



STATE BOARD OF PHARMACY

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

**INSPECTION:
Manufacturer
Form I-04**

INSPECTION INFORMATION

Manufacturer Name: _____ Registration Number: _____
Inspector Name: _____ Date: _____

GENERAL INFORMATION

Facility Type:

- Drugs-prescription and/or nonprescription Medical Gases
- Yes No N/A Registrations displayed: State & DEA—K.S.A. 65-1645(e)
DEA Number: _____
Person on Duty: _____
- Yes No N/A Policy and Procedures—K.A.R. 68-14-7(g)
- Yes No N/A Documentation of training, education, & experience—K.A.R. 68-14-5
- Yes No N/A Duration of record keeping—K.A.R. 68-20-16(a)
- Yes No N/A Adhere to all FDA requirements such as:
 - Yes No N/A Equipment Clean
 - Yes No N/A Calibration of thermometers, balances, gauges, etc.
 - Yes No N/A Documentation of calibration
 - Yes No N/A Labels secure/controlled
 - Yes No N/A Floors, walls, & ceiling smooth, hard, & clean
 - Yes No N/A Off floor storage
 - Yes No N/A Protective apparel (if needed)
 - Yes No N/A Batch records available
 - Yes No N/A Batch records signed by Quality Control prior to release
- Yes No N/A Adherence to good manufacturing practices—21 C.F.R. 211

FACILITIES

- Yes No N/A Suitable size and construction to facilitate cleaning, maintenance, & proper operation—K.A.R. 68-14-7(a)(1)
- Yes No N/A Adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, & security—
K.A.R. 68-14-7(a)(2)
- Yes No N/A Free from infestation by insects, rodents, birds, or vermin of any kind—K.A.R. 68-14-7(a)(5)
- Yes No N/A Quarantine Area—K.A.R. 68-14-7(a)(3)



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STORAGE

- Yes No N/A Drugs stored per manufacturer—K.S.A. 65-1634 & K.A.R. 68-14-7(c)
- Yes No N/A Outdated, mislabeled, or adulterated drugs have been removed from stock—K.S.A. 65-1634 & K.S.A. 65-657(a) & (b)

SECURITY

- Yes No N/A Secure from unauthorized entry—21 C.F.R. 211 & K.A.R. 68-14-7(b)(1)
- Yes No N/A Alarm system—21 C.F.R. 211 & K.A.R. 68-14-7(b)(2)
- Yes No N/A Controlled drugs locked—K.A.R. 68-20-15a & 21 C.F.R. 1301.71 & 1301.75

REVIEW OF DRUG RECORDS

- Yes No N/A Documentation of Examination of Materials; Certificate of Analysis on file—K.A.R. 68-14-7(d)
- Yes No N/A Records of ALL transactions in the receipt and distribution of prescription-only drugs—K.A.R. 68-14-7(f)
- Yes No N/A Records readily retrievable—K.A.R. 68-14-7(f)(3)
- Yes No N/A Annual Inventory of controlled substances—K.A.R. 68-20-16
Date: _____
- Yes No N/A C-II inventory filed separately—K.A.R. 68-20-16
- Yes No N/A C-II invoices filed separately—K.A.R. 68-20-16
- Yes No N/A DEA 222 forms completed—21 C.F.R. 1305.13
- Yes No N/A DEA 222 forms for C-II transfers—K.A.R. 68-20-17

COMMENTS