

**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: \_\_\_\_\_

**Facility Type:**

- Human Prescription Drugs    Animal Prescription Drugs  
 Oxygen/Medical Gases    Medical Devices    Nonprescription Drugs    Other

C-Compliant N/I-Needs Improvement N/C-Not Compliant  
U-Unassessed N/A-Not Applicable**GENERAL INFORMATION**

Person(s) on duty: \_\_\_\_\_

 C  N/I  N/C  U  N/A   Registration displayed—K.S.A. 65-1645(e) & K.A.R. 68-14-7(f)(5) C  N/I  N/C  U  N/A   DEA number: \_\_\_\_\_—21 C.F.R. 1301.11**FACILITIES** C  N/I  N/C  U  N/A   Suitable size and construction to facilitate cleaning, maintenance, & proper operation  
—K.A.R. 68-14-7(a)(1) C  N/I  N/C  U  N/A   Adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, & security  
—K.S.A. 65-656(m) & K.A.R. 68-14-7(a)(2) C  N/I  N/C  U  N/A   Quarantine area—K.A.R. 68-14-7(a)(3) C  N/I  N/C  U  N/A   Maintained in a clean and orderly condition—K.A.R. 68-14-7(a)(4) C  N/I  N/C  U  N/A   Free from infestation by insects, rodents, birds, or vermin of any kind—K.A.R. 68-14-7(a)(5) C  N/I  N/C  U  N/A   Drugs and devices stored per manufacturer—K.A.R. 68-14-7(c) C  N/I  N/C  U  N/A   Documentation of appropriate temperature—K.A.R. 68-14-7(c)(2)

Room temperature: \_\_\_\_\_

Refrigerator temperature: \_\_\_\_\_

Freezer temperature: \_\_\_\_\_

 C  N/I  N/C  U  N/A   Establish, maintain and adhere to policy and procedures—K.A.R. 68-14-7(g) C  N/I  N/C  U  N/A   Procedures for distribution of oldest approved stock first—K.A.R. 68-14-7(g)(1) C  N/I  N/C  U  N/A   Procedure for handling recalls and withdrawing drugs and devices—K.A.R. 68-14-7(g)(2) C  N/I  N/C  U  N/A   Procedure to prepare for, protect against and handle any crisis that affects security or operation of  
facility—K.A.R. 68-14-7(g)(3) C  N/I  N/C  U  N/A   Procedure for outdated, mislabeled, or adulterated drugs and devices to be removed from stock  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.68-14-7(e) & K.A.R. 68-14-7(g)(4)**MANUFACTURING PROCESSES—21 C.F.R. 211** C  N/I  N/C  U  N/A   Equipment clean



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- C  N/I  N/C  U  N/A Calibration of thermometers, balances, gauges, etc.
- C  N/I  N/C  U  N/A Documentation of calibration
- C  N/I  N/C  U  N/A Labels secure/controlled
- C  N/I  N/C  U  N/A Floors, walls, & ceiling smooth, hard, & clean
- C  N/I  N/C  U  N/A Off floor storage
- C  N/I  N/C  U  N/A Protective apparel (if needed)
- C  N/I  N/C  U  N/A Batch records available
- C  N/I  N/C  U  N/A Batch records signed by quality control prior to release

**SECURITY**

- C  N/I  N/C  U  N/A Secure from unauthorized entry—21 C.F.R. 211 & K.A.R. 68-14-7(b)(1)
- C  N/I  N/C  U  N/A Alarm and security systems—21 C.F.R. 211 & K.A.R. 68-14-7(b)(2) & (3)
- C  N/I  N/C  U  N/A Controlled drugs locked—21 C.F.R. 1301.71 thru 1301.76 & K.A.R. 68-14-7(b)(4), K.A.R. 68-20-15a
- C  N/I  N/C  U  N/A Verification that persons or entities that transport on their behalf utilize processes to ensure product security—K.A.R. 68-14-7(b)(5)

**RECORDS**

- C  N/I  N/C  U  N/A Documentation of education, training & experience—K.A.R. 68-14-5
- C  N/I  N/C  U  N/A Maintain list of responsible persons to include duties and qualifications —K.A.R. 68-14-7(h)
- C  N/I  N/C  U  N/A Documentation of examination of materials—K.A.R. 68-14-7(d)
- C  N/I  N/C  U  N/A Records of ALL transactions in the receipt and distribution of prescription-only drugs—K.A.R. 68-14-7(f)
- C  N/I  N/C  U  N/A Duration of record keeping—K.A.R. 68-20-16(a) & K.A.R. 68-14-7(f)(3)
- C  N/I  N/C  U  N/A Central record keeping—K.A.R. 68-14-7(f)(4) & 21 C.F.R. 1304.04(b)(3)

Location: \_\_\_\_\_

- C  N/I  N/C  U  N/A Records readily retrievable—K.A.R. 68-14-7(f)(3)&(4)

**REVIEW OF INVENTORY AND INVOICE RECORDS**

- C  N/I  N/C  U  N/A Drugs and devices distributed to registered sources  
—21 C.F.R. 1301.74, K.S.A. 65-1643(c), K.A.R. 68-14-7(f)(2) & K.A.R. 68-14-7(g)(5)
- C  N/I  N/C  U  N/A Inventories and records of all transactions—K.A.R. 68-14-7(f)
- C  N/I  N/C  U  N/A Annual inventory of controlled substances—K.A.R. 68-20-16

Date: \_\_\_\_\_

- C  N/I  N/C  U  N/A C-II inventory filed separately—K.A.R. 68-20-16
- C  N/I  N/C  U  N/A C-II invoices filed separately—K.A.R. 68-20-16



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- C  N/I  N/C  U  N/A CIII-V invoices filed separately or readily retrievable—K.A.R. 68-20-16
- C  N/I  N/C  U  N/A DEA 222 forms completed—21 C.F.R. 1305.12 & 1305.13
- C  N/I  N/C  U  N/A DEA 222 forms for C-II transfers—K.A.R. 68-20-17
- C  N/I  N/C  U  N/A Power of attorney—21 C.F.R. 1305.05

**COMMENTS**

Self-Inspection