

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Yes    No    N/A   Outdated, mislabeled, or adulterated drugs have been removed from stock—K.S.A. 65-1634 &  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