IDAHO

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

FACILITY
_test Facility
123 MAIN
BOISE, ID 83709
2083333333

LICENSE
License No: M51422
License Type: Manufacturer

Inspection Type:	Annual	**Inspection Date:**	5/28/2020 12:00:00 AM
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)	
27.01.01.104.10. 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.	
27.01.01.500. 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)	
27.01.01.500.03. 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)	
27.01.01.500.05. Drug Distributor Records. Wholesalers and other entities engaged in wholesale drug distribution must maintain inventories and records or transactions pertaining to the receipt and distribution or other disposition of drugs in accordance with federal law. The records must include at least: (4-11-19)	
27.01.01.500.05.a. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped; (4-11-19)	
27.01.01.500.05.b. The identity and quantity of the drugs received and distributed or disposed of; (4-11-19)	
27.01.01.500.05.c. The dates of receipt and distribution or other disposition of the drugs; and (4-11-19)	
27.01.01.500.05.d. Controlled substance distribution invoices, in the form and including the requirements of federal law. (4-11-19)	
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 Drug Oulet -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.

5/28/2020 12:00:00 AM

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