



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: _____

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

Yes No N/A Documentation of training, education, & experience

Yes No N/A Duration of record keeping—K.A.R. 68-20-16a

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.S.A. 65-625 & K.S.A. 65-656(o)

Yes No N/A Free from infestation by insects, rodents, birds, or vermin of any kind

Yes No N/A Quarantine Area

STORAGE

Yes No N/A Drugs stored per manufacturer—K.S.A. 65-1634

Yes No N/A No outdated, mislabeled, or adulterated drugs—K.S.A. 65-1634 & K.S.A. 65-657(a)(b)



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SECURITY

- Yes No N/A Secure from unauthorized entry—21 C.F.R. 211
- Yes No N/A Alarm system—21 C.F.R. 211
- 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
- Yes No N/A Records of ALL transactions in the receipt and distribution of prescription-only drugs
- Yes No N/A Records readily retrievable
- 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. 1305.12(e)
- Yes No N/A DEA 222 forms for C-II transfers—K.A.R. 68-20-17

COMMENTS