

Kentucky Board of Pharmacy

125 Holmes St.
Frankfort, KY 40601

Report

Pharmacy

Name: *Demo Manufacturer*

Permit No.: *MODEMO*

Address: *Test, Test, KY 40601*

Phone:

Fax:

Email: *bob@kentucky.gov*

Inspection

Date: *06/10/2019*

Time In: *11:48 AM*

Time Out:

Type: *Routine*

Notes: *None*

Wholesaler Area

Alarm System Maintained: 201 KAR 2:105 Section 4 (2)(a) *Compliant*

Authorized Access Maintained: 201 KAR 2:105 Section 4(2)(c) *Compliant*

Drug Storage Area: 201 KAR 2:105 Section 1 (4)(a) and Section 4 (1) *Compliant*

Lighting (Interior and Exterior): 201 KAR 2:320 Section1 (4)(a) and Section 4 (2)(b) *Compliant*

Quarantine Area for Outdated, Damaged or Opened: 201 KAR 2:105 Section 1 (4)(b) and Section 4(1)(b) *Compliant*

Refrigeration/Freezer: 201 KAR 2:105 Section 1 (4)(a) *Compliant*

Sanitation: 201 KAR 2:105 Section 4 (1)(a) *Compliant*

Suitable Size and Construction: 201 KAR 2:105 Section 4 (1)(a) *Compliant*

Ventilation/Temperature/Humidity: 201 KAR 2:105 Section 1 (4)(a) *Compliant*

General

Controlled Drugs Secure 201 KAR 2:105 Section 1(4)(d) and Section 4(12)(c), and 21 CFR 1301.72 and 1301.73 *Compliant*

Customer Verification 201 KAR 2:105 Section 1(4)(c) *Compliant*

Drug Loss/Theft Records Maintained 201 KAR 2:105 Section 1(4)(d) and Section 4(4)(a) and 21 CFR 1301.76 *Compliant*

Personnel Training Program: 201 KAR 2:105 Section 4 (2)(d) *Compliant*

General (*continued*)

Product and Process Controls: 201 KAR 2:105 Section 4 (3) and (7)	<i>Compliant</i>
Receipt and Distribution Transaction Records for 2 Years: 201 KAR 2:105 Section 4 (3)(a)	<i>Compliant</i>
Records Maintained and Complete: 201 KAR 2:105 Section 4 (3)	<i>Compliant</i>
Records Readily Retrievable: 201 KAR 2:105 Section 4 (3)	<i>Compliant</i>
Stock Rotation of Pharmaceuticals: 201 KAR 2:105 Section 4 (7)(b)	<i>Compliant</i>
Employee List with Qualifications: 201 KAR 2:105 Section 4 (2)(e)	<i>Compliant</i>
Established Returns Process: KRS 315.404 (4)	<i>Compliant</i>
Employees Screened Per DEA Requirements: 21 CFR 1301.90	<i>Compliant</i>
Biennial Controlled Substance Inventory: KRS 218A.200 (7)(a) Date: 06/10/2019	<i>Compliant</i>

Written Policies and Procedures

Distressed Drugs: 201 KAR 2:105 Section 4 (4)(b) and (5)	<i>Compliant</i>
Correcting Errors/Inaccuracies in Inventories: 201 KAR 2:105 Section 4 (4)(b)	<i>Compliant</i>
Outdated Pharmaceuticals: 201 KAR 2:105 Section 4 (4)(c)	<i>Compliant</i>
Shipping/Receiving of Stock: 201 KAR 2:105 Section 4 (4)(d)	<i>Compliant</i>
Recalled Drugs: 201 KAR 2:105 Section 4 (6)	<i>Compliant</i>
Crisis/Emergency Situations: 201 KAR 2:105 Section 4 (4)(a)	<i>Compliant</i>
Security/Diversion: 201 KAR 2:105 Section 4 (2)(c)	<i>Compliant</i>

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 and other form that I choose to send to the department.

Pharmacist: