

Biohazardous Drugs

1. What is a biohazardous drug?

BC Cancer pharmacy defines a biohazardous drug as a drug that contains living organisms with potential to cause infections in humans. This may include drugs identified elsewhere as gene therapy, biologicals or other biohazards. Bacille Calmette-Guerin (BCG), a vaccine used to treat bladder cancer, is an example of a biohazardous drug; it contains the attenuated microorganism *Mycobacterium bovis*. Newer biohazardous drugs are beginning to emerge in clinical trials. For example, pelareorep (REOLYSIN®), an oncolytic reovirus, is being studied for a variety of cancers (e.g., breast, colorectal, lung, multiple myeloma etc.).

2. I have heard other terms used to describe similar drugs (e.g., gene therapies, gene medicines, biological drugs, etc.). Are they the same as biohazardous drugs?

Drugs like gene therapies, gene medicines and biological drugs are sometimes biohazardous, but not always. The way to determine if a drug is biohazardous is to check for the presence of viable microorganisms with potential to cause infections in humans. For example, ritUXimab and BCG are both biological drugs made from a living organism or its products. ritUXimab is not biohazardous, because it does not contain any microorganisms; whereas, BCG is biohazardous, because it contains the viable microorganism *Mycobacterium bovis*.

3. Are biohazardous drugs considered to be hazardous drugs?

Yes, biohazardous drugs are included in the **Hazardous Drug Definition** listed in the **Glossary** of the [Safe Handling Standards Manual](#), and are included in the [BC Provincial Hazardous Drug List](#).

4. Why do biohazardous drugs require special precautions?

Although the microorganisms used in biohazardous drugs are unlikely to cause infections in healthy individuals, they do have the potential to cause infections in immunocompromised individuals. BCG has been implicated in causing nosocomial infections in immunocompromised patients when chemotherapy products became cross contaminated during preparation in the same cabinet. It has been postulated that the likely cause of the nosocomial transmission of BCG was failure to properly disinfect equipment used during sterile drug preparation. Theoretically, when other biohazardous drugs are prepared in the same Biological Safety Cabinet (BSC) as chemotherapy, cross contamination and nosocomial infections in immunocompromised patients could result; therefore, special handling procedures are required.

5. What procedures are required for biohazardous drugs?

Because biohazardous drugs are also hazardous drugs, procedures for both hazardous and biohazardous drugs must be followed.

Hazardous Drug Procedures

All health care professionals must follow the procedures outlined in the following ***Systemic Therapy Program Policies and Procedures*** [[SHOP](#)]:

- *V-10 Hazardous Drug Safe Handling Standards Policy*
- *V-20 Employee Health: Management of Risks Related Policy*
- *V-30 Hazardous Drug Spill Management Procedure*

Pharmacy staff must also follow specific Hazardous Drug Procedures:

- See *Section F* in the ***Safe Handling Standards Manual*** [[Module 1](#)]

Biohazardous Drug Procedures


Procedural additions/exceptions specifically for biohazardous drugs are outlined in the questions that follow.

6. How do you disinfect the BSC and other surfaces exposed to biohazardous drugs?

All surfaces exposed to biohazardous drugs during drug preparation, as well as any surfaces where a biohazardous drug spill has occurred, must be disinfected with effective disinfecting agent(s) for the required contact time after exposure.

See the appendix in **V-30 Hazardous Drug Spill Management Procedure** [[SHOP](#)] for examples of effective disinfecting agent for the specific biohazardous drugs. Pharmacy-specific procedures, including BSC decontamination and purging before preparing a different drug, can be found in the **Pharmacy Directive VI-40 Safe Handling of HD Dosage Forms** [[SHOP](#)].

7. Are special signs/labels required for biohazardous drugs?

A sign incorporating the universal biohazard symbol  must be posted on:

- the biohazardous drug storage bins/shelves
- the outside of the fridge where biohazardous drugs are stored
- at the entrance to the room where biohazardous drugs are prepared

Dispensed biohazardous drugs must be labelled as '**BIOHAZARDOUS**'.

8. Is the personal protective equipment (PPE) required for biohazardous drugs different than for other hazardous drugs?

No, the same PPE is required. The difference is that the PPE worn while preparing biohazardous drugs (chemotherapy gloves and gown) must be removed and disposed of into biohazardous (cytotoxic, hazardous) waste, hands washed, and then new PPE donned before the preparation of a different drug in the BSC.

9. Can we do other procedures in the sterile preparation room while performing procedures with biohazardous drugs?

The answer depends on the activity:

- In a clean room with multiple BSCs, while a biohazardous drug is being prepared in one BSC, the other BSCs may be used to prepare other drugs, unless the two BSC openings are face to face.
- No sterile hazardous drug preparation should take place in the clean room while a BSC viewing window is raised for decontamination or disinfection-following-biohazardous drug preparation.
- Sterile drug preparation may take place in another BSC(s) while a BSC in the same room is purging (with the viewing window lowered to the height specified by the manufacturer for hazardous drug preparation).