New Mexico Board of Pharmacy
NONSTERILE HAZARDOUS DRUG COMPOUNDING INSPECTION REPORT

Facility Name		License #
Street Address		City
Zip Code	Phone #	Fax #
NM Controlled Sub. Lic.#		DEA Registration #
Pharmacist-in-charge/Consultant RPh (Name and License #)		
Date of Inspection:		Inspector Signature:
Official Signature:		

PREPARATION LEVEL (circle all that apply)	
What type of non-sterile Hazardous Drug (HD) compounding will the pharmacy engage in? ☐ Compounding with HD Active Pharmaceutical Ingredients (APIs) ☐ Manipulating antineoplastic HDs	Check all that apply
Does the pharmacy compound hazardous nonsterile preparations (CHNSPs) pursuant to a prescription?	Yes/No
Does the pharmacy **distribute** non-patient-specific CHNSPs for office-use? (Allowed only for reasonable quantities of compounded veterinary preparations)	Yes/No
Has an assessment of risk been performed by the facility for conventionally manufactured HD products and final dosage forms of compounded HD preparations they only count or repackage?	Yes/No

STANDARDS FOR HAZARDOUS DRUG (HD) COMPOUNDING	YES/NO	COMMENTS
Only pharmacists, pharmacist interns and pharmacy technicians are compounding. A pharmacist performs the final check on all CHNSPs.		

All APIs (Active Pharmaceutical Ingredients) are pharmaceutical grade and obtained from FDA registered facilities.		
All APIs have a Certificate of Analysis (COA) that includes specifications and test results and shows that the API meets the specifications. Facility should put receipt date on APIs if lacking vendor expiration date. (NOTE: If the API lacks a vendor's expiration date the compounding facility cannot use the product after 3 years from the date of receipt.)		
HD standard operating procedures are reviewed at least every 12 months by designated personnel (they should be reviewed by the Pharmacist-in-Charge).		

INSPECTION CHECKLIST

I. CONTAINMENT PRIMARY & SECONDARY ENGINEERING CONTROLS (C-PEC/C-SEC) (See section 5 in USP General Chapter <800>)	Compliant? Yes/No	COMMENTS
Nonsterile HD compounding is performed in a containment primary engineering control (C-PEC) such as a Class I BSC or Containment Vented Enclosure (CVE). A Class II BSC or CACI may also be used.		What type of PEC is used?
The C-PEC used for HD compounding is externally vented or has redundant-HEPA filters in series.		
All HD compounding is performed in a containment secondary engineering control (C-SEC) that is physically separated from other compounding areas.		
The C-SEC has fixed walls.		

Surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the nonsterile compounding area are smooth, impervious, free from cracks and crevices, and non-shedding.		
The C-SEC is externally vented.		
*A doffing line is present inside the C-SEC? (Not required but best practice is to use in all designs.)		
A sink with warm water is available for hand washing.		
An eyewash station and/or other emergency or safety precautions that meet applicable laws and regulations is available.		
Pass-throughs, if used, have sealed, interlocking doors.		
The C-SEC has at least 12 air changes per hour (ACPH) as determined by independent third party company.		
The C-SEC has a negative pressure between 0.01 and 0.03 inches water column relative to adjacent areas. A pressure gauge is available to record pressure differentials.		
*Facility <u>should</u> perform environmental wipe sampling to detect uncontained hazardous drugs (initially as a benchmark and at least every 6 months). <u>Should</u> include: 1. Interior of the C-PEC and equipment contained in it 2. Pass-through chambers 3. Surfaces in staging or work areas near the C-PEC		

4. Areas adjacent to C-PECs (e.g., floors directly under C-PEC, staging, and dispensing area) 5. Areas immediately outside the C-SEC 6. Patient administration areas		

II. PERSONNEL CLEANSING AND GARBING (See section 7 in USP General Chapter <800>)		
Appropriate PPE is available: including gowns, head/hair covers, shoe covers and chemotherapy gloves. Two pairs of shoe covers must be worn when in the HD C-SEC, the outer shoe cover must be doffed when exiting the C-SEC.		
PPE <u>should</u> be stored away from the sink to avoid splash contamination.		
Gowns worn for HD compounding close in the back (i.e., no open front), are long sleeved, and have closed cuffs that are elastic or knit. Gowns must not have seams or closures that could allow HDs to pass through. (Gowns that are polyethylene-coated polypropylene or other laminate materials offer better protection) (check to see if available).		
Powder-free chemotherapy gloves are available for compounding activities. They must meet American Society for Testing and Materials (ASTM) standard D6978 (or its successor). Personnel must wear two pairs of chemotherapy gloves while compounding HDs.		

Appropriate eye and face protection (both goggles and face shields worn together or a full-facepiece respirator) is worn when there is a risk for spills or splashes of HDs or HD waste materials when working outside of a C-PEC (e.g., administration in the surgical suite, working at or above eye level, or cleaning a spill). (Eye glasses alone or safety glasses do not protect the eyes adequately from splashes.)		
*An appropriate full-facepiece, chemical cartridge-type respirator or powered air-purifying respirator (PAPR) <u>should</u> be worn when there is a risk of respiratory exposure to HDs, including when: 1. Attending to HD spills larger than what can be contained with a spill kit 2. Deactivating, decontaminating, and cleaning underneath the work surface of a C-PEC 3. There is a known or suspected airborne exposure to powders or vapors		

III. RECEIVING, STORAGE & COMPOUNDING (See section 5, 10 and 13 in USP General Chapter <800>)	Compliant? Yes/No	COMMENTS
Hazardous Drugs (antineoplastics and APIs) are unpacked in a specially designated area that is neutral/normal or negative pressure. They must not be unpacked in positive pressure areas.		
Hazardous drug spill kits are readily available in all areas where HDs are routinely handled (includes receiving area).		
Antineoplastic Hazardous Drugs and Hazardous Drug APIs are stored separately from non-HDs in an externally vented, negative pressure area with at least 12 air changes per hour. HDs cannot be stored on the floor.		

Refrigerated antineoplastic HDs are stored in a dedicated refrigerator in a negative pressure area with 12 ACPH.		
*When compounding HD preparations, a plastic-backed preparation mat should be placed on the work surface of the C-PEC. The mat should be changed immediately if a spill occurs and regularly during use, and should be discarded at the end of the daily compounding activity.		
*Final preparations should be wiped down with designated decontamination agent before removing from the PEC. *After labeling, the final preparation should be placed in a bag (Ziploc or comparable) for transport.		
All sharps, tubing, empty containers, supplies and PPE are disposed of in a yellow, hazardous products container, and container is kept closed. (Federal RCRA guideline)		
Bulk HD waste is discarded as Resource Conservation and Recovery Act (RCRA) waste in black containers. Bulk = vials or drug containers that are not empty, cleanup pads or swept up contents of HD spills. (Federal RCRA guideline)		

IV. CLEANING OF COMPOUNDING AREAS (See section 15 in USP General Chapter <800>)	Compliant? Yes/No	COMMENTS
The C-PEC is deactivated and decontaminated at least daily (when used), any time a spill occurs, any time voluntary interruption occurs, and if the ventilation tool is moved? *Floors and high touch areas are decontaminated at least weekly (best practice). (Check if decontaminating agent available)		

Equipment used to clean SECs and PECs where hazardous drug compounding is performed <u>should</u> be dedicated to those areas and not used elsewhere.		
The following sites <u>must</u> be cleaned according to the minimum frequencies specified below: Cleaning guidelines are from the revised USP 795, official November 2023.		
<u>Work Surfaces</u>	Beginning and end of shift on days when compounding occurs, after spills, when contamination known or suspected. Between compounding CNSPs with different components.	
<u>Floors</u>	Daily on days when compounding occurs, after spills, and when contamination known or suspected	
<u>Walls</u>	When visibly soiled, after spills, and when contamination known or suspected	
<u>Ceilings</u>	When visibly soiled and when contamination known or suspected	
<u>Storage Shelving</u>	Every 3 months, after spills, and when contamination known or suspected	
Personnel who perform deactivation, decontamination, cleaning, and activities in HD handling areas are trained in appropriate procedures to protect themselves and the environment from contamination.		
All personnel performing cleaning activities must wear appropriate PPE resistant to the cleaning agents used, including two pairs of chemotherapy gloves and impermeable disposable gowns. Eye protection and face shields are worn if splashing is likely. If warranted by the activity, respiratory protection must be used.		
Area under work tray/surface (if exists) is deactivated, decontaminated and cleaned at least monthly. Appropriate PPE (esp. respiratory protection) is worn during this process.		

Inspection items that have the * symbol indicate that the item is a recommendation by USP and/or CriticalPoint and may be considered best practice.

EMPLOYEE INFORMATION

NAME	Rph or Tech, LICENSE #	Initial and Annual Hazardous Training (per USP 800)	Confirmed in writing they understand risks of handling HDs	Initial and Annual Compounding Proficiency Assessment (per USP 795)