IDAHO

IDAHO STATE BOARD OF PHARMACY
1199 SHORELINE LN, SUITE 303
BOISE, ID 83702
PHONE: 208-334-2356
FAX: 208-334-3536

FACILITY

<Facility Name>
<Street Address>
<City, ST Zip Code>
<Phone Number>
Owner: <Name>

LICENSE

License No: <License #>

License Type: Veterinary Drug Outlet - PDO

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

Notes:
Remarks:

Checklist Results	
27.01.01.022.01.. - BOARD INSPECTIONS AND INVESTIG	
Question	**Answer**
27.01.01.022.01.. - 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.	Not Answered
27.01.03.201.01.. - MINIMUM FACILITY STANDARDS.	
Question	**Answer**
27.01.03.201.01 - Security. 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 us An alarm or other comparable monitoring system is required for any non-institutional drug outlet that stocks controlled substances and is new or remodeled after July 1, 2018.	Not Answered
27.01.03.201.02.. - Patient Privacy. All protected health information must be stored and maintained in accordance with HIPA In addition, a community pharmacy that is new or remodeled after March 21, 2012 must provide and maintain a patient consultation area that affords the patient auditory and visual privacy and is compliant with the Americans with Disabilities Act.	Not Answered
27.01.03.201.03 - Equipment. A drug outlet must be properly equipped to ensure the safe, clean, and sanitary condition necessary and appropriate for proper operation, the safe preparation of prescriptions, and to safeguard product integrity.	Not Answered
27.01.03.201.04.. - Staffing. A drug outlet must be staffed sufficiently to allow for appropriate supervision, to otherwise operate safely and, if applicable, to remain open during the hours posted as open to the public for business.	Not Answered
27.01.03.201.07 - Authorized Access to the Restricted Drug Storage Area	Not Answered
27.01.03.201.07.a. - Access to the restricted drug storage area can occur only when a pharmacist or prescriber is on duty.	Not Answered
27.01.03.201.07.b. - Access must be limited to pharmacists, technicians and pharmacist interns, or in the case of a prescriber drug outlet, to prescribers and appropriate support personnel in accordance with the prescriber's practice act. A pharmacist or prescriber may, however, authorize an individual temporary access to the restricted drug storage area to perform a legitimate non-pharmacy function if the individual remains under the direct supervision of the pharmacist or prescriber.	Not Answered
27.01.01.23.10 - Substandard, Misbranded, Adulterated, or Expired Products. Manufacturing, compounding, delivering, dispensing, or permitting to be manufactured, compounded, delivered, or dispensed substandard, misbranded, or adulterated drugs or preparations or those made using secret formulas. Failing to remove expired drugs from stock.	Not Answered
27.01.03.202... - MINIMUM PRESCRIPTION FILLING R	
Question	**Answer**
27.01.03.202 - Unless exempted by these rules, each drug outlet that dispenses prescription drugs to patients in Idaho must meet the following minimum requirements:	Not Answered
27.01.03.202.01 - 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.	Not Answered
27.01.03.202.02 - Prospective Drug Review. Prospective drug review, as defined in Section 54-1705, Idaho Code, must be provided as set forth in Section 54-1739, Idaho Code.	Not Answered
27.01.03.202.03.. - Labeling Each drug must bear a complete and accurate label as set forth in Subchapter D of these rules.	Not Answered
27.01.03.202.04 - 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, an electronic verification system must be used	Not

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.	Answered
27.01.03.202.05.. - Patient Counseling Counseling, as defined in Section 54-1705, Idaho Code, must be provided as set forth in Section 54-1739, Idaho Code.	Not Answered

27.01.03.302... - PRESCRIPTION DRUG ORDER: MINIMU

Question	Answer
27.01.03.302 - A prescription drug order must comply with applicable requirements of federal law and, except as differentiation is permitted for an institutional drug order, must include at least the following:	Not Answered
27.01.03.302.01 - Patient's Name. The patient's or authorized entity's name and: (a) If for a controlled substance, the patient's full name and address; and If for an animal, the species.	Not Answered
27.01.03.302.02 - Date. The date issue	Not Answered
27.01.03.302.03 - Drug Information. The drug name, strength, quantity and, if for a controlled substance, the dosage form	Not Answered
27.01.03.302.04 - Directions. The directions for use	Not Answered
27.01.03.302.05 - Prescriber Information. The name and, if for a controlled substance, the address and DEA registration number of the prescriber.	Not Answered
27.01.03.302.06 - Signature. If paper, the pre-printed, stamped or hand-printed name and written signature of the prescriber or, if statutorily allowed, the prescriber's agent's signature and, if electronic, the prescriber's electronic signature	Not Answered

27.01.03.307... - LABELING: STANDARD PRESCRIPTION

Question	Answer
27.01.03.307 - Unless otherwise directed by these rules, a prescription drug must be dispensed in an appropriate container that bears the following information:	Not Answered
27.01.03.307.01 - Dispenser Information. The name, address, and telephone number of the dispenser (person or business).	Not Answered
27.01.03.307.02 - Serial Number. The serial number.	Not Answered
27.01.03.307.03 - Date. The date the prescription is file	Not Answered
27.01.03.307.04 - Prescriber. The name of the prescriber.	Not Answered
27.01.03.307.05 - Name. (a) If a person, the name of the patient or other person authorized to possess a legend drug in accordance with Idaho Code; (b) If an animal, the name and species of the patient; or (c) If a facility or other entity is authorized to possess a legend drug in accordance with Idaho Code, the name of the facility or entity.	Not Answered
27.01.03.307.06 - Drug Name and Strength. Unless otherwise directed by the prescriber, the name and strength of each drug included (the generic name and its manufacturer's name or the brand name).	Not Answered
27.01.03.307.07 - Quantity. The quantity of item dispense.	Not Answered
27.01.03.307.08 - Directions. The directions for use.	Not Answered
27.01.03.307.09.. - Cautionary Information. Cautionary information as necessary or deemed appropriate for proper use and patient safety.	Not Answered
27.01.03.307.10.a - Expiration. An expiration date that is either: (i) One (1) year from the date of dispensing; (ii) The manufacturer's original expiration date;(a)(iii) The appropriate expiration date for a reconstituted suspension or beyond use date for a compounded product; or (iv) A shorter period if warranted.	Not Answered
27.01.03.307.10.b. - If dispensed in the original, unopened manufacturer packaging, the manufacturer's original expiration date.	Not Answered
27.01.03.307.11.. - Refills. The number of refills remaining, if any, or the last date through which the prescription is refillable.	Not Answered
27.01.03.307.12.. - Warning. A warning sufficient to convey that state or federal law, or both, prohibits the transfer of this drug to any person other than the patient for whom it was prescribed, except when dispensing to an animal, when a warning sufficient to convey "for veterinary use only" may be utilized	Not Answered
27.01.03.307.13 - Identification. The initials or other unique identifier of the dispensing pharmacist or dispensing prescriber.	Not Answered

27.01.03.400.01.. - RECORDKEEPING: MAINTENANCE A

Question	Answer
27.01.03.400.01 - 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.	Not Answered
27.01.03.400.02 - Prescription Retention. A prescription drug order must be retained in a readily retrievable manner by each drug outlet and maintained as follows:	Not Answered
27.01.03.400.02.a - Schedule II Prescriptions. Paper prescription drug orders for Schedule II controlled substances must be maintained at the registered location in a separate prescription file	Not Answered
27.01.03.400.02.b - Schedule III through V Prescriptions. Paper prescription drug orders for Schedules III, IV and V controlled substances must be maintained at the registered location either in a separate prescription file for Schedules III, IV and V controlled substances only or in a readily retrievable manner from other prescription records as required by federal law.	Not Answered
27.01.03.400.02.c - Electronic Prescriptions. Electronic prescription drug orders for controlled substances must be maintained in a system that meets the requirements of federal law. The records may be maintained at another location if readily retrievable at the registered location. The electronic application must be capable of printing or otherwise converting the records into a readily understandable format at the registered location and must allow the records to be sortable by prescriber name, patient name, drug dispensed, and date filed	Not Answered
27.01.03.400.03 - 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 inventory must be conducted as follows:	Not Answered
27.01.03.400.03.a - Annual Inventory of Stocks of Controlled Substances. Each registrant must conduct an inventory of controlled substances on hand annually at each registered location no later than seven (7) days after the date of the most recent inventory in a	Not

form and manner that satisfies the inventory requirements of federal law. A separate controlled substances inventory must be taken and retained at each DEA-registered location.	Answered
Date Inventory Completed	Not Answered
Open or Close	Not Answered
Name of Controlled Substance Practitioner	Not Answered
27.01.03.400.03.b - Inventory on PIC Change. A complete controlled substance inventory must be conducted by the incoming PIC or his delegate on or by the first day of employment of the incoming PIC	Not Answered
27.01.03.400.03.c - Inventory on Addition to Schedule of Controlled Substances. On the effective date of an addition of a substance to a schedule of controlled substances, each registrant that possesses that substance must take an inventory of the substance on hand, and thereafter, include the substance in each inventory.	Not Answered
27.01.03.400.03.d - Drugs Stored Outside a Drug Outlet. In addition to the annual inventory requirements, 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.	Not Answered
27.01.03.400.05 - Central Records. Storage Records may be retained at a central location in compliance with federal law.	Not Answered
27.01.03.400.06 - Electronic Records. Storage Any record required to be kept under this section may be electronically stored and maintained if they remain legible and are in a readily retrievable format, and if federal law does not require them to be kept in a hard copy format.	Not Answered
27.01.03.401... - RECORDKEEPING: ELECTRONIC SYSTEM	
Question	**Answer**
27.01.03.401 - A drug outlet that is new or remodeled after the effective date of this rule 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.	Not Answered
27.01.03.401.01.. - Real-time Online Retrieval of Information. The electronic recordkeeping system must be capable of real-time, online retrieval of information stored therein for a minimum of fifteen (15) months from the date of entry.	Not Answered
27.01.03.401.02.. - Immediately Retrievable Refill Date. The electronic recordkeeping system must have functionality that allows refill data to be immediately retrievable and produced upon request; for example, a refill-by- refill audit trail for a specified strength and dosage form of a drug.	Not Answered
27.01.03.401.03.. - Audit Trail Documentation. The electronic recordkeeping system must also 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. Systems that automatically generate user identification without requiring an entry by the responsible individual are prohibited Drug outlets that utilize offsite pharmacy services for product fulfillment or processing must track the identity and location of each individual involved in each step of the offsite pharmacy services.	Not Answered
27.01.03.401.04.. - System Security. The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including:	Not Answered
27.01.03.401.04.a. - Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription drug order information and patient medication records; and	Not Answered
27.01.03.401.04.b. - Functionality that documents any alteration of prescription drug order information after a prescription drug order is dispensed, including the identification of the individual responsible for the alteration.	Not Answered
27.01.03.401.05.. - System Downtime, Backup and Recovery. The pharmacy must have policies and procedures in place for system downtime, backup and recovery.	Not Answered
27.01.03.401.06.. - Exemption. Drug outlets are exempt from this section if they fill on average fewer than twenty (20) prescriptions per business day, and paper records must be maintained	Not Answered
CONTROLLED SUBSTANCES	
Question	**Answer**
27.01.03.201.05 - Controlled Substances Storage. Controlled substances must be stored in a securely locked, substantially constructed cabinet or safe However, a pharmacy may disperse substances listed in Schedules II, III, IV and V, in whole or in part, throughout the stock of non-controlled substances if doing so would be likely to obstruct the theft or diversion of the controlled substances.	Not Answered
27.01.03.205.04 - Controlled Substances. Controlled substances may only be stored in an alternative designated area as permitted by, and in accordance with, federal law.	Not Answered
27.01.03.201.06.. - Controlled Substances Disposal. Expired, excess or unwanted controlled substances that are owned by the drug outlet must be properly disposed of through the services of a DEA-registered reverse distributor or by another method permitted by federal law.	Not Answered
27.01.03.301.01.. - Faxed and Verbal Prescriptions. A Schedule II prescription must not be dispensed pursuant to a faxed or verbal prescription drug order, except as permitted by federal law.	Not Answered
27.01.03.301.02.. - Multiple Prescription Drug Orders. A prescriber may issue and a pharmacy may fill multiple prescription drug orders, written on and dated with the same date, that allow the patient to receive up to a ninety (90)- day supply of a Schedule II controlled substance in accordance with federal law.	Not Answered
27.01.03.311... - A potential recipient of a controlled substance must first be positively identified or the controlled substance must not be dispensed.	Not Answered
27.01.03.311.01.. - Positive Identification. Presumed Positive identification is presumed and presentation of identification is not required if dispensing directly to the patient and if:	Not Answered
27.01.03.311.01.a. - The controlled substance will be paid for, in whole or in part, by an insurer;	Not Answered
27.01.03.311.01.b. - The patient is being treated at an institutional facility or is housed in a correctional facility; or	Not Answered
27.01.03.311.01.c. - The filled prescription is delivered to the patient or patient's provider.	Not Answered
27.01.03.311.02.. - Personal Identification. Presentation of identification is also not required if the individual receiving the controlled substance is personally and positively known by a drug outlet staff member who is present and identifies the individual and the personal identification is documented by recording:	Not Answered
27.01.03.311.02.a. - The recipient's name (if other than the patient);	Not Answered

27.01.03.311.02.b. - A notation indicating that the recipient was known to the staff member; and	Not Answered
27.01.03.311.02.c. - The identity of the staff member making the personal identification.	Not Answered
27.01.03.311.03.. - Acceptable Identification. A valid government-issued identification must include an unaltered photograph and signature to be acceptable.	Not Answered
27.01.03.311.04.. - Identification Documentation. Documentation of the recipient's identification must be permanently linked to the record of the dispensed controlled substance and include:	Not Answered
27.01.03.311.04.a. - A copy of the identification presented; or	Not Answered
27.01.03.311.04.b. - A record that includes: The recipient's name; A notation of the type of identification presented; The government entity that issued the identification; and The unique identification number.	Not Answered
27.01.03.311.04.b.i - The recipient's name;	Not Answered
27.01.03.311.04.b.ii - A notation of the type of identification presented;	Not Answered
27.01.03.311.04.b.iii - The government entity that issued the identification; and	Not Answered
27.01.03.311.04.b.iv - The unique identification number.	Not Answered
27.01.03.312... - Limited quantities of a Schedule V non-prescription controlled substance may be dispensed to a retail purchaser as permitted by federal law.	Not Answered
27.01.03.500... - Specified data on controlled substances must be reported by the end of the next business day by all drug outlets that dispense controlled substances in or into Idaho and prescribers that dispense controlled substances to humans. Data on controlled substance prescription drug samples does not need to be reported	Not Answered
37.27.20... - Persons registered under this chapter shall keep records, store controlled substances and maintain inventories in conformance with the recordkeeping, storage and inventory requirements of federal law and with any additional rules the board issues.	Not Answered
37.27.22... - No person shall issue or dispense a prescription drug order for a controlled substance unless it is in compliance with applicable state and federal law and rules of the board.	Not Answered
37.27.22.a.. - Controlled substances included in schedule I shall be distributed only by a registrant to another registrant pursuant to the federal drug enforcement administration (DEA) order form 222.	Not Answered
37.27.22.b.. - Controlled substances included in schedule II shall:	Not Answered
37.27.22.b.1. - Be distributed only by a registrant to another registrant pursuant to DEA order form 222.	Not Answered
37.27.22.b.2. - Be dispensed only pursuant to a valid prescription drug order, except when dispensed directly by a prescriber.	Not Answered
37.27.22.b.3. - Not be refilled.	Not Answered
37.27.22.b.4. - Include a quantity that is both spelled out in English and written in numerical form, when a written prescription drug order is required.	Not Answered
37.27.22.c.. - Controlled substances included in schedule III or IV shall:	Not Answered
37.27.22.c.1. - Be dispensed only pursuant to a valid prescription drug order, except when dispensed directly by a prescriber.	Not Answered
37.27.22.c.2. - Not be filled or refilled more than six (6) months after the date thereof or be refilled more than five (5) times, unless renewed by the practitioner.	Not Answered
37.27.22.d.. - Controlled substance included in schedule V shall not be distributed or dispensed other than for a medical purpose.	Not Answered
37.27.25... - Paper prescription drug order blanks shall comply with federal law and shall utilize noncopyable paper that contains security provisions against copying that results in some indication on the copy that it is a copy and therefore rendering it null and void. The prescription drug order blank shall contain the name and address of the prescriber. Prescription drug order blanks may contain the printed names of multiple prescribers who are affiliated; provided however, such prescription drug order blanks shall contain a means, in addition to the signature of the prescriber, such as a box or a check, for clear identification of the printed name and address of the prescriber issuing the prescription.	Not Answered
37.27.26.1.. - All controlled substances dispensed for humans shall be filed with the board electronically in a format established by the board or by other method as required by board rule. The board may require the filing of other prescriptions by board rule. The board shall establish by rule the information to be submitted pursuant to the purposes of this section and the purposes set forth in section 37-2730A, Idaho Code.	Not Answered
37.27.31... - A practitioner with statutory authority to dispense a controlled substance shall affix to the package a label pursuant to board rule.	Not Answered

27.01.03.402.01.. - REPORTING REQUIREMENTS.

Question	**Answer**
27.01.03.402.01 - PIC Change. Both an outgoing and incoming PIC must report to the Board a change in a PIC designation within ten (10) days of the change.	Not Answered
27.01.03.402.02 - Theft or Loss of Controlled Substances. A registrant must report to the Board on the same day reported to the DEA a theft or loss of a controlled substance that includes the information required by federal law.	Not Answered
27.01.03.402.03 - 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.	Not Answered
27.01.03.402.04 - Reporting Adulteration or Misappropriation. A licensee or registrant must report to the Board any adulteration or misappropriation of a controlled drug in accordance with Section 37-117 Idaho Code.	Not Answered

27.01.03.314... - DESTRUCTION OR RETURN OF DRUGS O

Question	**Answer**
27.01.03.314 - 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 must only be accepted for return as follows:	Not Answered
27.01.03.314.01.. - Error. Those that were dispensed in a manner inconsistent with the prescriber's instructions may be returned for quarantine and destruction purposes only.	Not Answered

27.01.03.314.02.. - 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 assure Controlled substances may only be returned from a hospital daily delivery system under which a pharmacy dispenses no more than a twenty-four (24) hour supply for a drug order, or up to a seventy-two (72) hour supply for a drug order if warranted for good patient care	Not Answered

27.01.05.100.02.. - COMPOUNDING DRUG PRODUCT

Question	**Answer**
27.01.05.100.02.. - General Compounding Standards.	Not Answered
27.01.05.100.02.a. - Active Pharmaceutical Ingredients. All active pharmaceutical ingredients must be obtained from an FDA registered manufacturer. FDA registration as a foreign manufacturer satisfies this requirement.	Not Answered
27.01.05.100.02.b. - Certificate of Analysis (COA). Unless the active pharmaceutical ingredient complies with the standards of an applicable USP-NF monograph, a COA must be obtained for all active pharmaceutical ingredients procured for compounding and retained for a period of not less than three (3) years from the date the container is emptied, expired, returned, or disposed of. The following minimum information is required on the COA:	Not Answered
27.01.05.100.02.b.i - Product name;	Not Answered
27.01.05.100.02.b.ii - Lot number;	Not Answered
27.01.05.100.02.b.iii - Expiration date; and	Not Answered
27.01.05.100.02.b.iv - Assay.	Not Answered
27.01.05.100.02.c - Equipment. Equipment and utensils must be of suitable design and composition and cleaned, sanitized, or sterilized as appropriate prior to use.	Not Answered
27.01.05.100.02.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.	Not Answered
27.01.05.100.03.. - Prohibited Compounding Compounding any drug product for human use that the FDA has identified as presenting demonstrable difficulties in compounding or has withdrawn or removed from the market for safety or efficacy reasons is prohibited.	Not Answered
27.01.05.100.04.. - Limited Compounding.	Not Answered
27.01.05.100.04.b. - Commercially Available Products. A drug product that is commercially available may only be compounded if not compounded regularly or in inordinate amounts and if:	Not Answered
27.01.05.100.04.b.i - It is medically warranted to provide an alternate ingredient, dosage form, or strength of significance; or	Not Answered
27.01.05.100.04.b.ii - The commercial product is not reasonably available in the market in time to meet the patient's needs.	Not Answered
27.01.05.100.04.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.	Not Answered
27.01.05.100.05.a - Policies and Procedures. In consideration of the applicable provisions of USP 795 concerning pharmacy compounding of non-sterile preparations, USP 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:	Not Answered
27.01.05.100.05.a.i - Appropriate packaging, handling, transport, and storage requirements;	Not Answered
27.01.05.100.05.a.ii - Accuracy and precision of calculations, measurements, and weighing;	Not Answered
27.01.05.100.05.a.iii - Determining ingredient identity, quality, and purity;	Not Answered
27.01.05.100.05.a.iv - Labeling accuracy and completeness;	Not Answered
27.01.05.100.05.a.v - Beyond use dating;	Not Answered
27.01.05.100.05.a.vi - Auditing for deficiencies, including routine environmental sampling, quality and accuracy testing, and maintaining inspection and testing records;	Not Answered
27.01.05.100.05.a.vii - Maintaining environmental quality control; and	Not Answered
27.01.05.100.05.a.viii - Safe limits and ranges for strength of ingredients, pH, bacterial endotoxins, and particulate matter.	Not Answered
27.01.05.100.05.b. - Accuracy. Components including, but not limited to, bulk drug substances, used in the compounding or sterile prepackaging of drug products must be accurately weighed, measured, or subdivided, as appropriate The amount of each active ingredient contained within a compounded drug product must not vary from the labeled potency by more than the drug product's acceptable potency range listed in the USP-NF monograph for that product. If USP-NF does not publish a range for a particular drug product, the active ingredients must not contain less than ninety percent (90%) and not more than one hundred ten percent (110%) of the potency stated on the label.	Not Answered
27.01.05.100.05.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:	Not Answered
27.01.05.100.05.c.i - Production date;	Not Answered
27.01.05.100.05.c.ii - Beyond use date;	Not Answered

27.01.05.100.05.c.iii - List and quantity of each ingredient;	Not Answered
27.01.05.100.05.c.iv - Internal control or serial number; and	Not Answered
27.01.05.100.05.c.v - Initials or unique identifier of all persons involved in the process or the compounder responsible for the accuracy of these processes.	Not Answered

27.01.05.101.01.. - STERILE PRODUCT PREPARATION.

Question	**Answer**
27.01.02.060 - A drug outlet engaged in sterile product preparation must obtain a single endorsement for one (1) or more hood or aseptic environmental control devices.	Not Answered
27.01.05.101.02.. - Dosage Forms Requiring Sterility. The sterility of compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals must be maintained or the compounded drug product must be sterilized when prepared in the following dosage forms: (a)Aqueous bronchial and nasal inhalations, except sprays intended to treat bronchial mucosa only; (b) Baths and soaks for live organs and tissues; (c) Injections (for example, colloidal dispersions, emulsions, solutions, suspensions); (d) Irrigations for wounds and body cavities; (e) Ophthalmic drops and ointments; and (f) Tissue implants.	Not Answered
27.01.05.101.03.. - Compounder Responsibilities. Compounders and sterile prepackages are responsible for ensuring that sterile products are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed, as well as prepared in a manner that maintains sterility and minimizes the introduction of particulate matter;	Not Answered
27.01.05.101.03.a. - Unless following manufacturer's guidelines or another reliable literature source, opened or partially used packages of ingredients for subsequent use must be properly stored as follows;	Not Answered
27.01.05.101.03.a.i - Opened or entered (such as needle-punctured) single-dose containers, such as bags, bottles, syringes, and vials of sterile products and compounded sterile products shall be used within one (1) hour if opened in non-sterile conditions, and any remaining contents must be discarded;	Not Answered
27.01.05.101.03.a.ii - Single-dose vials needle-punctured in a sterile environment may be used up to six (6) hours after initial needle puncture;	Not Answered
27.01.05.101.03.a.iii - Opened single-dose ampules shall not be stored for any time period; and	Not Answered
27.01.05.101.03.a.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;	Not Answered
27.01.05.101.03.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;	Not Answered
27.01.05.101.03.c. - Food, drinks, and materials exposed in patient care and treatment areas shall not enter ante-areas, buffer areas, or segregated areas where components and ingredients of sterile products are prepared	Not Answered
27.01.05.101.04.. - Environmental Controls. Except when prepared for immediate administration, the environment for the preparation of sterile products 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.	Not Answered
27.01.05.101.04.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 relocate	Not Answered
27.01.05.101.04 - Environmental Controls. Except when prepared for immediate administration, the environment for the preparation of sterile products 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.	Not Answered
27.01.05.101.04.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 relocate	Not Answered
27.01.05.101.05.a. - Protective apparel including gowns, masks, and sterile (or the ability to sterilize) non-vinyl gloves, unless the PIC can provide aseptic isolator manufacturer's written documentation that any component of garbing is not required;	Not Answered
27.01.05.101.05 - Sterile Product Preparation Equipment. A drug outlet in which sterile products are prepared must be equipped with at least the following:	Not Answered
27.01.05.101.05.a - Protective apparel including gowns, masks, and sterile (or the ability to sterilize) non-vinyl gloves, unless the PIC can provide aseptic isolator manufacturer's written documentation that any component of garbing is not required;	Not Answered
27.01.05.101.05.b - A sink with hot and cold water in close proximity to the hood;	Not Answered
27.01.05.101.05.c - A refrigerator for proper storage of additives and finished sterile products prior to delivery when necessary; and	Not Answered
27.01.05.101.05.d - An appropriate laminar airflow hood or other aseptic environmental control device such as a laminar flow biological safety cabinet.	Not Answered
27.01.05.101.06.b. - Training records, evidencing that personnel are trained on a routine basis and are adequately skilled, educated, and instructed;	Not Answered
27.01.05.101.06.c. - Audits appropriate for the risk of contamination for the particular sterile product including:	Not Answered
27.01.05.101.06.c.i - Visual inspection to ensure the absence of particulate matter in solutions, the absence of leakage from bags and vials, and the accuracy of labeling with each dispensing;	Not Answered
27.01.05.101.06.c.ii - Periodic hand hygiene and garbing competency;	Not Answered
27.01.05.101.06.c.iii - Media-fill test procedures (or equivalent), aseptic technique, and practice related competency evaluation at least annually by each compounder or sterile prepackager;	Not Answered
27.01.05.101.06.c.iv - Environmental sampling testing at least upon registration of a new drug outlet, following the servicing or re-certification of facilities and equipment, or in response to identified problems with end products, staff techniques or patient-related infections, or every six (6) months, including:	Not Answered
27.01.05.101.06.c.iii - Media-fill test procedures (or equivalent), aseptic technique, and practice related competency evaluation at least annually by each compounder or sterile prepackager;	Not Answered
27.01.05.101.06.c.iv - Environmental sampling testing at least upon registration of a new drug outlet, following the servicing or re-certification of facilities and equipment, or in response to identified problems with end products, staff techniques or patient-related infections, or every six (6) months, including: Total particle counts: Viable air sampling: Gloved fingertip sampling: Surface sampling:	Not Answered
27.01.05.101.06.c.iv - (3) Gloved fingertip sampling;	Not Answered

27.01.05.101.06.c.iv - (4) Surface sampling;	Not Answered
27.01.05.101.06.c.v - Sterility testing of high risk batches of more than twenty-five (25) identical packages (ampules, bags, vials, et) before dispensing or distributing;	Not Answered
27.01.05.101.06.d. - Temperature, logged daily;	Not Answered
27.01.05.101.06.e. - Beyond use date and accuracy testing, when appropriate; and	Not Answered
27.01.05.101.06.f. - Measuring, mixing, sterilizing, and purification equipment inspection, monitoring, cleaning, and maintenance to ensure accuracy and effectiveness for their intended use	Not Answered
27.01.05.101.07.. - Policies and Procedures. Policies and procedures appropriate to the practice setting must be adopted by a drug outlet preparing sterile pharmaceutical products and must include a continuous quality improvement program for monitoring personnel qualifications and training in sterile technique, including:	Not Answered
27.01.05.101.06.f - Measuring, mixing, sterilizing, and purification equipment inspection, monitoring, cleaning, and maintenance to ensure accuracy and effectiveness for their intended us	Not Answered
27.01.05.101.07 - Policies and Procedures. Policies and procedures appropriate to the practice setting must be adopted by a drug outlet preparing sterile pharmaceutical products and must include a continuous quality improvement program for monitoring personnel qualifications and training in sterile technique, including:Antiseptic hand cleansing;Disinfection of non-sterile compounding surfaces: Selecting and appropriately donning protective garb: etc	Not Answered
27.01.05.101.07.c. - Selecting and appropriately donning protective garb;	Not Answered
27.01.05.101.07.d. - Maintaining or achieving sterility of sterile products while maintaining the labeled strength of active ingredients;	Not Answered
27.01.05.101.07.e. - Manipulating sterile products aseptically, including mixing, diluting, purifying, and sterilizing in the proper sequence;	Not Answered
27.01.05.101.07.f. - Choosing the sterilization method, pursuant to the risk of a contamination of particular compounded sterile product; and	Not Answered
27.01.05.101.07.g. - Inspecting for quality standards before dispensing or distributing	Not Answered
27.01.05.102... - HAZARDOUS DRUGS PREPARATION.	
Question	**Answer**
27.01.05.102 - In addition to all other applicable rules in this chapter, including the rules governing Compounding Drug Products and Sterile Product Preparation, these rules apply to all persons, including any business entity, engaged in the practice of compounding or sterile prepackaging with hazardous drugs. Such persons must:	Not Answered
27.01.05.102.01 -Ventilation. Ensure the storage and compounding areas have sufficient general exhaust ventilation to dilute and remove any airborne contaminants.	Not Answered
27.01.05.102.02 - Ventilated Cabinet. Utilize a ventilated cabinet designed to reduce worker exposures while preparing hazardous drugs.	Not Answered
27.01.05.102.02.a - Sterile hazardous drugs must be prepared in a dedicated Class II biological safety cabinet or a barrier isolator of appropriate design to meet the personnel exposure limits described in product material safety data sheets;	Not Answered
27.01.05.102.02.b - When asepsis is not required, a Class I BSC, powder containment hood or an isolator intended for containment applications may be sufficient.	Not Answered
27.01.05.102.02.c - A ventilated cabinet that re-circulates air inside the cabinet or exhausts air back into the room environment is prohibited, unless: (i) The hazardous drugs in use will not volatilize while they are being handled; or (ii) The PIC can provide manufacturer written documentation attesting to the safety of such ventilation.	Not Answered
27.01.05.102.03 - Clear Identification. Clearly identify storage areas, compounding areas, containers, and prepared doses of hazardous drugs.	Not Answered
27.01.05.102.04.. - Labeling Label hazardous drugs with proper precautions, and dispense them in a manner to minimize risk of hazardous spills.	Not Answered
27.01.05.102.05 - Protective Equipment and Supplies. Provide and maintain appropriate personal protective equipment and supplies necessary for handling hazardous drugs, spills and disposal.	Not Answered
27.01.05.102.06.. - 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 dose or unit-of-use packaging	Not Answered
27.01.05.102.07.. - Compliance With Laws. Comply with applicable local, state, and federal laws including for the disposal of hazardous waste	Not Answered
27.01.05.102.08 - Training Ensure that personnel working with hazardous drugs are trained in hygiene, garbing, receipt, storage, handling, transporting, compounding, spill control, clean up, disposal, dispensing, medical surveillance, and environmental quality and control.	Not Answered
27.01.05.102.09 - Policy and Procedures Manual. Maintain a policy and procedures manual to ensure compliance with this rule	Not Answered
27.01.01.022.03.. - BOARD INSPECTIONS AND INVESTIG	
Question	**Answer**
27.01.01.022.03 - Inspection Deficiencies. Deficiencies noted must be promptly remedied, and if requested, the Board office notified of corrective measures. If required, 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 and must pay within ninety (90) days of inspection.	Not Answered
27.01.01.022.04 BOARD INSPECTIONS REVIEW - 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.	Not Answered

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

Berk Fraser	Date/Time	Signature of Owner/Representative