

 Saving data...

Inspection Type

***Category:**

Wholesaler



Facility Information

Name:*DBA:*****Permit
Type:*****Permit
Class:*****Permit #:****Supervising
Pharmacist:*****Address 1:****DEA #:****DEA Expiration:****Address 2:*****Type of Wholesaler:*****City:*****State:*****Zip:*****County:**

Wholesale

	✓ Y	✗ N	! NA	! NI	Inspection Item	Comments
Wholesaler Area						
1)	☐	☐	☐	☐	Alarm System Maintained: 201 KAR 2:105 Section 5(2)(a)	
2)	☐	☐	☐	☐	Authorized Access Maintained: 201 KAR 2:105 Section 5(2)(c)	
3)	☐	☐	☐	☐	Drug Storage Area: 201 KAR 2:105 Section 1 (4)(a) and Section 4 (1)	
4)	☐	☐	☐	☐	Lighting (Interior and Exterior): 201 KAR 2:320 Section 2(4)(a) and Section 5(2)(b)	
5)	☐	☐	☐	☐	Quarantine Area for Outdated, Damaged or Opened: 201 KAR 2:105 Section 2 (5)(b) and Section 5(1)(b)	
6)	☐	☐	☐	☐	Refrigeration/Freezer: 201 KAR 2:105 Section 2(5)(a)	
7)	☐	☐	☐	☐	Sanitation: 201 KAR 2:105 Section 2(5)(a)	
8)	☐	☐	☐	☐	Suitable Size and Construction: 201 KAR 2:105 Section 5(1)(a)	

9)		▼	Ventilation/Temperature/Humidity: 201 KAR 2:105 Section 2 (5)(a)	
General				
10)		▼	Controlled Drugs Secure 201 KAR 2:105 Section 2(5)(d) and Section 5(2)(c), and 21 CFR1301.72 and 1301.73	
11)		▼	Customer Verification 201 KAR 2:105 Section 2(5) (c), Section 5(3)(c)and(d)	
12)		▼	Drug Loss/Theft Records Maintained 201 KAR 2:105 Section 2(5)(d) and Section 5(4)(a) and 21 CFR 1301.76	
13)		▼	Personnel Training Program: 201 KAR 2:105 Section 5(2)(d)	
14)		▼	Product and Process Controls: 201 KAR 2:105 Section 4 (3) and (7)	
15)		▼	Receipt and Distribution Transaction Records for 2 Years: 201 KAR 2:105 Section 4 (3)(a)	
16)		▼	Records Maintained and Complete: 201 KAR 2:105 Section 4 (3)	
17)		▼	Records Readily Retrievable: 201 KAR 2:105 Section 4 (3)	
18)		▼	Stock Rotation of Pharmaceuticals: 201 KAR 2:105 Section 4 (7)(b)	

19)		Employee List with Qualifications: 201 KAR 2:105 Section 4 (2)(e)	
20)		Established Returns Process: KRS 315.404 (4)	
21)		Employees Screened Per DEA Requirements: 21 CFR 1301.90	
22)		Biennial Controlled Substance Inventory: KRS 218A.200 (7)(a)	
Written Policies and Procedures			
23)		Distressed Drugs: 201 KAR 2:105 Section 4 (4)(b) and (5)	
24)		Correcting Errors/Inaccuracies in Inventories: 201 KAR 2:105 Section 4 (4)(b)	
25)		Outdated Pharmaceuticals: 201 KAR 2:105 Section 4 (4)(c)	
26)		Shipping/Receiving of Stock: 201 KAR 2:105 Section 4 (4)(d)	
27)		Recalled Drugs: 201 KAR 2:105 Section 4 (6)	
28)		Crisis/Emergency Situations: 201 KAR 2:105 Section 4 (4)(a)	

29)



Security/Diversion: 201 KAR 2:105 Section 4 (2)(c)

Additional Information

Inspector:**Start of Inspection:**

mm/dd/yyyy --:-- --

***End of Inspection:**

mm/dd/yyyy --:-- --

Type:**Follow Up:****Email Addresses to Receive Report: ?*****Email to Default Recipients:****Notes:**

Template Only

Person Providing Information

Full Name: