2024
RETAIL DRUG OUTLET and INSTITUTIONAL DRUG OUTLET
COMPOUNDING PHARMACY
SELF-INSPECTION FORM

ATTENTION: PHARMACIST-IN-CHARGE (PIC)

Failure to complete this form by July 1, 2024, and within 15 days of becoming PIC, may result in disciplinary action (OAR 855-115-0210(1)(h)).

Please note: **This is not a standalone self-inspection form. It is to be completed in conjunction with the appropriate Drug Outlet Self-Inspection Form (i.e., Retail, Institutional, Non-Resident, etc.).**

Requirements: Oregon law states the PIC and all pharmacists on duty are responsible for ensuring the pharmacy is compliant with all applicable state and federal laws and rules. This form must be provided to the board immediately upon request at the time of inspection and retained in compliance with OAR 855-104-0055.

Scope: The primary objective of completing the self-inspection is to identify and correct areas of non-compliance with any state and federal laws and rules. This process is not exhaustive, and laws and rules often change between annual updates to this form. Subsequently, it is your responsibility to ensure compliance with any changes, or applicable laws and rules, not referenced herein.

Internal Use: Following completion of the self-inspection form, ensure it is signed and dated by the PIC, reviewed with all pharmacy staff, and filed in a conspicuous manner (DO NOT SEND to the agency office). It is advisable to create a binder for this form, using tabs to organize and group documents where possible. Otherwise, please CLEARLY indicate on the form where auxiliary documents are located.

Agency Use: During an inspection, Compliance Officers use the self-inspection form as a general guide to assess pharmacy compliance. The PIC and all pharmacy staff should be prepared and able to retrieve this form and locate any auxiliary documents referenced within at the time of inspection.

Email all compliance-related questions to: *pharmacy.compliance@bop.oregon.gov*.

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Please list where the following items are specifically located inside the pharmacy. Once located, ensure each is compliant, and reflects currents practices within the outlet (if an item is not applicable, indicate with N/A). Unless otherwise specified, documents are to be retained for 3 years (the first of which must be on site) and must be provided to the Board upon request, as outlined in OAR 855-104-0055.

Compounding References (please list name(s) and location)

Initial and Ongoing Training and Certificates

- Nonsterile Compounding
- Sterile Compounding
    - Media Fill / Gloved Fingertip Competency

Policies and Procedures

- Training, Evaluation and Requalification
- Creating Compounding and Master Formulation Records (with documented pharmacist approval)
- Hygiene
- Cleaning Activities (to include sanitizing and disinfecting)
- Gowning and Garbing
- Material Selection, Handling, and Storage
- Handling, Packaging, Storage, and Transport of completed compounded preparations
- Continuous Quality Assurance and Quality Control (to include release-testing, end-product evaluation, and quantitative/qualitative testing)
- Adverse Event Reporting and Recalls

Testing (equipment, environmental, and product)

- Equipment Certifications and Calibrations
- Environmental Monitoring (air and surface sampling for viable and non-viable particles, as appropriate)
- Bulk Chemical Certificates of Analysis

Records

- Cleaning Logs
- Master Formulation Records
- Compounding Worksheets

You are required to confirm whether the outlet is compliant. Mark the appropriate box to the left of each item, resolve all deficiencies and write the date of correction, if applicable.

General Requirements

Yes	No	N/A			Rule Reference
☐	☐	☐	1	Does the pharmacy have access to current USP Chapters? **Note:** USP Chapters updated with effective date of 11/1/2023	OAR 855-041-1035 OAR 855-045-0200 OAR 855-045-0205
☐	☐	☐	2	Does the pharmacy have compounding accreditation? If yes, please specify (e.g., NABP, PCAB, Joint Commission): _____ Date of the last accreditation: _____ / _____ / _____ ***(Attach a copy of last accreditation to this form)***	

Compounded Non-Sterile Preparations (CNSPs) General Requirements □ N/A

			3.	What type of non-sterile compounding is performed? (check all that apply) ☐ Topical Creams ☐ Oral Suspensions	

				☐ Compounding Kits ☐ Hazardous / HRT ☐ Veterinary ☐ Other:	

Compounding Policies and Procedures

Yes	No	N/A			Rule Reference
			3	Describe the pharmacy's process for the supervision of compounding. **Note:** A technician may only compound under the supervision, direction, and control of a pharmacist.	ORS 689.486(6)
☐	☐	☐	4	Does the pharmacy have standard operating policies and procedures for the following? (mark each box once confirmed) ☐ Continuous quality assurance/ quality control ☐ Cleaning, testing, and calibration of all equipment and devices ☐ Establishing beyond-use dates (BUDs) for compounded products ☐ Extending BUDs (if practiced) ☐ Adverse event reporting and recalls (to include notifying the Board of a patient-level recall within 10 working days)	OAR 855-045-0220 OAR 855-045-0270
		☐	5	If the pharmacy extends BUD's beyond USP standards, please describe the QA process utilized to ensure sterility and/or stability are maintained: How often are samples sent for testing to an independent laboratory to account for the facility's unique processes?	OAR 855-045-0220

Compounding Operations

Yes	No	N/A			Rule Reference
☐	☐	☐	6	Are bulk drug substances acquired **only** from Board-registered manufacturers or wholesalers, and have the required certificate of analysis?	e-CFR 503A Guidance Document 503B Guidance Document
☐	☐	☐	7	Is the pharmacy **only** using active pharmaceutical ingredients (APIs) and excipients that are approved for use in humans, not laboratory/research grade products?	e-CFRs
☐	☐	☐	8	Does the pharmacy batch compounded products?	

Yes	No	N/A			Rule Reference
☐	☐	☐	9	Does the pharmacy provide samples of compounded products to prescribers, or sell compounded products OTC? **If yes, attach a copy of the pharmacy's manufacturing registrations from both the FDA, and Board of Pharmacy.**	OAR 855-060-0001 OAR 855-045-0210
☐ ☐	☐ ☐	☐ ☐	10	Does the pharmacy handle hazardous drugs (which includes receiving, storing, compounding, dispensing, etc.)? If yes, is the pharmacy currently in compliance with USP 800?	OAR 855-045-0200

Compounding Records

Yes	No	N/A			Rule Reference
☐	☐	☐	11	Do the master formulation records include the following required elements, where appropriate? (mark each box once confirmed) ☐ Complete instructions for preparing the product, including equipment, supplies, and description of compounding steps ☐ Ingredients, their amounts, and calculations used to determine/verify those amounts ☐ Sterilization method, if required (such as steam, dry heat, radiation, filtration, etc.) ☐ Quality control procedures and expected results ☐ Compatibility and stability information, including references ☐ BUD and storage requirements, including references ☐ Appropriate ancillary information such as cautionary statements, hazardous drug warning labels, etc. ☐ Name, strength, dosage form, and physical description of the **Note:** Be prepared to provide documentation at the time of inspection.	OAR 855-045-0270

Yes	No	N/A			Rule Reference
☐	☐	☐	12	Do completed compounding records include all of the following required elements? (mark each box once confirmed) ☐ Master formulation record reference for the preparation, when applicable ☐ Name, quantity (weight or measurement), manufacturer's lot number and expiration date for all ingredients used, including base, diluent, primary excipient, etc. ☐ Identity of all personnel involved in each step of the process ☐ Pharmacist documented verification of compounded product accuracy including the correct formula, calculations, and the correct measurements and drugs used ☐ Name, strength, dosage form, and physical description of final preparation ☐ Date and **time prepared** ☐ Quantity prepared ☐ Pharmacy unique lot number ☐ BUD and storage requirements (with reference, if different from master formulation record) ☐ Documentation of any quality control issues, adverse reactions, or preparation problems (including those reported by the patient, caregiver, or other person), with corresponding corrective actions ☐ Records of compound dispensation or transfer ☐ Any other information, as required by pharmacy policies and procedures	OAR 855-045-0270

Compounded Sterile Products (CSP's) General Requirements ☐ N/A

Yes	No			Rule Reference
		13	What type of sterile compounding is performed? (check all that apply) ☐ IV's ☐ TPN ☐ Intrathecal / Epidural ☐ Eye Drops ☐ Lyophilization ☐ Pellets ☐ Chemotherapy ☐ Other: ☐ Hazardous	
		14	How often does the pharmacy test **all** compounding personnel (including verifying pharmacists) in aseptic manipulative skills, gowning and garbing, and gloved fingertip sampling?	OAR 855-045-0220 OAR 855-045-0270
☐	☐	15	Do compounding procedures include requirements for use of gowns, shoe covers, hair covers, sterile gloves, and masks? **Note**: Makeup, jewelry, and artificial nails/fingernail polish are not permitted in the buffer room.	OAR 855-045-0220 OAR 855-045-0200
☐	☐	16	Are CSP's prepared in an ISO 5 certified Primary Engineering Control (PEC)?	OAR 855-045-0200

Yes	No			Rule Reference
☐	☐	17	Are all ISO classified areas checked and certified per USP standards every 6 months and whenever a PEC is relocated, or the physical structure of the buffer room or anteroom has been altered?	OAR 855-045-0220
☐	☐	18	Is ISO determination taken under dynamic conditions while simulated compounding is occurring?	OAR 855-045-0200
☐	☐	19	Are surfaces and equipment in buffer room and anteroom nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants?	OAR 855-045-0200
☐	☐	20	Does the pharmacy document environmental monitoring to ensure that the compounding environment is properly maintained, including temperature, humidity, and pressure differentials?	OAR 855-045-0270
☐	☐	21	Does the pharmacy have policies and procedures that routinely monitor the compounding environment for microbial or fungal growth?	OAR 855-045-0220 OAR 855-045-0270
		22	How often does the pharmacy perform surface sampling? What is the incubation **time** and **temperature**?	OAR 855-045-0220 OAR 855-045-0270
☐	☐	23	In addition to regular labeling requirements, do CSP labels include all of the following elements? (mark each box once confirmed) ☐ The generic or official name of each active ingredient ☐ The strength or concentration of each active ingredient (to include primary solution for a sterile parenteral preparation) ☐ The dosage form and route of administration ☐ Rate of infusion (for a sterile parenteral preparation) ☐ The total quantity of the drug product ☐ A BUD, compliant with current USP standards ☐ Storage and handling instructions, cautionary information or warnings as necessary to promote proper and safe use, and any relevant drug-specific information?	OAR 855-045-0240
☐	☐	24	In ISO 7 and 8 areas, are floors and work surface areas cleaned **daily**, and are walls, ceilings, and shelving cleaned at least **monthly**?	OAR 855-045-0200
☐	☐	25	Who performs cleaning and disinfecting of ISO classified areas in the pharmacy? Are these individuals trained in accordance with USP 797?	OAR 855-045-0220 OAR 855-045-0270

Yes	No			Rule Reference
		26	What cleaners/ germicides/ sporicides are used to clean and disinfect? _ How often are they used? What is the dwell time?	OAR 855-045-0220 OAR 855-045-0270

I hereby certify that to the best of my knowledge, this outlet is compliant with all applicable laws and rules, and that the answers marked on this form are true and correct.

Date: _____/_____/_____

Printed Name of PIC: _____

Signature of PIC: _____