

STATE BOARD OF PHARMACY

800 SW Jackson, Suite 1414 Topeka, Kansas 66612-1244 www.pharmacy.ks.gov (785)296-4056

INSPECTION: Third-party Logistics Provider Form I-23

INSPECTION INFORMATION

Facility Name:	Registration Number:	
Inspector Name:	Date:	
GENERAL INFORMATION	C-Compliant N/I-Needs Improvement N/C-Not Compliant	
Person(s) on duty:	U-Unassessed N/A-Not Applicable	
$\ \ \square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	Registration(s) displayed—K.S.A. 65-1645(e) & K.A.R. 68-14-7a(f)(4)	
$\ \ \square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	DEA number:	
$\ \ \square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	FDA registration number (EIN):	
FACILITIES		
$\ \ \square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	Suitable size and construction to facilitate cleaning, maintenance, & proper operation	
—K.A.R. 68-14-7a(a)(1)		
$\ \square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	Adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, & security	
—K.S.A. 65-656(m) & K.A.R. 68-14-7a(a)(2)		
$\ \square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	Quarantine area—K.A.R. 68-14-7a(a)(3)	
$\ \square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	Maintained in a clean and orderly condition—K.A.R. 68-14-7a(a)(4)	
$\ \ \square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	Free from infestation by insects, rodents, birds, or vermin of any kind—K.A.R. 68-14-7a(a)(5)	
$\ \ \square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	Drugs and devices stored per manufacturer—K.A.R. 68-14-7a(c)	
$\ \ \square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	Documentation of appropriate temperature—K.A.R. 68-14-7a(c)(2)	
Room temperature:		
Refrigerator temperature:		
Freezer temperature:		
	Establish, maintain and adhere to policy and procedures—K.A.R. 68-14-7a(g)	
$\ \ \square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	Procedures for distribution of oldest approved stock first—K.A.R. 68-14-7a(g)(1)	
$\square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	Procedure for handling recalls and withdrawing drugs and devices—K.A.R. 68-14-7a(g)(2)	
	Procedure to prepare for, protect against and handle any crisis that affects security or operation of	
facility—K.A.R. 68-14-7a(g)(3)		
$\ \ \square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	Procedure for outdated, mislabeled, or adulterated drugs and devices to be removed from stock	
—K.S.A. 65-1634, K.S.A. 65-657(a) & K.A.R. 68-14-7a(g)(4)		
SECURITY		
$\ \square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	Secure from unauthorized entry—21 C.F.R. 1301.71 thru 1301.76 & K.A.R. 68-14-7a(b)(1)	
$\ \square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	Perimeter of premises well lighted—K.A.R. 68-14-7a(b)(1)	
$\ \ \square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	Alarm and security systems—21 C.F.R. 1301.71 thru 1301.76 & K.A.R. 68-14-7a(b)(2)&(3)	
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	Controlled drugs locked—21 C.F.R. 1301.71 thru 1301.76 & K.A.R. 68-20-15a
RECORDS	
$\ \square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	Documentation of education, training & experience—K.A.R. 68-14-5
$\ \square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	Maintain list of responsible persons to include duties and qualifications —K.A.R. 68-14-7a(h)
$\ \square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	Documentation of examination of materials—K.A.R. 68-14-7a(d)
$\ \square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	Records of ALL transactions in the receipt and distribution of prescription-only drugs and devices
—K.A.R. 68-14-7a(f)	
$\ \square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	Duration of record keeping—K.A.R. 68-20-16(a) & K.A.R. 68-14-7a(f)(2)
$\ \square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	Central record keeping—K.A.R. 68-14-7a(f)(3) & 21 C.F.R. 1304.04(b)(3)
Location:	
$\ \square \ C \ \square \ N/I \ \square \ N/C \ \square \ U \ \square \ N/A$	Records readily retrievable—K.A.R. 68-14-7a(f)(3)
COMMENTS	