



**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- Yes  No  N/A Outdated, mislabeled, or adulterated drugs have been removed from stock—K.S.A. 65-1634 & K.S.A. 65-657(a) & (b)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**