National Association of Boards of Pharmacy®	West Virginia Board of Pharmacy
Universal Inspection Form	1207 Quarrier Street, Fourth Floor
USP 800 Hazardous Drugs - Compounding	Charleston, WV 25301
	Phone: 304-558-0558 Fax: (304)-558-0573

Pharmacy e-Profile ID: if available			Inspection Information
Legal Business Name:		Day 1:	
Doing Business As (DBA):		Start Time: 24-hour format (13:00)	
Address:		End Time: 24-hour format (13:00)	
City:		Day 2:	
State:		Start Time: 24-hour format (13:00)	
Zip Code:		End Time: 24-hour format (13:00)	
Telephone number:		Inspector Name:	
Toll free number:		Inspection Performed by (NABP, State, etc.):	West Virginia Board of Pharmacy
Fax number:		State Board of Pharmacy permit number:	
Website:		Observer Name/Affiliation (if applicable):	

Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open Start Time: (24-hour format)	End Time: (24-hour format)	Closed (X)
Sunday			
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge			
Nonsterile Compounding Supervisor			
Sterile Compounding Supervisor			
Hazardous Compounding Supervisor			

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Hazardous Drugs - Handling in Health Care Settings

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: «Name»,«DBA_Name»
e-Profile ID:
Inspection Date:

		Findings				Notes
	General Information and Scope:	**Yes**	**No**	**N/A**	**Unknown**	
1.00	Does the pharmacy handle any drugs on the National Institute for Occupational Safety and Health (NIOSH) list that **require** all the containment requirements of USP <800>?	☐	☐	☐	☐	
1.01	Does the pharmacy handle any ***hazardous drug*** active pharmaceutical ingredients (HD API)? *If yes, please list.*	☐	☐	☐	☐	
1.02	Does the pharmacy handle any antineoplastic requiring manipulations (which can produce particles, aerosols, or gases)? *If yes, please list.*	☐	☐	☐	☐	
2.00	Does the pharmacy handle any drugs on the NIOSH list that **do not** require all containment requirements of <800>?	☐	☐	☐	☐	
2.01	Does the pharmacy handle any final dosage forms of HDs (either compounded or manufactured unless required by the manufacturer) that do not require further manipulation other than counting and repackaging? *If yes, please list.*	☐	☐	☐	☐	
2.02	Does the pharmacy handle any dosage forms of other HDs **that are handled in full compliance** with containment requirements of <800>? *If yes, please list.*	☐	☐	☐	☐	
2.03	Does the pharmacy handle any dosage forms of other HDs **that are not handled** using all containment requirements of <800>? *If yes, please list.*	☐	☐	☐	☐	

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	List of Hazardous Drugs	Findings: Compliant	Non-compliant	N/A	Unknown	Notes
	Total Non-Compliant (Includes Unknowns)					
3.00	The pharmacy maintains a list of any items it handles that are included on the current NIOSH list of antineoplastic and other HDs. ***Review and attach list.*** *Verify that pharmacy has access to a copy of current NIOSH list.*	☐	☐	☐	☐	
4.00	The pharmacy reviews this list at least every 12 months for additions, deletions, or other changes and documents the review. *Verify documentation and* ***list date*** *of last change/review.*	☐	☐	☐	☐	
5.00	The pharmacy reviews this list whenever the pharmacy adds a new agent or dosage form to the items it handles.	☐	☐	☐	☐	
6.00	The pharmacy has a system in place for the evaluation of new drugs (purchased, stored, handled, and/or dispensed) to determine whether they are considered HD.	☐	☐	☐	☐	
6.01	Pharmacy evaluates the drugs against the current version of the NIOSH list.	☐	☐	☐	☐	
6.02	In the absence of information, the pharmacy treats any new drug as an HD.	☐	☐	☐	☐	
7.00	If the pharmacy handles any HDs not 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. *Review documentation of assessment and SOPs related to work practices/alternative containment.*	☐	☐	☐	☐	

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		Findings				Notes
8.00	The assessment of risk evaluation performed by the pharmacy's organization includes all required information, for each drug and dosage form. *The first five (5) items below must be included in the evaluation in order to be compliant.*	☐	☐	☐	☐	
8.01	Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk only);	☐	☐	☐	☐	
8.02	Dosage form;	☐	☐	☐	☐	
8.03	Risk of exposure;	☐	☐	☐	☐	
8.04	Packaging;	☐	☐	☐	☐	
8.05	Manipulation; and	☐	☐	☐	☐	
8.06	If applicable, Table II and III drugs have alternative containment strategies and/or work practices to minimize occupational exposure.	☐	☐	☐	☐	
8.07	The assessment of risk is reviewed at least every 12 months, and the review is documented. *Enter date of last review in the notes.*	☐	☐	☐	☐	
	Personnel Responsibilities	**Compliant**	**Non-compliant**	**N/A**	**Unknown**	
	Total Non-Compliant (Includes Unknowns)					
9.00	The pharmacy has a designated person(s) to oversee the handling of HDs who is qualified and trained for development of standard operating procedures (SOPs); overseeing compliance with standards, laws, and rules; ensuring competency of personnel; and ensuring environmental control.	☐	☐	☐	☐	

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		Findings				Notes
9.01	The designated person oversees the monitoring of the facility, including testing/sampling programs, maintaining, and documentation, and acting on results.	☐	☐	☐	☐	
	Documentation and Standard Operating Procedures (SOPs)	**Compliant**	**Non-compliant**	**N/A**	**Unknown**	
	Total Non-Compliant (Includes Unknowns)					
10.00	The assessment of risk and SOPs for handling HDs addresses all potential types of exposure, including all activities occurring within the operation that present an opportunity for exposure:					
10.01	**Receiving**: Contacting HD residues on packaging, work surfaces, floors	☐	☐	☐	☐	
10.02	**Dispensing**: Counting or packaging tablets and capsules	☐	☐	☐	☐	
10.03	**Compounding/other manipulations**: Crushing/splitting tablets, opening capsules, pouring liquids, weighing or mixing, constituting/reconstituting powdered/lyophilized HDs, expelling air from HD syringes, HD residue on personal protective equipment (PPE), cleaning activities of HD areas, and HD equipment maintenance.	☐	☐	☐	☐	
10.04	**Administration and other patient care activities** (if applicable).	☐	☐	☐	☐	
10.05	**Spills**: Spill generation, management, and disposal.	☐	☐	☐	☐	
10.06	**Transport**	☐	☐	☐	☐	
10.07	**Waste**: Collection and disposal of HD waste and trace contaminated waste	☐	☐	☐	☐	
11.00	SOPs are reviewed at least every 12 months by the designated person, and the review is documented.	☐	☐	☐	☐	

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		Findings				Notes
12.00	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.). *Describe whether P&Ps are available electronically, by paper, or both.*	☐	☐	☐	☐	
13.00	SOPs address at a minimum:					
13.01	Hazard communication program plan	☐	☐	☐	☐	
13.02	Competent personnel	☐	☐	☐	☐	
13.03	Occupational safety program	☐	☐	☐	☐	
13.04	Designation of HD areas	☐	☐	☐	☐	
13.05	Receiving HDs, including handling of damaged shipping containers/breakages	☐	☐	☐	☐	
13.06	A list of HDs	☐	☐	☐	☐	
13.07	Storage of HDs	☐	☐	☐	☐	
13.08	Compounding of HDs	☐	☐	☐	☐	
13.09	Use and maintenance of proper engineering controls (e.g., containment primary engineering control [C-PECs], containment secondary engineering control [C-SECs], and closed system drug transfer device [CSTDs]) to include SOPs for repairs, loss of power, moving, etc.	☐	☐	☐	☐	
13.10	Hand hygiene and proper use of appropriate PPE based on activity (e.g., receipt, transport, compounding, administration, spill, disposal).	☐	☐	☐	☐	
13.11	Deactivation, decontamination, cleaning, disinfection SOPs include all of the following:					

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Facility Name: «Name»,«DBA_Name»
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		Findings				Notes
13.11.01	Agents used	☐	☐	☐	☐	
13.11.02	Dilutions, if used	☐	☐	☐	☐	
13.11.03	Frequency	☐	☐	☐	☐	
13.11.04	PPE to be worn (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted--addressed in SOPs)	☐	☐	☐	☐	
13.11.05	Documentation requirements	☐	☐	☐	☐	
13.12	Receiving SOPs to include communications with suppliers about packaging and visual/other inspection of shipping containers for signs of damage and how to handle damaged containers.	☐	☐	☐	☐	
13.13	If a shipping container appears damaged and **does not need to be opened**:					
13.13.01	It is sealed without opening and wrapped in impervious plastic;	☐	☐	☐	☐	
13.13.02	Labeled as "hazardous"; and	☐	☐	☐	☐	
13.13.03	Returned to the supplier after contacting the supplier or disposed of as hazardous waste if supplier declines return.	☐	☐	☐	☐	
13.14	If a damaged shipping container **must be opened**:					
13.14.01	Container is sealed in plastic or an impervious container;	☐	☐	☐	☐	

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		Findings				Notes
13.14.02	It is transported to the C-PEC before opening, preferably nonsterile compounding C-PEC, if available;	☐	☐	☐	☐	
13.14.03	container is placed on a plastic-backed preparation mat;	☐	☐	☐	☐	
13.14.04	It is opened and undamaged items are removed and wiped down with a disposable wipe;	☐	☐	☐	☐	
13.14.05	Damaged item is enclosed in an impervious container and labeled "hazardous";	☐	☐	☐	☐	
13.14.06	Damaged item is returned to the supplier or disposed of as hazardous waste;	☐	☐	☐	☐	
13.14.07	Deactivate, decontaminate, and clean the C-PEC in accordance with SOPs; and	☐	☐	☐	☐	
13.14.08	If a sterile compounding C-PEC must be used, it is also disinfected after cleaning prior to resuming any sterile compounding activities.	☐	☐	☐	☐	
13.15	Safe work Practices SOPs	☐	☐	☐	☐	
13.16	Dispensing SOPs	☐	☐	☐	☐	
13.17	Packaging and labeling SOPs	☐	☐	☐	☐	
13.18	Transport SOPs	☐	☐	☐	☐	
13.19	Administering SOPs, if applicable	☐	☐	☐	☐	
13.20	Environmental monitoring (e.g., wipe sampling) SOPs	☐	☐	☐	☐	
13.21	HD waste segregation and disposal (including reference to following local, state, and federal regulations) SOPs	☐	☐	☐	☐	

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		Findings				Notes
13.22	Spill prevention and direction of spill cleanup and control SOPs must address the following:					
13.22.01	Size and scope of spill;	☐	☐	☐	☐	
13.22.02	Responsible person for handling spills;	☐	☐	☐	☐	
13.22.03	Location of spill kits and clean-up materials;	☐	☐	☐	☐	
13.22.04	Capacity of the spill kits;	☐	☐	☐	☐	
13.22.05	PPE to be worn during spills;	☐	☐	☐	☐	
13.22.06	Handling of worn PPE and any exposed clothing under PPE;	☐	☐	☐	☐	
13.22.07	Use of appropriate full-face, chemical cartridge-type respirator or powered air-purifying respirators (PAPR) if capacity of spill kit is exceeded or known or suspected airborne exposure to vapors/gases; and	☐	☐	☐	☐	
13.22.08	Medical evaluation/incident reporting/documentation/other handling of persons potentially exposed or with direct skin/eye contact to the HD.	☐	☐	☐	☐	
13.23	***Recommendation:*** *Does the pharmacy have a medical surveillance program? (a comprehensive control program to monitor and identify potential worker health care issues from HD exposure.)*	☐	☐	☐	☐	
14.00	The **hazard communication program** 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), based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).	☐	☐	☐	☐	

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		Findings				Notes
15.00	The pharmacy's hazard communication program includes, at a minimum, all of the following:					
15.01	A written plan that describes how the standard will be implemented;	☐	☐	☐	☐	
15.02	How containers of HDs/hazardous chemicals will be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings;	☐	☐	☐	☐	
15.03	SDSs are maintained for each hazardous chemical they use (29 CFR 1910.1200);	☐	☐	☐	☐	
15.04	How SDSs are readily accessible to personnel during each work shift and when they are in their work areas;	☐	☐	☐	☐	
15.05	Information and training provided to personnel prior to initial assignment to work with a hazardous chemical and whenever the hazard changes; and	☐	☐	☐	☐	
15.06	Personnel of reproductive capability confirm in writing that they understand the risks of handling HDs.	☐	☐	☐	☐	
	Personnel Training *--Check four employee files for documentation*	**Compliant**	**Non-compliant**	**N/A**	**Unknown**	
	Total Non-Compliant (Includes Unknowns)					
16.00	All personnel handling HDs are trained based on their job function prior to independently handling HDs.	☐	☐	☐	☐	
17.00	Personnel file contains the employee's acknowledgement of the risk of handling HD (as part of the hazardous communication program).	☐	☐	☐	☐	

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		Findings				Notes
18.00	For non-sterile HD compounding, personnel competency is observed and assessed at least annually for proper compounding technique, with no concerns identified.	☐	☐	☐	☐	
19.00	For sterile HD compounding, personnel competency is observed and assessed at least annually for proper sterile compounding aseptic technique, with no concerns identified.	☐	☐	☐	☐	
20.00	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.	☐	☐	☐	☐	
21.00	All HD training and assessments are documented for each employee who transports, compounds, or administers HDs, and meets Occupational Safety and Health Administration Standard 1910.120 and any other requirements of law or regulation.	☐	☐	☐	☐	
22.00	All personnel who perform custodial HD waste removal and cleaning in HD handling areas are trained in appropriate procedures to protect themselves and the environment.	☒	☐	☐	☐	
23.00	HD training, based on employee file review, all of the following are present:					
23.01	Overview of pharmacy's HD list and their risks;	☐	☐	☐	☐	
23.02	Review of the SOPs related to HDs;	☐	☐	☐	☐	
23.03	Proper use of PPE;	☐	☐	☐	☐	
23.04	Proper use of equipment and devices (e.g., engineering controls);	☐	☐	☐	☐	

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		Findings				Notes
23.05	Appropriate procedures for deactivation, decontamination, cleaning, and disinfection (if applicable);	☐	☐	☐	☐	
23.06	Response to known or suspected HD exposure;	☐	☐	☐	☐	
23.07	Spill management;	☐	☐	☐	☐	
23.08	Proper disposal of HDs and trace-contaminated materials; and	☐	☐	☐	☐	
23.09	New HD drug/new equipment or prior to any significant change in process or SOP.	☐	☐	☐	☐	
24.00	If respiratory protection is needed for any HDs handled, personnel are fit tested and trained in the proper use of the respirator.	☐	☐	☐	☐	
	Personal Protective Equipment	**Compliant**	**Non-compliant**	**N/A**	**Unknown**	
	Total Non-Compliant (Includes Unknowns)					
25.00	For sterile and nonsterile compounding with HDs, personnel wear gowns; head, hair, and shoe covers; and two pairs of chemotherapy gloves.	☐	☐	☐	☐	
26.00	Appropriate PPE is readily accessible where HD is handled, include all of the following:					
26.01	Receipt (PPE appropriate to HD as set forth in SOPs, and at a minimum, chemotherapy gloves worn);	☐	☐	☐	☐	
26.02	Storage;	☐	☐	☐	☐	
26.03	Transport;	☐	☐	☐	☐	

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Inspection Date:

		Findings				Notes
26.04	Nonsterile Compounding (if performed by the pharmacy);	☐	☐	☐	☐	
26.05	Sterile Compounding (if performed by the pharmacy);	☐	☐	☐	☐	
26.06	Administration, if applicable;	☐	☐	☐	☐	
26.07	Deactivation/decontamination, cleaning, and disinfecting (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted/addressed in SOPs);	☐	☐	☐	☐	
26.08	Spill control;	☐	☐	☐	☐	
26.09	Waste disposal; and	☐	☐	☐	☐	
26.10	If administering injectable antineoplastics, two pairs of chemotherapy gloves and permeability resistant gowns are worn.	☐	☐	☐	☐	
27.00	Disposable PPE is not reused.	☐	☐	☐	☐	
28.00	Reusable PPE is decontaminated and cleaned after each use.	☐	☐	☐	☐	
29.00	**Gloves:** 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) and are resistant to cleaning agents used.	☐	☐	☐	☐	
29.01	**Recommendation**: Are chemotherapy *gloves worn for handling all HDs including non-antineoplastics and for reproductive risk only HDs?*	☐	☐	☐	☐	
29.02	Chemotherapy gloves are powder-free.	☐	☐	☐	☐	
29.03	Chemotherapy gloves are inspected for physical defects before use and defective gloves (e.g., pin holes, tears, weak spots) are discarded.	☐	☐	☐	☐	

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Hazardous Drugs - Handling in Health Care Settings

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: «Name»,«DBA_Name»
e-Profile ID:
Inspection Date:

		Findings				Notes
29.04	For sterile compounding, the outer chemotherapy gloves are sterile.	☐	☐	☐	☐	
29.05	Chemotherapy gloves are changed when torn, punctured, or contaminated.	☐	☐	☐	☐	
29.06	**Recommendation**: *Are chemotherapy gloves changed every 30 minutes (unless otherwise recommended by the manufacturer)?*	☐	☐	☐	☐	
29.07	Hands are washed with soap and water after removing chemotherapy gloves.	☐	☐	☐	☐	
30.00	**Gowns**: The pharmacy is using appropriate gowns for the activities conducted (if required for type of compounding based on standards or assessment of risk).	☐	☐	☐	☐	
30.01	Gowns are disposable.	☐	☐	☐	☐	
30.02	Gowns resist permeability of HDs and are not laboratory coats, surgical scrubs, or isolation gowns (selected based on HDs handled).	☐	☐	☐	☐	
30.03	Gowns close in the back, are long sleeved, and have closed cuffs that are elastic or knit.	☐	☐	☐	☐	
30.04	Gowns do not have seams or closures that will allow HDs to pass through.	☐	☐	☐	☐	
30.05	Gowns are changed in accordance with the manufacturer's instructions, or if no permeation information is available, they are changed every two to three hours or immediately after a spill or splash.	☐	☐	☐	☐	
30.06	Gowns worn in HD areas are not worn to other areas.	☐	☐	☐	☐	

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Facility Name: «Name»,«DBA_Name»
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		Findings				Notes
31.00	**Head, hair** (beard and moustache, if appropriate)**, and shoe and sleeve covers.** The pharmacy is using appropriate head, hair, and shoe and sleeve covers for the type of compounding based on standards or assessment of risk to provide protection from contact with HD residue, if required.	☐	☐	☐	☐	
31.01	When HD compounding, a second pair of shoe covers are donned before entering the C-SEC and doffed when exiting the C-SEC.	☐	☐	☐	☐	
31.02	Shoe covers worn in HD areas are not worn into other areas of the facility.	☐	☐	☐	☐	
32.00	**Eye and Face Protection**: 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.	☐	☐	☐	☐	
32.01	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.*	☐	☐	☐	☐	
32.02	If a risk to face and eyes, goggles plus a face shield (or a full-face respirator) are worn.	☐	☐	☐	☐	
33.00	**Respiratory Protection**: The pharmacy is using appropriate respiratory PPE protection for the activities conducted (receiving, transport, compounding, administration, and waste disposal) based on assessment of risk based on type of HD and type of activity, if required. *Indicate what type of PPE which is available to employees (and is fit-tested, when required).*	☐	☐	☐	☐	

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Facility Name: «Name»,«DBA_Name»
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		Findings				Notes
33.01	Fit-tested NIOSH-certified N95 respirator;	☐	☐	☐	☐	
33.02	Elastomeric half-mask with a multi-gas cartridge and P100-filter;	☐	☐	☐	☐	
33.03	Full-face piece, chemical cartridge-type respirator;	☐	☐	☐	☐	
33.04	PAPR; and/or	☐	☐	☐	☐	
33.05	Other (describe in notes).	☐	☐	☐	☐	
34.00	Surgical masks are **not** used as PPE when respiratory protection is needed.	☐	☐	☐	☐	
35.00	The pharmacy uses an appropriate respiratory PPE for large HD spills; deactivating, decontaminating, and cleaning underneath the work surface of the C-PEC; and when there is known or suspected airborne exposure to powders or vapors. *Indicate what type of PPE which is available to employees (and is fit-tested, when required).*	☐	☐	☐	☐	
35.01	Fit-tested NIOSH-certified N95 respirator;	☐	☐	☐	☐	
35.02	Elastomeric half-mask with a multi-gas cartridge and P100-filter;	☐	☐	☐	☐	
35.03	Full-facepiece, chemical cartridge-type respirator;	☐	☐	☐	☐	
35.04	PAPR; and/or	☐	☐	☐	☐	

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Facility Name: «Name»,«DBA_Name»
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Inspection Date:

		Findings				Notes
35.05	Other (describe in notes).	☐	☐	☐	☐	
36.00	Surgical masks are **not** used as PPE when respiratory protection is needed.	☐	☐	☐	☐	
37.00	**Disposal of Used PPE**: Is all PPE worn during handling of HDs considered contaminated with at least trace quantities?	☐	☐	☐	☐	
37.01	Worn PPE is placed in an appropriate HD waste container.	☐	☐	☐	☐	
37.02	The HD waste container is located in reasonable proximity to HD PPE doffing activities.	☐	☐	☐	☐	
37.03	Chemotherapy gloves, and sleeve covers if worn, are carefully removed and discarded immediately into an approved HD trace waste container inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC.	☐	☐	☐	☐	
	Facilities and Engineering Controls	**Compliant**	**Non-compliant**	**N/A**	**Unknown**	
	Total Non-Compliant (Includes Unknowns)					
38.00	There are signs prominently displayed before the entrance to all HD handling areas designating the hazard.	☐	☐	☐	☐	
38.01	Access to these areas is restricted to authorized personnel who have been appropriately trained.	☐	☐	☐	☐	
38.02	HD areas are located away from breakrooms/refreshment areas for personnel, patients, and/or visitors.	☐	☐	☐	☐	
39.00	There are designated HD areas for any of the following:					
39.01	Receiving and unpacking of HDs	☐	☐	☐	☐	
39.02	Storage of HDs	☐	☐	☐	☐	

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Facility Name: «Name»,«DBA_Name»
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Inspection Date:

		Findings				Notes
39.03	Nonsterile HD compounding (if performed by the pharmacy)	☐	☐	☐	☐	
39.04	Sterile HD compounding (if performed by the pharmacy)	☐	☐	☐	☐	
40.00	***Recommendation:*** *If there is a requirement for certain designated areas to have negative pressure from surrounding areas, is there an uninterrupted power source (UPS) to the ventilation systems in order to maintain negative pressure in the case of power loss?*	☐	☐	☐	☐	
41.00	**Receipt**: Are HDs received and unpacked (removed from external shipping containers) in an appropriate environment? *Describe.*	☐	☐	☐	☐	
41.01	Antineoplastics and HD APIs are unpacked in an area with air pressure relative to surrounding areas that is either neutral or negative pressure. *Indicate the type of environment. If the environment is positive pressure, it is non-compliant.*	☐	☐	☐	☐	
41.01.01	Neutral	☐	☐	☐	☐	
41.01.02	Negative	☐	☐	☐	☐	
42.00	HDs are not unpacked in a sterile compounding area (e.g., no external containers are brought into C-SEC).	☐	☐	☐	☐	
43.00	**Storage**: Are HDs stored in a manner to minimize accidental exposure? *Describe.*	☐	☐	☐	☐	
43.01	HDs are not stored on the floor.	☐	☐	☐	☐	
43.02	HDs are stored in a manner to minimize breakage and spillage.	☐	☐	☐	☐	
43.03	If facility is in an area prone to specific types of natural disasters, appropriate precautions are taken (e.g., raised front lips on shelving in earthquake prone areas).	☐	☐	☐	☐	

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Facility Name: «Name»,«DBA_Name»
e-Profile ID:
Inspection Date:

		Findings				Notes
44.00	Antineoplastic HDs that require manipulation (other than counting and repackaging final dosage forms) and HD API are stored separately from non-HDs.	☐	☐	☐	☐	
44.01	These HDs are stored in an externally ventilated, negative pressure room.	☐	☐	☐	☐	
44.02	The HD storage room has at least 12 air changes per hour (ACPH).	☐	☐	☐	☐	
44.03	Refrigerated antineoplastic HDs are stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH (e.g., storage room, buffer room, or containment segregated compounding area [C-SCA]).	☐	☐	☐	☐	
44.04	**Recommendation**: *If the refrigerator is located in a buffer room, is an exhaust located adjacent to the refrigerator's compressor and behind the refrigerator?*	☐	☐	☐	☐	
45.00	If non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastics are stored with other non-HD inventory, there is a written policy/SOP addressing it.	☐	☐	☐	☐	
46.00	**Compounding**: There are appropriate engineering controls to protect the HD preparation from cross-contamination, and if sterile compounding, from microbial contamination, during all phases of the compounding process.	☐	☐	☐	☐	
47.00	All HD compounding are performed within a C-PEC located in a C-SEC room.	☐	☐	☐	☐	
47.01	The C-SEC for both sterile and nonsterile HD compounding has all of the following:					

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Facility Name: «Name»,«DBA_Name»
e-Profile ID:
Inspection Date:

		Findings				Notes
47.01.01	Has fixed walls;	☐	☐	☐	☐	
47.01.02	Is externally vented;	☐	☐	☐	☐	
47.01.03	Is able to meet (12) or exceed ACPH requirements;	☐	☐	☐	☐	
47.01.04	Is physically separated (i.e., a different room) from other preparation areas; and	☐	☐	☐	☐	
47.01.05	Has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to all adjacent areas.	☐	☐	☐	☐	
48.00	The C-PEC operates continuously if it supplies some or all of the negative pressure in the C-SEC or if it is used for sterile compounding.	☐	☐	☐	☐	
49.00	There is a sink readily available for handwashing on the hazardous side.	☐	☐	☐	☐	
49.01	There is an eyewash station readily available.	☐	☐	☐	☐	
49.02	Water sources and drains are a minimum of 1 meter away from the C-PEC.	☐	☐	☐	☐	
50.00	Does the pharmacy engage in **nonsterile HD compounding**? If yes, complete 50.01-54. If no, skip to 55:	☐	☐	☐	☐	
50.01	Select the location where **nonsterile HD compounding** is performed type(s):					
50.01.01	C-PECs used for sterile HD compounding are located in a different room than C-PECs used for nonsterile HD compounding	☐	☐	☐	☐	
50.01.02	C-PECs used for sterile HD compounding are located in the same room as C-PECs used for nonsterile HD compounding.	☐	☐	☐	☐	

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Facility Name: «Name»,«DBA_Name»
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		Findings				Notes
50.02	Select the type(s) of containment primary engineering control(s) used for **nonsterile HD compounding**:					
50.02.01	Class I biological safety cabinet (BSC)	☐	☐	☐	☐	
50.02.02	Class II BSC	☐	☐	☐	☐	
50.02.03	Containment ventilated enclosure (CVE)	☐	☐	☐	☐	
50.02.04	Compounding aseptic containment isolator (CACI)	☐	☐	☐	☐	
50.02.05	Other, describe	☐	☐	☐	☐	
51.00	Indicate if the C-PEC used for **nonsterile HD compounding** (must be one of two below in order to be compliant):					
51.01	Is externally vented *(preferred);* **and/or**	☐	☐	☐	☐	
51.02	Has redundant High Efficiency Particulate Air (HEPA) filters in series	☐	☐	☐	☐	
52.00	Does the pharmacy use the same C-PEC (Class II BSC or CACI) used for sterile HD compounding and nonsterile HD compounding?	☐	☐	☐	☐	
52.01	Is **nonsterile HD compounding** only "occasional"? *If yes, please describe frequency and quantity.*	☐	☐	☐	☐	

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		Findings				Notes
52.02	Is the **nonsterile HD compounding** activity only occurring when sterile HD compounding is not being performed?	☐	☐	☐	☐	
52.03	Is the C-PEC decontaminated, cleaned, and disinfected prior to resuming sterile compounding?	☐	☐	☐	☐	
53.00	The C-SEC has at least 12 ACPH. *Verify documentation and monitoring.*	☐	☐	☐	☐	
54.00	The ceilings, walls, floors, fixtures, shelving, counters, and cabinets are smooth, impervious, free from cracks and crevices, and non-shedding. *If non-compliant describe.*	☐	☐	☐	☐	
55.00	Does the pharmacy engage in **sterile HD compounding**? If yes, complete 55.01-61.02.03. If no, skip to 62.	☐	☐	☐	☐	
55.01	Select the type(s) of containment primary engineering control(s) used for **sterile HD compounding**:					
55.01.01	CACI	☐	☐	☐	☐	
55.01.02	Class II BSC, Type A1 (formerly Type A and not suitable for volatile toxic chemicals and volatile radionuclides)	☐	☐	☐	☐	
55.01.03	Class II BSC, Type A2 (formerly Type B3)	☐	☐	☐	☐	
55.01.04	Class II BSC, Type B1	☐	☐	☐	☐	
55.01.05	Class II BSC, Type B2 (total exhaust for volatile components)	☐	☐	☐	☐	
55.01.06	Class III BSC	☐	☐	☐	☐	

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		Findings				Notes
55.01.07	LAFW (not for antineoplastics)	☐	☐	☐	☐	
55.01.08	CAI (not for antineoplastics)	☐	☐	☐	☐	
56.00	The C-PEC maintains ISO Class 5 or better air quality and is under continuous operation, unless power loss or repair occurs.	☐	☐	☐	☐	
57.00	Is the C-PEC used for **sterile HD compounding** externally vented?	☐	☐	☐	☐	
58.00	If a BSC or CACI that is used for **sterile HD compounding** is also used for non-HD preparations, is the non-HD preparation placed into a protective outer wrapper during removal from the C-PEC?	☐	☐	☐	☐	
58.01	If used for both, is the non-HD preparation labeled to require PPE handling precautions?	☐	☐	☐	☐	
59.00	If the C-SEC is an unclassified containment segregated HD compounding area (C-SCA: enclosed separate room with fixed walls, but not ISO classified), beyond-use dates (BUDs) are limited in accordance with <797> as Category 1 compounded sterile preparations.	☐	☐	☐	☐	
59.01	The C-SEC (C-SCA) has at least 12 ACPH. *Verify documentation and monitoring.*	☐	☐	☐	☐	
59.02	A handwashing sink is at least one meter or more away from the C-PEC	☐	☐	☐	☐	
59.02.01	Describe whether the sink is inside the C-SCA or directly outside the C-SCA					
60.00	If BUDs are longer than the Category 1 BUDs specified in <797>, the PEC is located in a C-SEC, which is an ISO Class 7 buffer room adjacent to an ISO Class 7 anteroom.	☐	☐	☐	☐	

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		Findings				Notes
60.01	The buffer room has fixed walls.	☐	☐	☐	☐	
60.02	The buffer room is externally vented.	☐	☐	☐	☐	
60.03	The buffer room has HEPA-filtered supply air.	☐	☐	☐	☐	
60.04	The buffer room has at least 30 ACPH.	☐	☐	☐	☐	
60.05	The buffer room has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to the anteroom.	☐	☐	☐	☐	
60.06	The anteroom has fixed walls.	☐	☐	☐	☐	
60.07	The ante room has a minimum of 30 ACPH of HEPA-filtered supply air.	☐	☐	☐	☐	
60.08	The ante room maintains positive pressure of at least 0.02 inches water column relative to any adjacent unclassified areas.	☐	☐	☐	☐	
60.09	The handwashing sink is located in the anteroom at least 1 meter or more away from the door to the buffer room to prevent contamination into the negative pressure buffer room.	☐	☐	☐	☐	
61.00	If the negative-pressure HD buffer room is entered through a positive-pressure non-HD buffer room, there is a line of demarcation within the buffer room for donning and doffing PPE.	☐	☐	☐	☐	
61.01	There is a design and method to contain and minimize HD contamination when **transporting** HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room:	☐	☐	☐	☐	

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Hazardous Drugs - Handling in Health Care Settings

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: «Name»,«DBA_Name»
e-Profile ID:
Inspection Date:

		Findings				Notes
61.02	Indicate how HD contamination is minimized:					
61.02.01	Pass-through chamber between negative pressure buffer room and adjacent space included in the facility's certification not compromising air quality in the buffer room *(verified in the facility's semi-annual certification report that pass through has not compromised air quality in the bufferroom).*	☐	☐	☐	☐	
61.02.02	Use of sealed containers	☐	☐	☐	☐	
61.02.03	Other, *describe*	☐	☐	☐	☐	
	Environmental Quality and Control - Surface wipe sampling	**Yes**	**No**	**N/A**	**Unknown**	
62.00	**Recommendation**: **Surface wipe sampling** is performed routinely (initially and at least every six months) to monitor HD containment processes and trends, which includes all of the following:	☐	☐	☐	☐	
62.01	Interior of C-PEC and equipment within the C-PEC	☐	☐	☐	☐	
62.02	Pass-through chambers	☐	☐	☐	☐	
62.03	Surfaces in staging or work areas near the C-PEC	☐	☐	☐	☐	
62.04	Areas adjacent to the C-PEC (e.g., floors directly under, staging, and dispensing areas)	☐	☐	☐	☐	
62.05	Areas immediately outside the HD buffer room or the C-SCA	☐	☐	☐	☐	

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		Findings				Notes
	Receiving	**Compliant**	**Non-compliant**	**N/A**	**Unknown**	
	Total Non-Compliant (Includes Unknowns)					
63.00	**Recommendation**: HDs are packaged by the supplier in impervious plastic to segregate them from other drugs and decrease possibility of exposure during unpacking and internal transfer.	☐	☐	☐	☐	
64.00	HDs are delivered to the HD storage area immediately after unpacking.	☐	☐	☐	☐	
65.00	A spill kit is readily accessible in the receiving area.	☐	☐	☐	☐	
66.00	Containers are visually examined for signs of damage or breakage prior to opening.	☐	☐	☐	☐	
67.00	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.	☐	☐	☐	☐	
67.01	If a damaged shipping container must be opened, it is done so according to SOPs, to include sealing the container in plastic or an impervious container, transporting it to the C- PEC for unpacking, 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 C-PEC.	☐	☐	☐	☐	

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		Findings				Notes
68.00	Damaged packages are considered spills and reported to the designated person. ***List last date of damaged package receipt.***	☐	☐	☐	☐	
	Labeling, Packaging, Transport, and Disposal	**Compliant**	**Non-compliant**	**N/A**	**Unknown**	
	Total Non-Compliant (Includes Unknowns)					
69.00	HDs requiring special HD handling are always clearly labeled as hazardous during transport and in accordance with any laws related to labeling of HDs.	☐	☐	☐	☐	
70.00	Labeling processes do not introduce contamination into non-HD handling areas.	☐	☐	☐	☐	
71.00	Packaging materials are chosen that protect the HD and healthcare worker against damage, leakage, contamination, and degradation during transport, but also maintains the physical integrity, stability, and sterility of the HD.	☐	☐	☐	☐	
72.00	Pneumatic tubes are not used for transporting any liquid HDs or antineoplastic HDs.	☐	☐	☐	☐	
73.00	Labeling on HDs shipped outside the pharmacy meets all of the following requirements:					
73.01	Labeling specified in SDS for transport;	☐	☐	☐	☐	
73.02	Storage and disposal instructions; and	☐	☐	☐	☐	
73.03	Labeled with HD category.	☐	☐	☐	☐	

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		Findings				Notes
	Dispensing, Packaging, and Compounding Processes	**Compliant**	**Non-compliant**	**N/A**	**Unknown**	
	Total Non-Compliant (Includes Unknowns)					
74.00	Counting of antineoplastics is done by hand (e.g., not placed into automated counting devices).	☐	☐	☐	☐	
75.00	Clean, dedicated (not used for non-HD purposes), or disposable equipment is used for counting, packaging, and compounding of HDs.	☐	☐	☐	☐	
75.01	**Recommendation**: Equipment is decontaminated after every use.	☐	☐	☐	☐	
75.02	**Recommendation**: When compounding, a plastic-backed preparation mat is placed on the C-PEC work surface and changed and discarded appropriately as HD waste. All of the following should apply in order to make this a Yes.	☐	☐	☐	☐	
75.02.01	Immediately if a spill occurs	☐	☐	☐	☐	
75.02.02	Regularly during use	☐	☐	☐	☐	
75.02.03	At the end of a shift	☐	☐	☐	☐	
76.00	APIs or other powdered HDs are handled in a C-PEC during particle-generating activities, such as crushing, opening capsules, and weighing powders.	☐	☐	☐	☐	

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		Findings				Notes
	Deactivating and Decontaminating (Cleaning and Disinfecting are performed in accordance with Chapters <795> and <797>)	**Compliant**	**Non-compliant**	**N/A**	**Unknown**	
	Total Non-Compliant (Includes Unknowns)					
77.00	The pharmacy has chosen appropriate oxidizing agent(s) for deactivation and decontamination and proven effective by testing.	☐	☐	☐	☐	
78.00	Wipes or other appropriate delivery mechanisms (e.g., not a spray bottle) are used for deactivation and decontamination.	☐	☐	☐	☐	
79.00	The C-PEC must be decontaminated. *All of the following must be done to be compliant:*	☐	☐	☐	☐	
79.01	Between compounding of different HDs	☐	☐	☐	☐	
79.02	At least daily when used	☐	☐	☐	☐	
79.03	Any time a spill occurs	☐	☐	☐	☐	
79.04	Before and after certification	☐	☐	☐	☐	
79.05	Any time voluntary interruption occurs	☐	☐	☐	☐	
79.06	If the ventilation tool is moved	☐	☐	☐	☐	
80.00	HD containers are wiped down prior to placing them in the C-PEC and the solution used does not alter the product label.	☐	☐	☐	☐	
81.00	Areas, other than the work surface of the C-PEC, where contamination can build up (such as areas under the work tray), are deactivated, decontaminated, and cleaned at least monthly.	☐	☐	☐	☐	
82.00	Additional PPE (e.g., respirator) is used in accordance with SOPs, to protect the worker if containment airflows are compromised by opening the cabinets to get to these areas.	☐	☐	☐	☐	

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		Findings				Notes
	Spill Control	**Compliant**	**Non-compliant**	**N/A**	**Unknown**	
	Total Non-Compliant (Includes Unknowns)					
83.00	Spills are contained and cleaned immediately.	☐	☐	☐	☐	
84.00	Trained/qualified personnel are always available during operation with HDs to handle spills.	☐	☐	☐	☐	
85.00	Only trained/qualified personnel engage in spill containment and cleanup.	☐	☐	☐	☐	
86.00	There are signs available to restrict access to spill areas.	☐	☐	☐	☐	
87.00	Spill kits, containing all ingredients necessary to clean HD spills, are readily available in all areas where HDs are routinely handled.	☐	☐	☐	☐	
88.00	Spill materials are disposed of as hazardous waste.	☐	☐	☐	☐	
89.00	The circumstances and management of all spills are documented. ***Review documentation for spills for the last year and list the most recent date.***	☐	☐	☐	☐	

PIC Signature _____ Date _____ Inspector Signature _____ Date _____