



**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: Manufacturer

<b>Inspection Type:</b>	Annual	<b>Inspection Date:</b>	
<b>Result:</b>			

**Notes:**  
**Remarks:**

**Checklist Results**

<b>27.01.01.022.01 BOARD INSPECTIONS</b>	
<b>Question</b>	<b>Answer</b>
27.01.01.022.01 BOARD INSPECTIONS 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
<b>27.01.06.050 - DRUG MANUFACTURERS</b>	
<b>Question</b>	<b>Answer</b>
27.01.06.050.01 - Standards. A manufacturer must ensure compliance with the federal "Current Good Manufacturing Practice" requirements.	Not Answered
27.01.06.050.02 - Records. A manufacturer must adopt policies and procedures for maintaining records pertaining to production, process control, labeling, packaging, quality control, distribution, complaints, and any information required by state or federal law.	Not Answered
<b>27.01.06.041 - FACILITY REQUIREMENTS</b>	
<b>Question</b>	<b>Answer</b>
27.01.06.041 - Facilities where drugs are stored, warehoused, handled, held, offered, marketed, or displayed for wholesale distribution must:	Not Answered
27.01.06.041.01 - Minimum Physical Standards. Be of suitable size, construction, and location to accommodate cleaning, maintenance, and proper operations;	Not Answered
27.01.06.041.02 - Minimum Environmental Standards. Have adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;	Not Answered
27.01.06.041.03 - Quarantine. Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated or that are in immediate or sealed secondary containers that have been opened;	Not Answered
27.01.06.041.04 - Maintenance Requirements. Be maintained in a clean and orderly condition	Not Answered
27.01.06.041.05 - Pest Controls. Be free from infestation by insects, rodents, birds, or vermin of any kind	Not Answered
<b>27.01.06.042 - FACILITY SECURITY REQUIREMENTS</b>	
<b>Question</b>	<b>Answer</b>
27.01.06.042 - Facilities used for wholesale drug distribution must be secure from unauthorized entry, as follows:	Not Answered
27.01.06.042.01 - Access from Outside. Access from outside the premises must be kept to a minimum and well controlled;	Not Answered
27.01.06.042.02 - Perimeter Lighting. The outside perimeter of the premises must be well lighted;	Not Answered
27.01.06.042.03 - Authorized Entry. Entry into areas where drugs are held must be limited to authorized personnel;	Not Answered
27.01.06.042.04 - Alarm Systems. Facilities must be equipped with an alarm system to detect entry after hours	Not Answered
27.01.06.042.05 - Security Systems. Facilities must be equipped with security systems sufficient to protect against theft, diversion, and record tampering	Not Answered
<b>27.01.06.043 / 044 - DRUG STORAGE &amp; SHIPMENT RQMTS</b>	

Question	Answer
27.01.06.043 - Drugs must be stored at temperatures and under conditions required by the labeling of the drugs, if any, or by current requirements of the USP-NF, to preserve product identity, strength, quality, and purity. Temperature and humidity recording equipment, devices, or logs must document proper storage of drugs.	Not Answered
27.01.06.044.01 - Examination on Receipt. Each shipping container must be visually examined on receipt for identity and to avoid acceptance of drugs that are contaminated or otherwise unfit for distribution.	Not Answered
27.01.06.044.02 - Outgoing Shipment Inspections. Outgoing shipments must be inspected to verify the accuracy and product integrity of the shipment contents.	Not Answered
<b>27.01.06.046 - RECORDKEEPING REQUIREMENTS</b>	
Question	Answer
27.01.06.046 -Wholesalers and other entities engaged in wholesale drug distribution must establish and maintain inventories and records of transactions pertaining to the receipt and distribution or other disposition of drugs.	Not Answered
27.01.06.046.01 - Record Contents. The records must include at least:	Not Answered
27.01.06.046.01.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;	Not Answered
27.01.06.046.01.b - The identity and quantity of the drugs received and distributed or disposed of;	Not Answered
27.01.06.046.01.c - The dates of receipt and distribution or other disposition of the drugs.	Not Answered
27.01.06.046.02 - Records Maintenance. Records may be maintained in an immediately retrievable manner at the inspection site or in a readily retrievable manner at a central location.	Not Answered
<b>27.01.06.048 - POLICIES AND PROCEDURES</b>	
Question	Answer
27.01.06.048 - Wholesalers must adopt policies and procedures for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting errors and inaccuracies in inventories, and as necessary to ensure compliance with the following:	Not Answered
27.01.06.048.01 - Distribution of Oldest Approved Stock First. The oldest approved stock of a drug product must be distributed first except if extraordinary circumstances require a temporary deviation.	Not Answered
27.01.06.048.02 - Recalls and Withdrawals. Drugs must be recalled or withdrawn upon: (a) A request by the FDA or other local, state, or federal law enforcement or other government agency, including the Board; (b) A voluntary action by a manufacturer to remove defective or potentially defective drugs from the market; or (c) An action undertaken to promote public health and safety by replacing existing merchandise with an improved product or a new package design.	Not Answered
27.01.06.048.03 - Crisis Preparation. Wholesalers must prepare for, protect against, and competently handle a crisis affecting the security or operation of a facility, including a fire, flood, or other natural disaster, a strike, or other situations of local, state, or national emergency.	Not Answered
<b>27.01.06.030.02 - DRUG DISTRIBUTION</b>	
Question	Answer
27.01.06.030.02.a. - Drug product only to a person licensed by the appropriate state licensing agency to dispense, conduct research with or independently administer such drugs;	Not Answered
27.01.06.030.02.b. - Scheduled controlled substances only to a person who has been issued a valid controlled substance registration by the DEA and the Board, unless exempt by state or federal law;	Not Answered
27.01.06.030.02.d. - Drug product only to the registered address of the authorized receiving person. Delivery to a hospital pharmacy receiving area satisfies this requirement, provided that authorized receiving personnel sign for receipt at the time of delivery.	Not Answered
<b>27.01.01.022 - Inspection Deficiencies &amp; Review</b>	
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