

Inspection Type



*** Category:**

Manufacturer ▼

Facility Information

*** Name:**

DBA:

*** Permit
Type:**

*** Permit
Class:**

*** Permit #:**

**Supervising
Pharmacist:**

*** Address 1:**

DEA #:

DEA Expiration:

Address 2:

*** City:**

*** State:**

*** Zip:**

*** County:**

Manufacturer

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	Quarantine Area for Outdated, Damaged or Opened: 201 KAR 2:320 Section 2 (4)(b) and Section 5 (1)(b)	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

9)	<input type="text"/>	▼	Ventilation/Temperature/Humidity: 201 KAR 2:320 Section 2 (4)(a)	<input type="text"/>
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10)	<input type="text"/>	▼	Defined Production Area: 21 CFR 211.42 (c)	<input type="text"/>
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General

11)	<input type="text"/>	▼	Controlled Drugs Secured: 201 KAR 2:320 Section 2(4)(d) and Section 5(2)(c), and 21 CFR 1301.72	<input type="text"/>
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12)	<input type="text"/>	▼	Customer Verification: 201 KAR 2:320 Section 5(3) (d) and (e)	<input type="text"/>
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13)	<input type="text"/>	▼	Drug Loss/Theft Records Maintained: 201 KAR 2:320 Section 2(4)(d) and Section 5(2)(c) and (3)(f)	<input type="text"/>
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14)	<input type="text"/>	▼	Personnel Training Program: 201 KAR 2:320 Section 5 (2)(d)	<input type="text"/>
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15)	<input type="text"/>	▼	Product and Process Controls: 201 KAR 2:320 Section 5 (7)	<input type="text"/>
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16)	<input type="text"/>	▼	Receipt and Distribution Transaction Records for 2 Years: 201 KAR 2:320 Section 5 (3)(a)	<input type="text"/>
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17)	<input type="text"/>	▼	Records Maintained and Complete: 201 KAR 2:320 Section 5 (3)(b)	<input type="text"/>
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18)	<input type="text"/>	▼	Records Readily Retrievable: 201 KAR 2:320 Section 5 (3)(b)	<input type="text"/>
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19)	<input type="text"/>	▼	Stock Rotation of Pharmaceuticals: 201 KAR 2:320 Section 5 (7)(b)	<input type="text"/>
20)	<input type="text"/>	▼	Quarterly PIC Inspection Complete: 201 KAR 2:105 Section 5	<input type="text"/>
21)	<input type="text"/>	▼	Finished Product Appropriately Labeled: KRS 217.065	<input type="text"/>
22)	<input type="text"/>	▼	Label Security and Control: 21 CFR 211.125	<input type="text"/>
23)	<input type="text"/>	▼	Batch Records Maintained: 201 KAR 2:105 Section 4 (3)(a) and KRS 217.155(1)(c)	<input type="text"/>
24)	<input type="text"/>	▼	Established Quality Assurance Process: KRS 217.055	<input type="text"/>
25)	<input type="text"/>	▼	Established Returns Process: KRS 315.404(4)	<input type="text"/>
26)	<input type="text"/>	▼	Employees Screened Per DEA Requirements: 21 CFR 1301.90	<input type="text"/>
27)	<input type="text"/>	▼	Biennial Controlled Substance Inventory: KRS 218A. 200(7)(a)	<input type="text"/>
28)	<input type="text"/>	▼	Most Recent FDA Inspection	<input type="text"/>

Written Policies and Procedures

29)	<input type="text"/>	Distressed Drugs: 201 KAR 2:320 Section 5 (5)	<input type="text"/>
30)	<input type="text"/>	Correcting Errors/Inaccuracies in Inventories: 201 KAR 2:320 Section 5(4)(b)	<input type="text"/>
31)	<input type="text"/>	Outdated Pharmaceuticals: 201 KAR 2:320 Section 5(4)(c)	<input type="text"/>
32)	<input type="text"/>	Shipping/Receiving of Stock: 201 KAR 2:320 Section 5(4)(d)	<input type="text"/>
33)	<input type="text"/>	Security/Diversion: 201 KAR 2:320 Section 5(2)(c) and (4)(a)	<input type="text"/>
34)	<input type="text"/>	Recalled Drugs: 201 KAR 2:320 Section 5 (6)	<input type="text"/>
35)	<input type="text"/>	Crisis/Emergency Policy: 201 KAR 2:320 Section 5(4)(a)	<input type="text"/>

Additional Information

***Inspector:**

***Start of Inspection:**

***End of Inspection:**

Type:

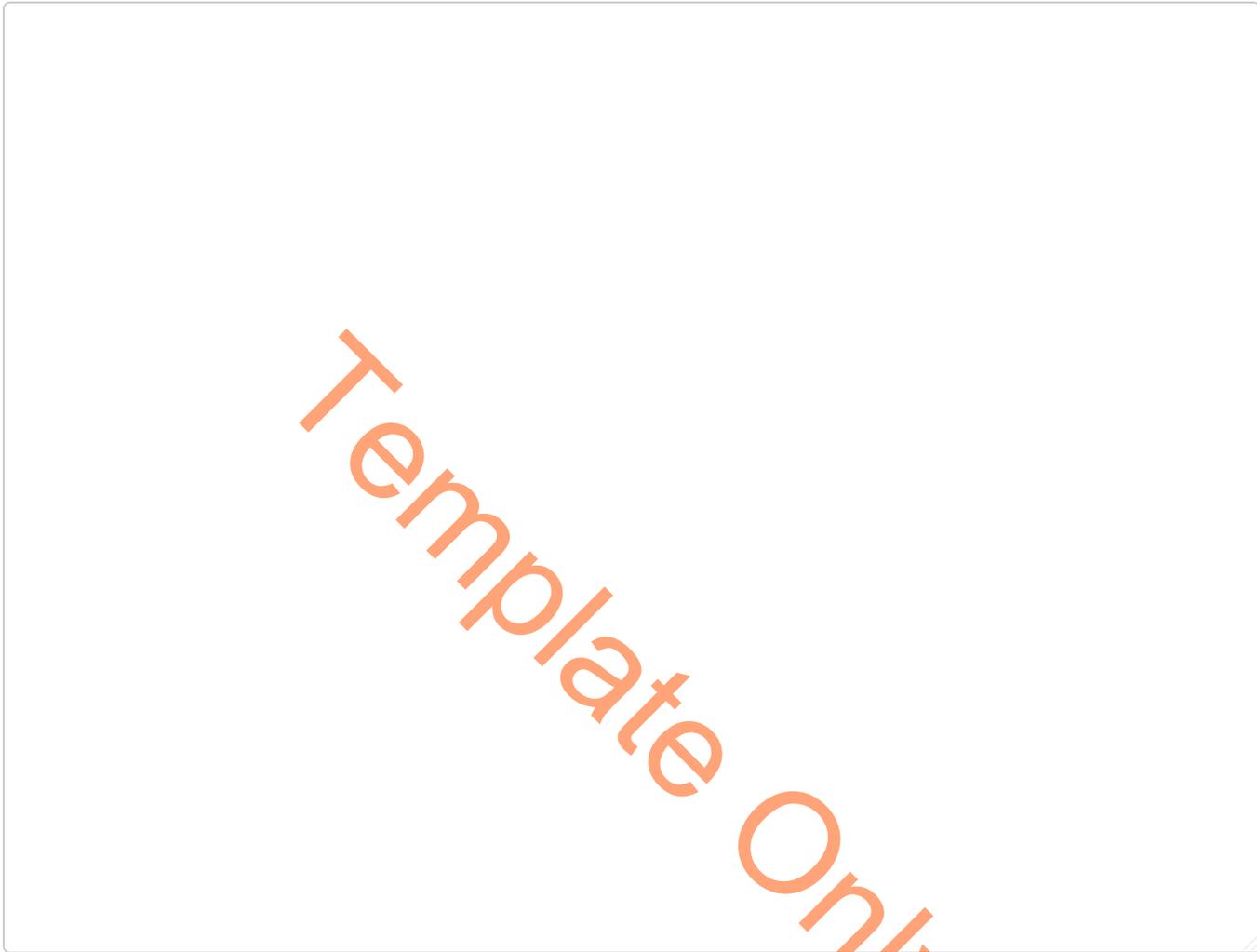
Follow Up:

Email Addresses to Receive Report: 

***Email to Default Recipients:**

Notes:

Template Only



Person Providing Information

Full Name: