IDAHO STATE BOARD OF PHARMACY
1199 SHORELINE LN, SUITE 303
BOISE, ID 83702
PHONE: 208-334-2356
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FACILITY

_test Facility
5613 MAIN
BOISE, ID 83709
2082222222

LICENSE

License No: 50087HP
License Type: Institutional Pharmacy

Inspection Type:	Annual	**Inspection Date:**	
Result:			

Notes:
Remarks:

Checklist Results	
27.01.01.103. BOARD INSPECTIONS AND INVESTIGATIONS	
Question	**Answer**
27.01.01.103.01. Records Subject to Board Inspection. Records created, maintained, or retained by Board licensees or registrants in compliance with statutes or rules enforced by the Board must be made available for inspection upon request by Board inspectors or authorized agents. It is unlawful to refuse to permit or to obstruct a Board inspection. (7-1-18)	
27.01.01.103.02. Inspections. Prior to the commencement of business, as applicable, and thereafter at regular intervals, registrants and licensees must permit the Board or its compliance officers to enter and inspect the premises and to audit the records of each drug outlet for compliance with laws enforced by or under the Board's jurisdiction. (7-1-18)	
27.01.01.300. DRUG OUTLETS: MINIMUM FACILITY STAND	
Question	**Answer**
27.01.01.300.01. Security and Privacy. A drug outlet must be constructed and equipped with adequate security to protect its equipment, records and supply of drugs, devices and other restricted sale items from unauthorized access, acquisition or use. All protected health information must be stored and maintained in accordance with HIPAA. (7-1-18)	
27.01.01.300.02. Controlled Substance Storage. Drug outlets that dispense prescription drugs must store controlled substances in accordance with federal law. (7-1-18)	
27.01.01.300.03. Authorized Access to the Restricted Drug Storage Area. Access to the restricted drug storage area must be limited to authorized personnel. (7-1-18)	
27.01.01.300.05. Electronic Recordkeeping System. A drug outlet that dispenses more than twenty (20) prescriptions per day must use an electronic recordkeeping system to establish and store patient medication records and prescription drug order, refill, transfer information, and other information necessary to provide safe and appropriate patient care. The electronic recordkeeping system must have audit trail functionality that documents for each prescription drug order the identity of each individual involved at each step of its processing, filling, and dispensing or, alternatively, the identity of the pharmacist or prescriber responsible for the accuracy of these processes. (7-1-18)	
27.01.01.104.10. Substandard, Misbranded, Adulterated, or Expired Products. Manufacturing, compounding, delivering, distributing, dispensing, or permitting to be manufactured, compounded, delivered, distributed or dispensed substandard, misbranded, or adulterated drugs or preparations or those made using secret formulas. Failing to remove expired drugs from stock.	
27.01.01.501.02. Individual Information Changes. Changes in employment or changes to information provided on or with the initial or renewal application must be reported to the Board within ten (10) days of the change.	
27.01.01.301. MINIMUM PRESCRIPTION FILLING REQUIRE	
Question	**Answer**
27.01.01.301.01. Valid Prescription Drug Order. Prescription drugs must only be dispensed pursuant to a valid prescription drug order as set forth in Subchapter D of these rules. (7-1-18)	
27.01.01.301.03. Labeling. Each drug must bear a complete and accurate label as set forth in these rules. (7-1-18) 27.01.01.301.04. Verification of Dispensing Accuracy. Verification of dispensing accuracy must be performed to	
27.01.01.301.04. Verification of Dispensing Accuracy. Verification of dispensing accuracy must be performed to compare the drug stock selected to the drug prescribed. If not performed by a pharmacist or prescriber, and electronic verification system must be used that confirms the drug stock selected to fill the prescription is the same as indicated on the prescription label. A compounded drug may only be verified by a pharmacist or prescriber. (6-30-19)T	
27.01.01.408. DESTRUCTION OR RETURN OF DRUGS OR DE	
Question	**Answer**
27.01.01.408. DESTRUCTION OR RETURN OF DRUGS OR DEVICES: RESTRICTIONS. A drug outlet registered with the DEA as a collector may collect controlled and non-controlled drugs for destruction in accordance with applicable federal law. Otherwise a dispensed drug or prescription device may only be accepted for return as follows: (7-1-18) 01. Potential Harm. When the pharmacist	

determines that harm could result if the drug is not returned. (7-1-18)02. Did Not Reach Patient. Non-controlled drugs that have been maintained in the custody and control of the institutional facility, dispensing pharmacy, or their related clinical facilities may be returned if product integrity can be assured. Controlled substances may only be returned from a hospital daily delivery system under which a pharmacy dispenses no more than a seventy-two (72) hour supply for a drug order. (6-30-19)T 03. Donation. Those that qualify for return under the provisions of the Idaho Legend Drug Donation Act as specified in Section 54-1762, Idaho Code. (7-1-18)	
27.01.01.500. RECORDKEEPING: MAINTENANCE AND INVEN	
Question	**Answer**
27.01.01.500.01. Records Maintenance and Retention Requirement. Unless an alternative standard is stated for a specified record type, form, or format, records required to evidence compliance with statutes or rules enforced by the Board must be maintained and retained in a readily retrievable form and location for at least three (3) years from the date of the transaction. (7-1-18)	
27.01.01.500.02. Prescription Retention. A prescription drug order must be retained in a readily retrievable manner by each drug outlet and maintained in accordance with federal law: (7-1-18)	
27.01.01.500.03. Inventory Records. Each drug outlet must maintain a current, complete and accurate record of each controlled substance manufactured, imported, received, ordered, sold, delivered, exported, dispensed or otherwise disposed of by the registrant. Drug outlets must maintain inventories and records in accordance with federal law. An annual inventory must be conducted at each registered location no later than seven (7) days after the date of the most recent inventory in a form and manner that satisfies the inventory requirements of federal law. Drugs stored outside a drug outlet in accordance with these rules must be regularly inventoried and inspected to ensure that they are properly stored, secured, and accounted for. Additional inventories are necessary when required by federal law. (7-1-18)	
Date of Inventory Completed	
Open or Closed	
Name of Pharmacist	
27.01.01.303 DRUGS STORED OUTSIDE OF A DRUG OUTLET FOR RETRIEVAL BY A LICENSED HEALTH PROFESSIONAL. Drugs may be stored in an alternative designated area outside the drug outlet, including, but not limited to, floor stock, in an emergency cabinet, in an emergency kit, or as emergency outpatient drug delivery from an emergency room at a registered institutional facility, provided the following conditions are met: (7-1-18) .03. Controlled Substances. Controlled substances may only be stored in an alternative designated area as permitted by, and in accordance with, federal law. (7-1-18)	
37-3303A PSE Electronic Tracking System in use	
27.01.01.700. COMPOUNDING DRUG PREPARATIONS	
Question	**Answer**
27.01.01.700. COMPOUNDING DRUG PREPARATIONS.Any compounding that is not permitted herein is considered manufacturing. (7-1-18)	
27.01.01.700.02.c. Equipment. Equipment and utensils must be of suitable design and composition and cleaned, sanitized, or sterilized as appropriate prior to use. (7-1-18)	
27.01.01.700.02.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. (7-1-18)	
27.01.01.700.04.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. (7-1-18)	
27.01.01.700.05. Drug Compounding Controls. (7-1-18) 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: (7-1-18) i. Appropriate packaging, handling, transport, and storage requirements; (7-1-18) ii. Accuracy and precision of calculations, measurements, and weighing; (7-1-18) iii. Determining ingredient identity, quality, and purity; (7-1-18) iv. Labeling accuracy and completeness; (7-1-18) v. Beyond use dating; (7-1-18) vi. Auditing for deficiencies, including routine environmental sampling, quality and accuracy testing, and maintaining inspection and testing records; (7-1-18) vii. Maintaining environmental quality control; and (7-1-18) viii. Safe limits and ranges for strength of ingredients, pH, bacterial endotoxins, and particulate matter. (7-1-18)	
27.01.01.700.05.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: (7-1-18) i. Production date; (7-1-18) ii. Beyond use date; (7-1-18) iii. List and quantity of each ingredient; (7-1-18) iv. Internal control or serial number; and (7-1-18) v. Initials or unique identifier of all persons involved in the process or the compounder responsible for the accuracy of these processes. (7-1-18)	
27.01.01.701. STERILE PREPARATION.	
Question	**Answer**
27.01.01.230.08. 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. (7-1-18)	
27.01.01.701.03. 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; (7-1-18) ii. Single-dose vials needle-punctured in a sterile environment may be used up to six (6) hours after initial needle puncture; (7-1-18) iii. Opened single-dose ampules may not be stored for any time period; and (7-1-18) 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; (7-1-18)	
27.01.01.701.03.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 endotoxins; (7-1-18)	
27.01.01.701.04. 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. (7-1-18) 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. (7-1-18)	
27.01.01.701.05. Sterile Preparation Equipment. A drug outlet in which sterile preparations are prepared must be equipped with at least the following: (7-1-18) 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; (7-1-18) b. A sink; (4-11-19) c. A refrigerator for proper storage of additives and finished sterile preparations prior to delivery when	

necessary; and (7-1-18) 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. (4-11-19)	
27.01.01.701.06. Documentation Requirements. The following documentation must also be maintained by a drug outlet in which sterile preparations are prepared: (7-1-18) a. Justification of beyond use dates assigned, pursuant to direct testing or extrapolation from reliable literature sources; (7-1-18) b. Training records, evidencing that personnel are trained on a routine basis and are adequately skilled, educated, and instructed; (7-1-18) d. Temperature, logged daily; (7-1-18) e. Beyond use date and accuracy testing, when appropriate; and (7-1-18) f. Measuring, mixing, sterilizing, and purification equipment inspection, monitoring, cleaning, and maintenance to ensure accuracy and effectiveness for their intended use. (7-1-18)	
27.01.01.701.07. 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: (7-1-18) a. Antiseptic hand cleansing; (7-1-18) b. Disinfection of non-sterile compounding surfaces; (7-1-18) c. Selecting and appropriately donning protective garb; (7-1-18) d. Maintaining or achieving sterility of sterile preparations while maintaining the labeled strength of active ingredients; (7-1-18) e. Manipulating sterile preparations aseptically, including mixing, diluting, purifying, and sterilizing in the proper sequence; (7-1-18) f. Choosing the sterilization method, pursuant to the risk of a contamination of particular compounded sterile preparation; and (7-1-18) g. Inspecting for quality standards before dispensing or distributing. (7-1-18)	

27.01.01.702. HAZARDOUS DRUGS PREPARATION.

Question	**Answer**
27.01.01.702.01. Ventilation. Ensure the storage and compounding areas have sufficient general exhaust ventilation to dilute and remove any airborne contaminants. (7-1-18)	
27.01.01.702.02. Ventilated Cabinet. Utilize a ventilated cabinet designed to reduce worker exposures while preparing hazardous drugs. (7-1-18)	
27.01.01.702.05. Protective Equipment and Supplies. Provide and maintain appropriate personal protective equipment and supplies necessary for handling hazardous drugs, spills and disposal. (7-1-18)	
27.01.01.702.06. 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. (7-1-18)	
27.01.01.702.07. Compliance With Laws. Comply with applicable local, state, and federal laws including for the disposal of hazardous waste. (7-1-18)	
27.01.01.702.09. Policy and Procedures Manual. Maintain a policy and procedures manual to ensure compliance with this rule. (7-1-18)	

27.01.01.350. PHARMACIST PRESCRIBING: GENERAL REQ

Question	**Answer**
27.01.01.350. PHARMACIST PRESCRIBING: GENERAL REQUIREMENTS. In accordance with Section 54-1704, Idaho Code, a pharmacist may independently prescribe drugs, drug categories and devices provided the following general requirements are met: (7-1-18)	
27.01.01.350.07. Documentation. The pharmacist must maintain documentation adequate to justify the care provided, including, but not limited to the information collected as part of the patient assessment, the prescription record, and the follow-up care plan. (7-1-18)	

27.01.01.103.03. Inspection Deficiencies

Question	**Answer**
27.01.01.103.03. Inspection Deficiencies. Deficiencies noted must be promptly remedied, and if requested, the Board office notified of corrective measures. One (1) follow-up inspection may be performed by the Board at no cost. For additional follow-up inspections, the drug outlet will be charged actual travel and personnel costs incurred in the inspection to be paid within ninety (90) days of inspection. (7-1-18)	
27.01.01.103.04. 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. (7-1-18) [Discussed with]	
Deficiencies- Education of Code and Rule provided?	
Deficiencies- Issued Warning to Pharmacy -Possible Discipline?	
Disclaimer - Any items not discussed specifically by compliance officer on this inspection does not constitute compliance nor approval.	

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

Date/Time

Signature of Owner/Representative