

West Virginia Board of Pharmacy

Phone (304) 558-0558

Fax (304) 558-0572

1207 Quarrier St, 4th Floor
Charleston, West Virginia 25301

WHOLESALE DRUG DISTRIBUTOR - INSPECTION REPORT

	Date: WV BOP#: DEA License#: Responsible Person/Attorney-in-Fact:			
Email:	Phone:			
Fax:	Hours:			
Item	Question	Observation	Reference	Inspector Comments
1	Has the facility obtained the proper licensure with the Board <u>before</u> engaging in the wholesale distribution of prescription drugs? (Inspector to verify licensing)		15-5-3.1	
2	Have there been any convictions of the applicant under any Federal, State, or local laws relating to wholesale drug distribution or distribution of controlled substances?		15-5-5.1.1	
3	Has any suspension or revocation by Federal, State, or local government of any license, permit, or other authorization currently or previously held by the applicant for the distribution of any drugs, including controlled substances?		15-5-5.1.5	
4	Is there a list of officers, directors, managers, and other persons in charge of wholesale drug management including a description of their duties and a summary of their qualifications?		15-5-8.8	
5	Are records regarding purchase and sales transactions stored at a central location and if so, could they be made available for inspection within two working days of the request? (If the Wholesale Drug Distributer does not keep records at a central location, this should be marked "N/A")		15-5-10.2	
6	Does each employee have the education, training, and experience needed to perform the assigned functions in order to provide assurance that the drug product quality, safety and security will at all times be maintained?		15-5-6.1	
7	Does this facility handle controlled substances? (If the Wholesale Drug Distributer does not handle controlled substances, this should be marked "N/A")		15-5-8.9.2	
8	Does the facility have the proper licensure to handle controlled substances? (If the Wholesale Drug Distributer does not handle controlled substances, this should be marked "N/A")		15-5-8.9.2	
9	Is there a proper biennial inventory of controlled substances as required by law? (If the Wholesale Drug Distributer does not handle controlled substances, this should be marked "N/A")		15-2-7.8 15-2-7.5	
10	Are proper records maintained for each controlled substance? (If the Wholesale Drug Distributer does not handle controlled substances, this should be marked "N/A")		15-2-7.12 15-2-7.14	
11	Are suspicious orders for controlled substances reported to the proper regulatory agencies when discovered? (If the Wholesale Drug Distributer does not handle controlled substances, this should be marked "N/A")		15-2-5.3	
12	Has any loss or theft of controlled drugs been reported to the proper authorities using the appropriate forms? (If there has been no loss or theft since the last inspection or the Wholesale Drug Distributer does not handle controlled substances, this should be marked "N/A")		15-2-5.4 15-2-9.3.1	
13	Does this facility maintain inventories and records of all transactions of prescription drugs including the source, identity, quantity and dates. (Inspector to review inventory and receipt records)		15-5-8.6.1	
14	Are there written policies and procedures for prescription drugs? (Inspector to review policies and procedures)		15-5-8.7	
15	Do the P & P's include provisions for distributing the oldest approved stock of a prescription drug product first?		15-5-8.7.1	
16	Do the P & P's include provisions for handling recalls and withdrawals of prescription drugs?		15-5-8.7.2	
17	Do the P & P's include provisions to ensure preparation for, protection against, and handling any crisis that affects the security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency?		15-5-8.7.3	
18	Do the P & P's include provisions to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed?		15-5-8.7.4	
19	Is the facility of suitable size and construction to facilitate cleaning, maintenance, and proper operations?		15-5-8.1.1	
20	Does the facility have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions?		15-5-8.1.2	
21	Does the facility have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened?		15-5-8.1.3	

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		Responsible Person/Attorney-in-Fact:		
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Item	Question	Observation	Reference	Inspector Comments
22	Is the facility maintained in a clean and orderly condition?		15-5-8.1.4	
23	Is there a security system that will provide adequate and effective protection against theft and diversion, including by tampering with computers or electronic records?		15-5-8.2.3	
24	Are only authorized personnel allowed in areas where prescription drugs are held?		15-5-8.2	
25	Does the security system adequately and effectively prevent entry by unauthorized personnel?		15-5-8.2	
26	Is the outside perimeter of the facility well-lighted?		15-5-8.2	
27	Is this facility equipped with an alarm system to detect entry after hours?		15-5-8.2.2	
28	Is the area of drug storage temperature controlled between 20 to 25°C (68 to 77°F)? (List the current drug storage area temperature in Inspector Comments)		15-1-11.2.4 15-1-14.1.5	Storage area room temperature:
29	Are refrigerator temperatures all between 2 to 8°C (36 to 46°F)? (List the current refrigerator temperatures in Inspector Comments; if drugs are not currently being stored in the refrigerator, this should be marked "N/A")		15-1-11.2.4 15-1-14.1.5	Refrigerator temperature(s):
30	Are freezer temperatures between -10 to -25°C (-13 to 14°F)? (List the current freezer temperatures in Inspector Comments; if drugs are not currently being stored in the freezer this should be marked "N/A")		15-1-11.2.4 15-1-14.1.5	Freezer temperature(s):
31	Are temperature and humidity recording devices, and/or logs, where appropriate, utilized to document proper storage of prescription drugs?		15-5-8.3.2	
32	Is each outside shipping container visually examined for identity and evidence of contamination upon receipt in order to prevent the acceptance of prescription drugs that are unfit for distribution?		15-5-8.4.1	
33	Is each outgoing shipment carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions?		15-5-8.4.2	
34	Are prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier?		15-5-8.5.1	
35	If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, is the drug destroyed, returned to the supplier and/or investigated to prove that the drug meets appropriate standards?		15-5-8.5.3	

Controlled Substance Audit

ALL QUESTIONS HAVE NOT BEEN ANSWERED, PLEASE REVIEW!

Responsible Person/Attorney-in-Fact:

Date

Inspector:

Date