

# West Virginia Board of Pharmacy

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## GENERAL PHARMACY HAZARDOUS DRUG HANDLING INSPECTION - USP STANDARDS

«Name» «DBA_Name» «Address_Line_1», «City», «State» «Zip_Code»	E-Mail Address «Email»	Date
	Phone «PhoneDaytime»	Fax «Fax»
	DEA License # «DEA_Number»	WVBOP # «License_Number»
	Pharmacist-in-Charge «PharmacistInCharge»	License # «PIC_License»

THIS INSPECTION IS BASED ON WV PHARMACY LEGISLATIVE RULES & LAW  
AND THE MOST CURRENT VERSION OF USP CHAPTER <800>

	(If inspection element is Not Applicable, select n/a)	Y	N	?	n/a
	<b>LIST OF HAZARDOUS DRUGS</b>				
1.	The pharmacy maintains a list of any items handled within the individual pharmacy, which are included on the current NIOSH list of antineoplastic and other HDs. <b>Review.</b> <i>Verify that pharmacy has access to a copy of current NIOSH list</i>				
2.	The pharmacy reviews this list at least every 12 months for additions, deletions, or other changes and documents the review. <i>Verify documentation and list date of last change/review.</i> _____				
3.	The pharmacy has a system in place for the evaluation of new drugs (purchased, stored, handled, and/or dispensed) against the current version of the NIOSH list to determine whether or not they are considered HD. Check all boxes which apply: <input type="checkbox"/> In the absence of information, the pharmacy treats any new drug as an HD				
4.	If the pharmacy handles any HDs <b>not</b> using all containment requirements of <800>, an assessment of risk was performed for each drug and dosage form, individually, to determine alternative containment strategies, if needed, and work practices for each. <i>Review documentation of assessment and SOPs related to work practices/alternative containment.</i>				
5.	The assessment of risk (AoR) evaluation performed by the pharmacy's organization includes all required information, for each drug and dosage form. Check the boxes which are recorded in the assessment of risk. The AoR must, at a minimum, consider the first five items of the following: <input type="checkbox"/> Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk only) <input type="checkbox"/> Dosage form <input type="checkbox"/> Risk of exposure <input type="checkbox"/> Packaging <input type="checkbox"/> Manipulation <input type="checkbox"/> Required PPE				
6.	The assessment of risk is reviewed at least every 12 months and the review is documented. <b>Date of Last Review:</b> _____				
	<b>PERSONNEL RESPONSIBILITIES</b>				
7.	The pharmacy has a designated person(s) to oversee the handling of HDs who is qualified and trained for: development of SOPs; overseeing compliance with standards, laws and rules; and ensuring competency of personnel. <b>Name of person(s):</b> _____				

	(If inspection element is Not Applicable, select n/a)	Y	N	?	n/a
<b>DOCUMENTATION AND STANDARD OPERATING PROCEDURES (SOPs)</b>					
8.	SOPs are reviewed at least every 12 months by the designated person(s) and the review is documented. <b>Date of Last Review:</b> _____				
9.	SOPs are readily available to all who may need to handle HD or respond to a spill (pharmacy employees, housekeeping, nursing personnel, delivery personnel, etc.) <i>Describe whether SOPs are available electronically, paper, or both.</i>				
10.	Transport, if required. <i>(Will be n/a for most outpatient pharmacies)</i> <input type="checkbox"/> Packaging <input type="checkbox"/> Labeling				
11.	HD Waste segregation and Disposal (including reference to following local, state, and federal regulations) <i>(DEP in WV)</i>				
12.	Spill prevention and direction of spill cleanup and control must address the following: <input type="checkbox"/> size and scope of spill <input type="checkbox"/> responsible person for handling spills <input type="checkbox"/> location of spill kits and clean-up material <input type="checkbox"/> capacity of the spill kits <input type="checkbox"/> PPE to be worn during spills <input type="checkbox"/> handling of worn PPE and any exposed clothing under PPE <input type="checkbox"/> use of appropriate full-face, chemical cartridge-type respirator or PAPR if capacity of spill kit is exceeded or known or suspected airborne exposure to vapors/gases				
13.	The <b>hazard communication program</b> SOP has policies and procedures that ensure worker safety in all aspects of HD handling relevant to the pharmacy and ensure effective personnel training in proper labeling, transport, storage, and disposal of HDs, use of Safety Data Sheets (SDSs).				
14.	The hazard communication program must include, at a minimum, all of the following: <input type="checkbox"/> A written plan that describes how the standard will be implemented <input type="checkbox"/> How containers of HDs/hazardous chemicals will be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings <input type="checkbox"/> SDSs are maintained for each hazardous chemical they use (29 CFR 1910.1200) <input type="checkbox"/> How SDSs are readily accessible to personnel during each work shift and when they are in their work areas <input type="checkbox"/> Information and training provided to personnel prior to initial assignment to work with a hazardous chemical and whenever the hazard changes <input type="checkbox"/> Personnel of reproductive capability must confirm in writing that they understand the risks of handling HDs				
<b>PERSONNEL TRAINING</b>					
15.	All personnel handling HDs are trained based on their job function prior to independently handling HDs.				
16.	Personnel file contains the employee's acknowledgement of the risk of handling HD (as part of the hazardous communication program).				
17.	After initial HD training, personnel are trained prior to introduction of any new HD or new equipment, or prior to any significant change in process or SOP.				
18.	HD training, based on employee demonstration and file review, includes all of the following: <input type="checkbox"/> Overview of pharmacy's HD list <input type="checkbox"/> Utilization of AoR <input type="checkbox"/> Review of the SOPs related to HDs <input type="checkbox"/> Proper use of PPE <input type="checkbox"/> Appropriate procedures for deactivation, decontamination, cleaning, and disinfection (if applicable) <input type="checkbox"/> Response to known or suspected HD exposure <input type="checkbox"/> Spill Management <input type="checkbox"/> Proper disposal of HDs and trace-contaminated materials <input type="checkbox"/> New HD drug/ new equipment/ or prior to any significant change in process or SOP				

(If inspection element is Not Applicable, select n/a)		Y	N	?	n/a
<b>PERSONAL PROTECTIVE EQUIPMENT</b>					
19.	<b>Gloves:</b> The pharmacy is using appropriate gloves for the activities conducted. Chemotherapy gloves meet ASTM standard D6978 (or its successor) and are resistant to cleaning agents used). <ul style="list-style-type: none"> <li><input type="checkbox"/> Chemotherapy gloves are powder-free.</li> <li><input type="checkbox"/> Chemotherapy gloves are inspected for physical defects before use and defective gloves (e.g., pin holes, tears, weak spots) are discarded.</li> <li><input type="checkbox"/> Chemotherapy gloves are changed when torn, punctured, or contaminated.</li> </ul>				
20.	<b>Gowns:</b> The pharmacy is using appropriate gowns for the activities conducted (if required based on assessment of risk). <ul style="list-style-type: none"> <li><input type="checkbox"/> Gowns are disposable.</li> <li><input type="checkbox"/> Gowns resist permeability of HDs and are not laboratory coats, surgical scrubs, or isolation gowns (selected based on HDs handled).</li> <li><input type="checkbox"/> Gowns close in the back, are long sleeved, and have closed cuffs that are elastic or knit.</li> <li><input type="checkbox"/> Gowns do not have seams or closures that will allow HDs to pass through.</li> <li><input type="checkbox"/> Gowns worn in HD areas are not worn to other areas.</li> </ul>				
21.	<b>Eye and Face Protection:</b> The pharmacy is using appropriate eye and face PPE protection for the activities conducted (based on assessment of risk that HDs are irritating to the eyes and mucous membranes, where there is risk of spills or splashes when working outside of a C-PEC), if required. <ul style="list-style-type: none"> <li><input type="checkbox"/> If a risk to eyes, goggles (or a full-face respirator) are worn. Eyeglasses or safety glasses with side shields are not substituted for goggles.</li> <li><input type="checkbox"/> If a risk to face and eyes, goggles plus a face shield (or a full-face respirator) are worn. <i>(Face shields are not worn alone.)</i></li> </ul>				
22.	<b>Respiratory Protection:</b> The pharmacy is using appropriate respiratory PPE protection for the activities conducted (receiving, transport, and waste disposal) based on assessment of risk based on type of HD and type of activity, if required. <ul style="list-style-type: none"> <li><input type="checkbox"/> Surgical masks are not used as PPE when respiratory protection is needed.</li> </ul>				
23.	<b>Disposal of Used PPE:</b> Is all PPE worn during handling of HDs considered contaminated with at least trace quantities? <ul style="list-style-type: none"> <li><input type="checkbox"/> Worn PPE is placed in an appropriate HD waste container.</li> <li><input type="checkbox"/> Disposable PPE is NOT reused.</li> <li><input type="checkbox"/> Reusable PPE is decontaminated and cleaned after each use.</li> </ul>				
<b>FACILITIES AND ENGINEERING CONTROLS</b>					
24.	There are designated HD areas for all of the following: <ul style="list-style-type: none"> <li><input type="checkbox"/> Receiving and unpacking of HDs</li> <li><input type="checkbox"/> Storage of HDs</li> </ul>				
25.	<b>Receipt:</b> Are HDs received and unpacked (removed from external shipping containers) in an appropriate environment? <i>Describe</i> <ul style="list-style-type: none"> <li><input type="checkbox"/> Antineoplastics are unpacked in an area with air pressure relative to surrounding areas that is either neutral or negative pressure</li> </ul>				
26.	<b>Storage:</b> Are HDs stored in a manner to minimize accidental exposure? <i>Describe</i> <ul style="list-style-type: none"> <li><input type="checkbox"/> HDs are stored in a manner to minimize breakage and spillage.</li> </ul>				
<b>RECEIVING</b>					
27.	HDs are delivered to the HD storage area immediately after unpacking.				
28.	A spill kit is readily accessible in the receiving area.				
29.	Containers are visually examined for signs of damage or breakage prior to opening.				
30.	If a shipping container appears damaged and does not need to be opened, it is sealed, enclosed in an impervious container, labeled "Hazardous" on the outside, and returned to the supplier after contact or disposed of as hazardous waste.				
31.	If a damaged shipping container must be opened, it is done so according to SOPs, to include sealing the container in plastic or impervious container removing and wiping the outside of the undamaged items with disposable wipes, resealing the damaged items in an impervious container and marking it "Hazardous", returning it to the supplier after contact or disposing as hazardous waste, and deactivating, decontaminating, and cleaning the receiving area				
32.	Damaged packages are considered spills and reported to the designated person(s). <i>List last date of damaged package receipt.</i> <i>List Date:</i> _____				

	(If inspection element is Not Applicable, select n/a)	Y	N	?	n/a
	<b>DISPENSING AND PACKAGING PROCESSES</b>				
33.	Counting of antineoplastics is done by hand (e.g., not placed into automated counting devices).				
34.	Clean, dedicated (not used for non-HD purposes), or disposable equipment is used for counting and packaging of HDs.				
	<b>DEACTIVATING AND DECONTAMINATING</b>				
35.	The pharmacy has chosen the appropriate agent, as determined appropriate, for: <input type="checkbox"/> Deactivation (mark n/a if no compounding or manipulation). <b>List agent:</b> _____ <input type="checkbox"/> Decontamination. <b>List agent:</b> _____				
36.	Wipes or other appropriate delivery mechanisms, (e.g., not a spray bottle), are used for deactivation and decontamination.				
	<b>SPILL CONTROL</b>				
37.	Spills are contained and cleaned immediately.				
38.	Trained and qualified personnel are available at all times during operation with HDs to handle spills.				
39.	Spill kits, containing all items necessary to clean HD spills, are readily available in all areas where HDs are routinely handled.				
40.	The circumstances and management of all spills are documented. <b>Review documentation for spills for the last year and list the most recent date.</b> <b>List Date:</b> _____				

Inspector Comments:


P.I.C.

Date

Inspector

Date