

# Kentucky Board of Pharmacy

125 Holmes St.  
Frankfort, KY 40601

## Inspection Report

### Pharmacy

Name: *Demo Pharmacy*

Permit No.: *P0DEMO*

Address: *State Off. Bldg. Annex Ste 300, Frankfort, KY 40601*

Phone: *(859) 246-2820*

Fax: *(859) 246-2823*

Email: *steve.hart@ky.gov*

Current:

### Inspection

Date: *06/10/2019*

Time In: *8:05 AM*

Time Out:

Type: *Routine*

Notes: *None*

### Pharmacist and Interns

#### General

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Valid R.Ph License Displayed (KRS 315.110) (2) *Compliant*

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Valid Intern Registration Identification Card: (201 KAR 2:040) Section 4 *Compliant*

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Valid Pharmacy Permit (KRS 315.035) *Compliant*

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Valid Technician Registration Certificate (KRS 315.138) (2) *Compliant*

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Automated Dispensing Systems: (201 KAR 2:074) Section 6 and Section 7 *Compliant*

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Employee Outpatient Prescription Dispensing: (201 KAR 2:074) Section 4 (6)(b) *Compliant*

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Repackaged Unit Dose Requirements: 201 KAR 2:074 Section 4 (6)(a), (7) and Section 7 (7) and KRS 217.065 *Compliant*

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Outdated Stock Removed: 201 KAR 2:074 Section 6 (9) *Compliant*

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Prescription Labeling Requirements (KRS 217:065), 201 KAR 2:074 Section 4 (6)(b) *Compliant*

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Collaborative Care Agreements (201 KAR 2:220) *Compliant*

#### Main Pharmacy Area

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Policy/Procedures Manual: 201 KAR 2:074 Section 2 (3) *Compliant*

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Assuring Rational Drug Therapy (201 KAR 2:074) Section 5 *Compliant*

Main Pharmacy Area (*continued*)

Reference Materials: 201 KAR 2:090 Section 1 & 201 KAR 2:074 Section 3 (5)	<i>Compliant</i>
Drug Distribution and Control (201 KAR 2:074) Section 4	<i>Compliant</i>
Physical Facility Requirements (201 KAR 2:074) Section 3 (1) and 201 KAR 2:076 Section 2	<i>Compliant</i>
Security and Control (201 KAR 2:100) Section 3 (4) and 201 KAR 2:100 Section 1	<i>Compliant</i>
Equipment: 201 KAR 2:076 Section 2 and 2:090 Section 2	<i>Compliant</i>
Exclusive Compounding Area: KRS 217.055(2) and 201 KAR 2:076 Section 2	<i>Compliant</i>
Drug Storage: (201 KAR 2:180) Section 5	<i>Compliant</i>
Refrigeration (201 KAR 2:090) Section 2 (1)(h) and 201 KAR 2:076 Section 2 (2)(e)	<i>Compliant</i>
Sanitation (201 KAR 2:180) Section 1	<i>Compliant</i>
Sink/Hot & Cold Water (201 KAR 2:180) Section 3 and 201 KAR 2:076 Section 2 (2)(b)	<i>Compliant</i>
Floor Stock Secured (201 KAR 2:074) Section 4 (11)	<i>Compliant</i>

## Sterile Compounding

Certified ISO Class 5 Compounding Area(s) (PEC) (USP 797; 201 KAR 2:076)	<i>N/A</i>
Certified ISO Class 7 Buffer Area(s) (USP 797; 201 KAR 2:076)	<i>N/A</i>
Buffer and Ante-Areas Appropriately Maintained (USP 797; 201 KAR 2:076)	<i>N/A</i>
Hazardous Drugs Stored Separately in Ante-Area (USP 797; 201 KAR 2:076)	<i>N/A</i>
Pressure Differential Monitored and Documented (USP 797; 201 KAR 2:076)	<i>N/A</i>
IV Labeling (201 KAR 2:076)	<i>N/A</i>
Hand Hygiene & Garbing Practices Observed (USP 797; 201 KAR 2:076)	<i>N/A</i>
Personnel Training and Competency Documented (USP 797; 201 KAR 2:076)	<i>N/A</i>
Daily Cleaning and Disinfection Practices Observed (USP 797; 201 KAR 2 :076)	<i>N/A</i>
Monthly Cleaning and Disinfecting Documented (USP 797; 201 KAR 2:076)	<i>N/A</i>

## Controlled Substances

Biennial Inventory Complete: 21 CFR 1304.11 and KRS 218A. 200 (7)	<i>Compliant</i>
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Biennial Inventory Complete: 21 CFR 1304.11 and KRS 218A. 200 (7) <i>(continued)</i> Last Date:: 06/10/2019	Compliant
CII Prescription Requirements (KRS 218A.180 and 902 KAR 55:105 and 55:095)	Compliant
CII Medical Order Requirements (KRS 218A.180)	Compliant
Power-of-Attorney Current (21 CFR 1305.05)	Compliant
Proof-of-Use Sheets Properly Completed (201 KAR 2:074) Section 4 (9)	Compliant
Purchase Records/DEA 222 Forms (KRS 218A.200)	Compliant
Written CIII-V Prescription Requirements (KRS 218A.180 and 902 KAR 55:105)	Compliant

Ancillary Pharmacy Areas

Inpatient Areas (ER, ICU, Surgery, etc.) 201 KAR 2:074 Section 2 (1)(d) and Section 4 (11)	Compliant
Outpatient Clinics 201 KAR 2:074 Section 2 (1)(d) and Section 4 (11)	Compliant

Inspector's Signature

I have completed this inspection in accordance with the statutes and administrative codes.

Inspector: *Katie Busroe*

Pharmacist's Signature

I have read and understand the statutes and administrative codes. I acknowledge that the items noted in this report have been discussed with me. I understand that if I disagree with any of the deficiencies cited, that I have the right to refute them on this report or on another form that I choose to send to the department.

Pharmacist: *B. Steven Hart*