remove personal outer garments (e.g., bandanas, coats, hats, jackets, scarves, sweaters, vests) because they shed flakes and particles.

E.1.2 Personal Protective Equipment

- Appropriate PPE (including hair cover, mask, gown, 2 pairs of chemotherapy gloves and shoe covers) must be donned prior to entering the cleanroom and/or working in the BSC.
- Hair covers (covering hair and ears completely) and masks must be worn by all personnel working in the BSC and/or present in the cleanroom.
- Shoe covers must be put on by all workers before stepping inside the cleanroom and must be removed with gloved hands at the doorway/demarcation line upon exiting.
- Chemotherapy gowns worn when preparing hazardous drugs must be non-linting, impermeable and disposable with long sleeves, tightly-fitting cuffs, a closed front, and tied in the back.
- Chemotherapy gowns worn in the cleanroom must be removed for storage or disposal while still in the HD preparation area, to prevent the spread of HD contamination from one area to another.
- Lab coats must not be worn in the cleanroom in place of chemotherapy gowns.
- Two pairs of disposable chemotherapy gloves must be worn at all times by all personnel working in the cleanroom. Both pairs of chemotherapy gloves must be inspected for visible defects.
Gloves should be powder-free. If powder-free gloves are not available, the powder must be removed using a towel moistened with 70% alcohol prior to entering the cleanroom – alcohol must not be sprayed to remove powder.

Gloves must be disinfected with 70% alcohol before performing aseptic compounding activities inside the BSC.

Gloves worn during chemotherapy preparation must be changed every 30 minutes or when torn, punctured or in the event of suspected contamination. Hands must be washed every time gloves are removed.

Pharmacy personnel who must be present in the cleanroom or in the area of the biological safety cabinet must wear an N95 or better respirator mask in addition to all other PPE if the viewing window is raised.

E.1.3 Biological Safety Cabinet

- The UV light may cause eye damage and must not be turned on when personnel are working in the cleanroom.
- All interior surfaces of the BSC (except under the work surface) must be cleaned and disinfected prior to commencing daily compounding. The BSC must purge for 15 minutes after cleaning.
- The viewing window must be kept at the manufacturer’s recommended level during HD preparation.
- Unnecessary items must not be taken into the BSC since airflow is disrupted in an overcrowded BSC.
- While working in the BSC, a path of first air must be maintained to critical sites at all times.
- Rapid arm movements that could disrupt the air curtain must be minimized.
- The front air intake grill and the rear air exhaust route must not be blocked.
- Manipulations must be performed at least six inches in from the front opening and side walls of the BSC.

E.1.4 General Procedures

- HD vials must be wiped with low-lint towels or gauze moistened with 70% alcohol to physically remove HD contamination prior to placement inside the BSC.
- Prior to placement inside the BSC, the outer wrapping of unopened supplies (e.g., syringes) must be disinfected with 70% alcohol.
- Best practice standards for aseptic technique in vertical airflow must be adhered to when preparing sterile hazardous drug admixtures.
- To decrease particle generation inside the BSC, paper coverings must be peeled away from needle hubs (critical sites) rather than pushing them through.
- Critical sites must be protected as soon as possible after being exposed and must not be touch contaminated.
- Infusion solution bag ports and vial stoppers must be disinfected with sterile 70% alcohol prior to accessing.
- A new sterile alcohol swab must be used to disinfect each critical site.
- When reconstituting, the drug must be completely dissolved before withdrawing a dose or storing for future use.
- The date and time of puncture/reconstitution or the expiry date and time must be written directly on the vials for future reference.
- Syringes must not be overfilled with hazardous drug. In most cases, syringes should not be more than three-quarters (75%) full, although some preparations require accurate volume measurements that necessitate the use of a smaller volume syringe.
- Negative pressure technique must not be used for hazardous drug reconstitution or withdrawal if filter venting devices or closed system drug transfer devices are available.
- A puncture-proof sharps container must be used for disposal of all sharp objects including needles, chemotherapy dispensing pins, and chemotherapy vents.
- All non-sharp waste generated during compounding must be placed inside a HD waste container (e.g., zip lock bag or sharps container) in the BSC for later removal and disposal.
E.1.5 Removing Products from the BSC

- Infusion solution bag ports that have been accessed must be wiped with an alcohol swab prior to removal from the BSC\(^6\) to remove possible HD residue
- Outer gloves worn when compounding hazardous drugs must be removed,\(^3\) discarded within the BSC\(^2\) and replaced or wiped with a clean soap-moistened towel prior to touching items for removal from the BSC\(^1,10,12\)
- Surfaces of final preparation(s) may be contaminated with HD and must be wiped with a new soap-moistened towel (not previously used on gloves) before removal from the BSC\(^1,6,10\)
- To remove a vial of HD that will be saved for reuse from the BSC:
  - the vial stopper must be wiped with a sterile 70% alcohol swab to remove possible HD residue\(^5,6\) (if there is not a chemotherapy dispensing pin or CSDTD inserted)
  - the puncture date and time or expiry date and time must be written directly on the vial with a thin-tipped permanent marker\(^7,10\)
  - the vial must be wiped with a new soap-moistened towel\(^10\)
  - the vial must be placed inside a zip lock bag sealed above the front grill upon removal from the BSC\(^10\)
- Containers used for HD waste (sharp and non-sharp) must be sealed and wiped with a new soap-moistened towel inside the BSC before removal from the cabinet\(^2,7,10\)

E.1.6 Warning Labels

- All hazardous drugs and hazardous drug preparations must be easily identifiable by personnel involved in their handling\(^7\)
- The HD warning label must display a ‘Cytotoxic’ hazard symbol and/or the words CAUTION – Cytotoxic/Antineoplastic\(^34\)/Chemotherapy/Hazardous\(^27\) to indicate that HD safe practices must be followed while handling

E.1.7 Exiting the Cleanroom

- PPE must be removed upon exiting the cleanroom\(^5,7,9\)
  - Removal of chemotherapy gowns for storage or disposal must be done with care to avoid spreading HD contamination to other non-contaminated garments\(^22\)
  - Outer gloves must be discarded in a hazardous waste container (inside\(^2\) or outside of the BSC) prior to exiting the cleanroom – outer gloves must NOT be worn outside the cleanroom once compounding hazardous drugs in the BSC has occurred\(^1,10\)
  - Used shoe covers must be removed with gloved hands at the door leading out of the cleanroom and must be discarded as hazardous waste\(^3\)
  - Mask and hair cover(s) must be removed outside of the cleanroom while wearing inner gloves\(^3\)
  - Mask, hair cover(s) and inner gloves must be discarded in a hazardous waste container\(^3\) outside of the cleanroom
  - Hands must be washed immediately with soap and water every time gloves are removed\(^1,2,4,10\)
  - A buttoned lab coat (or isolation gown) must be donned over scrubs upon exiting the anteroom\(^3,10\)

E.2 Aseptic/Protective Routines

E.2.1 Critical Sites

Critical sites must be protected as much as possible and must not be touch-contaminated\(^5,10\). Critical sites of supplies or devices must not contact the work surface of the BSC.\(^10\) Protection of critical sites by precluding physical contact and airborne contamination must be given the highest priority in aseptic compounding practice.\(^5,10,11\)

E.2.2 First Air

While working in the BSC, a path of first air must be maintained to critical sites at all times. It is vital to avoid reaching over or working directly above or in front of exposed or previously swabbed critical sites.\(^5,10,11\)
E.2.3 Swabbing

The stopper on a vial or the port on an infusion solution bag must be disinfected with a sterile 70% alcohol swab just prior to penetration. At least 10 seconds must be allowed for the alcohol to dry (act) before manipulations begin.5

The correct swabbing technique is to make several firm strokes in the same direction over the rubber closure. A new sterile swab must be used on each new surface.11 The surface of sterile 70% IPA swabs used to disinfect entry points on infusion solution bags and vials shall not contact any other object before contacting the surface of the entry point.5

Prior to removal from the BSC, the stopper of a vial or the port of an infusion solution bag that has had drug added must be wiped with an alcohol swab to remove possible HD residue.6

E.2.5 Capping Needles Safely

Needles are a critical site and therefore must be capped when not being used for injection or withdrawal.11 Prior to manipulation of a hazardous drug-filled syringe, the needle must be capped to reduce aerosol release and prevent splashes from the needle tip.10

For worker safety, two-handed recapping of a needle used for HD preparation is never an acceptable practice.11

E.3 Safe Handling Aseptic Techniques

E.3.1 Transfer of Hazardous Drug Solution from a Syringe

If too much hazardous drug solution has been drawn into a syringe, care must be taken to minimize aerosol and vapour production, and to contain hazardous drug solution while removing the excess volume.6,8

Note:

- Excess hazardous drug must NOT be ejected into the needle cap, sharps container, or any other open container8 as this could cause HD aerosolization, vaporization or contamination.

E.3.2 Removal of Bubbles/Air from a Syringe

Bubbles and air must be removed carefully in a manner that prevents the release of HD solution and minimizes the production of HD aerosols in the BSC.6,8

E.3.3 Attaching and Priming Solution / Administration Sets

Priming any intravenous administration set with hazardous drug solution in an uncontrolled environment must be avoided.1 To minimize exposure to HD, the administration tubing/line must be primed with HD-free solution.2,6,8

Section F

F.1 Clean Up and Waste Disposal

F.1.1 Biological Safety Cabinet Waste Cleanup

The entire aseptic preparation area must be kept clean so that aseptically prepared products remain as free from potential microbial and hazardous drug contamination as possible.5,7
F.1.2 Hazardous Waste Disposal

Hazardous waste containers must be available in all areas where hazardous drugs are received, stored, prepared and administered.3,4,8,9

All disposable items that may have come in contact with hazardous drugs during receipt, storage, preparation or administration must be treated as hazardous waste including PPE.1,6,7,10 Hazardous waste must be disposed of separately from general waste in hazardous waste containers with lids.6 The hazardous waste container must be distinctly different from other types of waste containers.3,4,6,7

All disposable non-sharp HD waste must be disposed of in 4 mil thick plastic bags which are placed inside a rigid HD waste container or carton so that all waste is essentially ‘double-bagged’.3,4 The warning label must identify the contents as hazardous so that individuals transporting the waste are alerted to the need for special handling.3,4,7,8

All sharps used for the preparation and administration of hazardous drug admixtures must be placed into a puncture-proof hazardous drug sharps container for disposal3,4,6,7 without being crushed or clipped.3,6,8 Chemotherapy dispensing pins and chemotherapy vents removed from HD vials must also be disposed of in a hazardous drug sharps container. The HD sharps container must be sealed when it is no more than three-quarters full or at the indicated maximum fill line.3

HD waste containers must not be overfilled3 and the contents must not be pushed down to make more room due to the risk of HD exposure.7 Two pairs of chemotherapy gloves must be worn while handling hazardous waste.1,2,7

While awaiting removal from the facility for disposal, hazardous waste must be stored in a secure area in securely sealed and properly labelled containers.3 Hazardous waste must be transported and disposed of according to Federal and Provincial regulations after leaving the facility.3,4

Section G

G.1 Safe Handling of Oral, Topical and Pre-Packaged Hazardous Drug Dosage Forms

All drugs listed on the facility’s hazardous drug list must be handled according to hazardous drug safe handling guidelines.2 Oral, topical and pre-packaged hazardous drug dosage forms must be handled in a manner that prevents skin contact and minimizes the liberation of powdered or aerosolized HD into the air and cross contamination with other drugs.7

G.1.1 Oral Preparations

- Two pairs of chemotherapy gloves must be worn when handling hazardous drug tablets and capsules and when pouring HD oral solutions or suspensions1 in a designated area of the pharmacy dispensary35
- Dedicated ‘chemotherapy’ counting trays and spatulas must be used to count loose HD tablets and capsules1,2,35
- Hands must be washed immediately after removing chemotherapy gloves1,2,4,6
- Gloves worn when handling hazardous drugs must be discarded in HD waste1
- Automated counting machines must not be used to count hazardous drug tablets and capsules1,2,6,35

G.1.2 Topical Preparations

- Two pairs of chemotherapy gloves must be worn when handling hazardous drug topical preparations that have been removed from the original packaging1

Note:

- All interior surfaces of a BSC (except under the work surface) used for both sterile and non-sterile HD preparations must be cleaned following non-sterile HD preparations. Once cleaned, the BSC must purge for 15 minutes prior to compounding sterile HD products1
Section H

H.1 Hazardous Drug Spills

To minimize exposure of staff and patients to hazardous drugs, spills must be managed appropriately, according to established policies and procedures. Spill kits must be located in all areas where exposures may occur.1,7,9

H.1.1 Recommended Spill Kit Contents

New employees must be advised of hazardous drug spill control procedures9 and be required to demonstrate competency in spill handling.1

H.2 Accidental Exposure to Hazardous Drugs

Healthcare workers must be made aware of how to manage accidental exposure to hazardous drugs.9

Any accidental HD exposure as a result of a spill, needle stick or other accident must be reported immediately to the professional practice leader/department manager 6 and by calling the Provincial Workplace Health Call Centre reporting line at 1-866-922-9464. Appropriate documentation must be completed.3,6-8

H.2.2 Ingestion

Staff must not take food, gum, drinks, cigarettes or personal medication into an area where hazardous drugs are handled2 (e.g., received, stored,9 prepared, 9 administered1,9 and disposed).

Section I

I.1 Receipt and Storage

Personnel receiving and storing hazardous drugs must be made aware of precautions and follow special handling procedures.1,2,7

Safe handling procedures must be followed to avoid breakage of hazardous drug containers, to minimize exposure to hazardous drugs, and to contain spills that occur when receiving and storing hazardous drugs within the pharmacy.1

I.1.1 Receipt

➢ Two pairs of chemotherapy gloves must be worn when packing and unpacking boxes containing hazardous drugs1,2,4,5,7
➢ The outside of cartons must be examined for possible damage prior to opening1,7
➢ Hazardous drugs requiring refrigeration must be unpacked and refrigerated immediately upon receipt4,11

I.1.2 Receipt of a Damaged Shipment

Policies and procedures must be in place for handling damaged shipment of hazardous drugs.1

Damaged cartons, totes, and/or packages containing hazardous drugs that are received must NOT be opened and the receiver must don full PPE including a respirator mask and safety goggles to handle the package1,10 following procedures outlined in the BCCA Directive VI-10 Hazardous Spill Control in Pharmacy.

When cartons, totes, and/or packages are opened unknowingly with damaged contents inside, the receiver must don full PPE including a respirator mask and safety goggles4,10 and follow procedures outlined in the BCCA Directive VI-10 Hazardous Spill Control in Pharmacy.

HD spill kits with written procedures for use must be located in all areas where hazardous drugs are received.2,3
I.1.3 Storage

- Containers, shelves and bins used for HD storage must be properly labelled with hazard warning labels identifying the drugs that require special handling\(^1,^4,^9\).
- Barriers and other design features on bins and shelves must be present to contain accidental leakage and reduce the chance of drugs falling to the floor\(^1,^4\).
- Hazardous drugs must be stored separately from other inventory in a manner that prevents HD contamination and personnel exposure.\(^1,^2,^4,^5,^7\)
- To prevent errors from occurring, medication that can be easily mistaken for another (sounds alike, looks alike, similar labelling) must be separated in all areas of the pharmacy\(^1,^7\).
- Hazardous drugs in the refrigerator must be stored in individual leak and break-proof bins separately from non-hazardous drugs\(^4,^8\).
- Access to areas where hazardous drugs are stored must be limited to authorized personnel\(^4,^8\).
- Hazardous drugs spill kits with written procedures for use must be readily available in areas where hazardous drugs are stored.\(^3,^7,^9\)

I.2 Packaging and Transportation

Hazardous drugs must be packaged and transported in a manner which minimizes the risk of HD exposure due to a spill or breakage during transit.\(^1,^2,^4,^7\).
Module 2 – Pharmacy Medication Checks

Section A

A.1 Clinical Medication Order Check

The following must be reviewed and verified by a pharmacist for all parenteral, oral and topical oncology prescriptions prior to dispensing:

- pharmacy medication profile
- protocol code and cycle number (if appropriate)
- drug, dose (a maximum of a 5% variance is permitted in dose calculation unless a variance is prohibited by the treatment protocol), route, administration, timing and duration of each medication ordered; for cyclical therapies, no more than one cycle of medication will be dispensed at a time
- benefit status of the medication(s) and receipt of appropriate approval forms, if required
- patient-specific factors including allergies, alerts, and protocol required laboratory values; for new patients or patients beginning a new course of cancer treatment, baseline tests must have been conducted within four weeks of the start of therapy
- body surface area, calculated by the Mosteller equation, for the first treatment of each chemotherapy protocol only (based on actual body weight except for the designated high dose protocols described above, where ideal body weight is used) unless recalculated by the physician and documented in the patient’s chart - if required for the cancer treatment being prescribed

A.2 Final Product and Computer Order Entry Check

The final product must be checked prior to dispensing.

- a pharmacist must double check the volume/quantity calculation, ensure all components used are appropriate and perform a visual inspection of the final product
- a pharmacist must check that the drug volume(s) added to a final container matches the dose prescribed on the medication order
  - reconstitution solution and volumes must be checked by any qualified person other than the individual who measured the solution

The pharmacist performing the final product check must ensure correct computer order entry on the patient-specific label.

The patient-specific label must be:

- affixed to the correct final product container;
- checked for completion; and
- checked that it accurately reflects what is written on the corresponding medication order.

The final product must have the appropriate patient specific label, a HD warning label (if applicable) and any necessary auxiliary warning labels affixed to the container.

Section B

B.1 Documentation of Pharmacy Medication Checks

Standard operating procedures must be developed which include signed documentation that all the required pharmacy checks have been completed for each medication.

- the pharmacist performing the clinical medication order review must indicate that the order is approved for preparation by documenting on the appropriate form prior to compounding
- a pharmacist must indicate by documenting on a permanent record that they have performed a complete final product check including the computer order entry (e.g., patient label) check
Module 3 – Hazardous Drug Cleanroom Standards

Section A

A.2 Hazardous Drug Cleanroom and Anteroom

All parenteral cytotoxic/hazardous drug admixtures must be prepared in a minimum Class II Type B Biological Safety Cabinet (BSC) that maintains an ISO Class 5 environment.5

- The cleanroom or buffer room housing the BSC must be an ISO Class 7 environment physically separated from an adjacent ISO Class 7 or better ante-area.5,7
- A differential of at least 0.01 inch water column (negative pressure) must be maintained between the cleanroom and the pharmacy (anteroom).5
- Floors, walls, ceilings and all exposed surfaces must be nonporous and washable.5,7
- Cleaning must take place in the cleanroom at a time when no aseptic operations are in progress.5,7
- Essential furniture in buffer rooms and cleanrooms must be nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants.1,5
- Access to the cleanroom must be limited to authorized personnel who are assigned to work there.1-3,5,7,10,11
- A warning sign must clearly identify the hazard and state that access to the cleanroom is controlled and limited to authorized personnel only.7,9
- Doors must not be left open.10
- Appropriate personal protective equipment (PPE) must be donned by all personnel prior to entering the cleanroom to minimize the spread of skin particles that may shed.5
- Lab coats must not be worn in the cleanroom in place of chemotherapy gowns.5
- No shipping or other external cartons may be taken into the cleanroom or the compounding area.5,7
- Hazardous drugs must be stored separately from other inventory in a manner that prevents HD contamination and personnel exposure.1,5,7,11

A.2.1 Location of Biological Safety Cabinets

A BSC used for HD compounding must be located away from doorways, traffic corridors, and air conditioning and heating vents 1,5,6,14 inside a restricted access negative pressure ISO Class 7 cleanroom.5

Section B

B.1 Cleaning

Staff must be instructed on how to safely carry out their cleaning responsibilities within the cleanroom, the anteroom and in the vicinity of the BSC in order to minimize HD exposure to themselves and the environment.5,7

Section C

C.1 Documentation

Documentation records of routine BSC, cleanroom and anteroom cleaning must be completed and maintained.7
Module 4 – Improving Patient Safety and Compliance

Section A

A.1 Intrathecal (IT) Doses

Preparation of IT doses must be performed accurately given the limitations of syringe technology while following the principles of aseptic technique for the safety of the patient and to minimize exposure of staff to the hazardous drugs.27

All intrathecal doses will have a label stating the patient name, date, generic drug name, dose and route in full (i.e. By INTRATHECAL Injection). The route will be highlighted by using all upper case letters and/or a coloured highlighting pen. This labelling will be attached to the syringe and to the outer zip-lock bag. Intrathecal doses will be provided in luer lock syringes (WorkSafe BC Health and Safety Regulation 6.54). Intrathecal syringes and labels will have an auxiliary label stating ‘IT’ attached to the syringe and the outer zip-lock bag. These will be bright in colour and clearly visible.

Intrathecal doses will be packaged in separate outer containers for transport to the centre specific treatment location (i.e. intrathecal doses will be delivered separately from all other chemotherapy doses).

For protocols in which intrathecal drugs and drugs administered by other parenteral routes are all to be given in one same treatment cycle, the non-intrathecal drugs will NOT be released from pharmacy until the nurse or physician confirms that the intrathecal drug administration is completed.

Note:
- All drug and diluent used in the preparation of IT doses MUST be preservative free26
- All drug used MUST be labelled ‘for intrathecal use’ by the manufacturer26
- Gloves MUST be changed immediately prior to preparing the intrathecal dose27

Section B

B.1 Vinca Alkaloids

1. **Vincristine** should be dispensed in a 50mL minibag to be given over 5-15 minutes and labelled with an auxiliary label with the words ‘WARNING: FOR INTRAVENOUS USE ONLY – FATAL IF GIVEN BY OTHER ROUTES’38

2. **Other Vinca Alkaloids** dispensed in syringes or minibags are labelled with an auxiliary label with the words ‘WARNING: FOR INTRAVENOUS USE ONLY – FATAL IF GIVEN BY OTHER ROUTES’.
   a. The auxiliary labels are placed directly on the syringe barrel or infusion bag so that they are clearly visible to the person administering the drug. This should be done regardless of whether the patient is also scheduled to receive additional medication(s) by the intrathecal route
   b. The auxiliary labels are brightly coloured in contrast to the white medication label
Section D

D.1 Outpatient Hazardous Drug Prescription Labelling

All hazardous drugs dispensed for outpatient use must be labelled according to the current labelling standards found in the Health Professions Act (HPA) Bylaws; College of Pharmacists of BC.

A recognized strategy to improve comprehension of the directions on outpatient prescription labels and to reduce inadvertent medication errors is to standardize drug labelling practices.39

- All boxes/bottles must be individually labelled; multiple boxes must not be affixed together with a label on a single box40
- Vials, blister cards, boxes, bottles and jars containing hazardous drugs must be clearly labelled with a “Chemotherapy” warning auxiliary label1,40

Section E

E.1 Latex Allergies

Medication for patients allergic to latex must be prepared and administered in a latex-free environment. All surfaces of the biological safety cabinet must be cleaned and disinfected prior to compounding hazardous drug (HD) admixtures for latex-sensitive patients.17


References


27. BCCA Division of Pharmacy. BCCA Best Practice Safe Handling Standards. 2008.


32. BCCA Division of Pharmacy. BCCA Systemic Therapy Update - Elastomeric Infusors. 2008 June;2(11).


