

**STATE BOARD OF PHARMACY**

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

**INSPECTION:
Distributor
Form I-05**

INSPECTION INFORMATION

Distributor Name: _____ Registration Number: _____

Inspector Name: _____ Date: _____

GENERAL INFORMATION**Facility Type:**

Dialysates—K.S.A. 65-1660 Prescription Drugs Oxygen/Medical Gases Medical Devices

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)

To include: Recalls, rotation of stock, natural disasters, etc. See regulation for total list.

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. 68-20-16a & K.A.R. 68-14-7(f)(2)

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 & 65-656(o) & 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)

STORAGE

Yes No N/A Drugs stored per manufacturer—K.A.R. 68-14-7(c)

Yes No N/A Documentation of appropriate temperature—K.A.R. 68-14-7(c)(2)

Yes No N/A Outdated, mislabeled, or adulterated drugs have been removed from stock—K.S.A. 65-1634 &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

Yes No N/A Alarm system—K.A.R. 68-14-7(b)(2) & (3)

Yes No N/A Controlled drugs locked—K.A.R. 68-20-15a & 21 C.F.R. 1301.71

REVIEW OF DRUG RECORDS

Yes No N/A Documentation of Examination of Materials—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 Inventories of all held drugs—K.A.R. 68-14-7(f)



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- 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. 1305.12 & 1305.13
- Yes No N/A DEA 222 forms for C-II transfers—K.A.R. 68-20-17
- Yes No N/A Power of Attorney—21 C.F.R. 1305.05

WHOLESALE DISTRIBUTORS (VETERINARY)

- Yes No N/A Copy of the written prescription—K.A.R. 68-14-8(a) & (b)
- Yes No N/A Requirements for a Veterinary Prescription—K.A.R. 70-7-1(l) & (m)
(l) is companion animals, (m) is large animal/herd

COMMENTS