State of Idaho
Division Of Occupational and Professional Licenses
Board of Pharmacy

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FACILITY
_test Facility
123 Articss
address line two.
Boise, ID 83709
208999999

LICENSE
License No: OSF59592
License Type: Resident Drug Outlet

Inspection Type:	Compounding	**Inspection Date:**	6/1/2023 12:00:00 AM
Result:	Finalized		

Notes:
Remarks:

Checklist Results

24.36.01.700. COMPOUNDING DRUG PREPARATIONS.

Question	Answer
24.36.01.700. COMPOUNDING DRUG PREPARATIONS.Any compounding that is not permitted herein is considered manufacturing.	Compliant
24.36.01.700.02.c. Equipment. Equipment and utensils must be of suitable design and composition and cleaned, sanitized, or sterilized as appropriate prior to use.	Compliant
24.36.01.700.02.d. Disposal of Compromised Drugs. When the correct identity, purity, strength, and sterility of ingredients and components cannot be confirmed (in cases of, for example, unlabeled syringes, opened ampoules, punctured stoppers of vials and bags, and containers of ingredients with incomplete labeling) or when the ingredients and components do not possess the expected appearance, aroma, and texture, they must be removed from stock and isolated for return, reclamation, or destruction.	Compliant
24.36.01.700.05.c. Non-Patient Specific Records. Except for drug products that are being compounded or sterile prepackaged for direct administration, a production record of drug products compounded or sterile prepackaged in anticipation of receiving prescription drug orders or distributed in the absence of a patient specific prescription drug order ("office use") solely as permitted in these rules, must be prepared and kept for each drug product prepared, including: i. Production date; ii. Beyond use date; iii. List and quantity of each ingredient; iv. Internal control or serial number; and v. Initials or unique identifier of all persons involved in the process or the compounder responsible for the accuracy of these processes.	Compliant
24.36.01.700.04.c. Anticipatory Compounding. Limited quantities of a drug product may be compounded or sterile prepackaged prior to receiving a valid prescription drug order based on a history of receiving valid prescription drug orders for the compounded or sterile prepackaged drug product.	Compliant
24.36.01.700.05. Drug Compounding Controls. a. Policies and Procedures. In consideration of the applicable provisions of USP Chapter 795 concerning pharmacy compounding of non-sterile preparations, USP Chapter 797 concerning sterile preparations, Chapter 1075 of the USP-NF concerning good compounding practices, and Chapter 1160 of the USP-NF concerning pharmaceutical calculations, policies and procedures for the compounding or sterile prepackaging of drug products must ensure the safety, identity, strength, quality, and purity of the finished product, and must include any of the following that are applicable to the scope of compounding practice being performed: i. Appropriate packaging, handling, transport, and storage requirements; ii. Accuracy and precision of calculations, measurements, and weighing; iii. Determining ingredient identity, quality, and purity; iv. Labeling accuracy and completeness; v. Beyond use dating; vi. Auditing for deficiencies, including routine environmental sampling, quality and accuracy testing, and maintaining inspection and testing records; vii. Maintaining environmental quality control; and viii. Safe limits and ranges for strength of ingredients, pH, bacterial endotoxins, and particulate matter.	Compliant

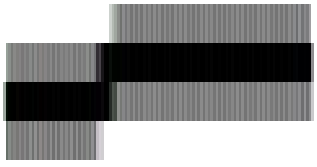
24.36.01.701. STERILE PREPARATION

Question	Answer
24.36.01.230.08. Sterile Preparation Endorsement. A drug outlet engaged in sterile preparation must obtain a single endorsement for one (1) or more hood or aseptic environmental control devices.	Yes
24.36.01.701.03. Compounder Responsibilities. i. Opened or entered (such as needle-punctured) single-dose containers, such as bags, bottles, syringes, and vials of sterile products and compounded sterile preparations are to be used within one (1) hour if opened in non-sterile conditions, and any remaining contents must be discarded; ii. Single-dose vials needle-punctured in a sterile environment may be used up to six (6) hours after initial needle puncture; iii. Opened single-dose ampules may not be stored for any time period; and iv. Multiple-dose containers (for example, vials) that are formulated for removal of portions on multiple occasions because they contain antimicrobial preservatives, may be used for up to twenty-eight (28) days after initial opening or entering, unless otherwise specified by the manufacturer;	Compliant
24.36.01.701.03.b. Water-containing compounded sterile products that are non-sterile during any phase of the compounding procedure must be sterilized within six (6) hours after completing the preparation in order to minimize the generation of bacterial	Compliant

endotoxins;	
24.36.01.701.04. Environmental Controls. Except when prepared for immediate administration, the environment for the preparation of sterile preparations in a drug outlet must be in an isolated area, designed to avoid unnecessary traffic and airflow disturbances, and equipped to accommodate aseptic techniques and conditions. a. Hoods and aseptic environmental control devices must be certified for operational efficiency as often as recommended by the manufacturer or at least every six (6) months or if relocated.	Compliant
24.36.01.701.05. Sterile Preparation Equipment. A drug outlet in which sterile preparations are prepared must be equipped with at least the following: a. Protective apparel including gowns, masks, and sterile (or the ability to sterilize) non-vinyl gloves, unless written documentation can be provided from the aseptic isolator manufacturer that any component of garbing is not necessary; b. A sink; c. A refrigerator for proper storage of additives and finished sterile preparations prior to delivery when necessary; and d. An appropriate laminar airflow hood or other aseptic environmental control device such as a laminar flow biological safety cabinet, or a comparable compounding area when authorized by USP Chapter 797.	Compliant
24.36.01.701.06. Documentation Requirements. The following documentation must also be maintained by a drug outlet in which sterile preparations are prepared: a. Justification of beyond use dates assigned, pursuant to direct testing or extrapolation from reliable literature sources; b. Training records, evidencing that personnel are trained on a routine basis and are adequately skilled, educated, and instructed; d. Temperature, logged daily; e. Beyond use date and accuracy testing, when appropriate; and f. Measuring, mixing, sterilizing, and purification equipment inspection, monitoring, cleaning, and maintenance to ensure accuracy and effectiveness for their intended use.	Compliant
24.36.01.701.07. Policies and Procedures. Policies and procedures appropriate to the practice setting must be adopted by a drug outlet preparing sterile pharmaceutical preparations and must include a continuous quality improvement program for monitoring personnel qualifications and training in sterile technique, including: a. Antiseptic hand cleansing; b. Disinfection of non-sterile compounding surfaces; c. Selecting and appropriately donning protective garb; d. Maintaining or achieving sterility of sterile preparations while maintaining the labeled strength of active ingredients; e. Manipulating sterile preparations aseptically, including mixing, diluting, purifying, and sterilizing in the proper sequence; f. Choosing the sterilization method, pursuant to the risk of a contamination of particular compounded sterile preparation; and g. Inspecting for quality standards before dispensing or distributing.	Compliant
24.36.01.702. HAZARDOUS DRUGS PREPARATION.	
Question	**Answer**
24.36.01.702.01. Ventilation. Ensure the storage and compounding areas have sufficient general exhaust ventilation to dilute and remove any airborne contaminants.	Compliant
24.36.01.702.02. Ventilated Cabinet. Utilize a ventilated cabinet designed to reduce worker exposures while preparing hazardous drugs.	Compliant
24.36.01.702.05. Protective Equipment and Supplies. Provide and maintain appropriate personal protective equipment and supplies necessary for handling hazardous drugs, spills and disposal.	Compliant
24.36.01.702.06. Contamination Prevention. Unpack, store, prepackage, and compound hazardous drugs separately from other inventory in a restricted area in a manner to prevent contamination and personnel exposure until hazardous drugs exist in their final unit-of-use packaging.	Compliant
24.36.01.702.07. Compliance With Laws. Comply with applicable local, state, and federal laws including for the disposal of hazardous waste.	Compliant
24.36.01.702.09. Policy and Procedures Manual. Maintain a policy and procedures manual to ensure compliance with this rule.	Compliant
24.36.01.103.04. Inspection Reports.	
Question	**Answer**
24.36.01.103.04. Inspection Reports. Inspection reports must be reviewed with the Board inspector and signed by an agent of the drug outlet upon completion of the exit interview.	Yes

THE UNDERSIGNED LICENSEE OR REPRESENTATIVE AT THE TIME OF INSPECTION ACKNOWLEDGES RECEIPT OF THIS INSPECTION REPORT.

6/1/2023 12:00:00 AM



Berk Fraser | Date/Time | Signature of Owner/Representative