

**STATE BOARD OF PHARMACY**800 SW Jackson, Suite 1414
Topeka, Kansas 66612-1244
www.pharmacy.ks.gov (785)296-4056**INSPECTION:**
Analytical Lab
Form I-08**INSPECTION INFORMATION**

Analytical Lab Name: _____ Registration Number: _____

Inspector Name: _____ Date: _____

GENERAL INFORMATION

Person(s) on duty: _____

C-Compliant N/I-Needs Improvement N/C-Not Compliant
U-Unassessed N/A-Not Applicable C N/I N/C U N/A Registration displayed—K.S.A. 65-1645(e) 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 Facility clean, well lit, etc.—K.S.A. 65-656(m) & K.S.A. 65-1642(a) C N/I N/C U N/A Drugs stored per manufacturer—K.S.A. 65-1634

Room temperature: _____

Refrigerator temperature: _____

Freezer temperature: _____

 C N/I N/C U N/A Outdated, mislabeled, or adulterated drugs have been removed from stock
—K.S.A. 65-1634 & K.S.A. 65-657(a)**SECURITY** C N/I N/C U N/A Controlled drugs locked—21 C.F.R. 1301.71 thru 1301.76 & K.A.R. 68-20-15a**RECORDS** C N/I N/C U N/A Duration of record keeping—K.A.R. 68-20-16(a) C N/I N/C U N/A Central record keeping—21 C.F.R. 1304.04(b)(3)

Location: _____

 C N/I N/C U N/A Records of all transactions in the receipt and distribution of prescription-only drugs
—21 C.F.R. 1304.22(c) & 1304.23 C N/I N/C U N/A Records readily retrievable—21 C.F.R. 1300.01(b)Records consist of: name of controlled substances, form
(tablet, powder, crystals, etc.), (total quantity received, date
received and from whom and quantity distributed/destroyed)**REVIEW OF INVENTORY AND INVOICE RECORDS** 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 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 Drugs received from registered sources—K.S.A. 65-1643(c) C N/I N/C U N/A DEA 222 forms completed—21 C.F.R. 1305.13Controlled substances that are received as
evidence do not need to be inventoried but if
maintained by the lab, an explanation as why
the drug is being maintained must be recorded.



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- 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 Controlled substance ordering system—21 C.F.R. 1305.21
- C N/I N/C U N/A Power of attorney—21 C.F.R. 1305.05

COMMENTS

Self-Inspection