| Kansas | **STATE BOARD OF PHARMACY**<br>800 SW Jackson, Suite 1414<br>Topeka, Kansas 66612-1244<br>www.pharmacy.ks.gov (785)296-4056 | **INSPECTION:**<br>**Outsourcing Facility**<br>Form I-20 |
|---|---|---|

Clear Answers

**INSPECTION INFORMATION**

Facility Name:_____ Registration Number:_____

Inspector Name: _____ Date: _____

**GENERAL INFORMATION**

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

Person(s) on duty: _____

Pharmacist in Charge: _____

○C ○N/I ○N/C ○U ○N/A Registration(s) displayed—K.S.A. 65-1645(e) & K.A.R. 68-14-7b(f)(4)

○C ○N/I ○N/C ○U ○N/A DEA number: _____—21 C.F.R. 1301.11, K.A.R. 68-14-7b(f)(4) & K.A.R. 68-14-7b(i)(1)

○C ○N/I ○N/C ○U ○N/A FDA registration number (EIN): _____—21 U.S.C. 353b & K.A.R. 68-14-7b(f)(4)

Date of last FDA inspection: _____

○C ○N/I ○N/C ○U ○N/A Pharmacist license(s) posted—K.S.A. 65-1641 & K.S.A. 65-1655b(a)(6)

**PRACTICE SETTING**

Registered pharmacy: ☐Yes ☐No

Pharmacy registration number: _____

If yes: ☐see separate form ☐not inspected at this visit

Facility compounds sterile product: ☐Yes ☐No

If yes: ☐see separate form ☐not inspected at this visit

Facility compounds nonsterile Products: ☐Yes ☐No

If yes: ☐see separate form ☐not inspected at this visit

**FACILITIES**

○C ○N/I ○N/C ○U ○N/A Suitable size and construction to facilitate cleaning, maintenance, & proper operation —K.A.R. 68-14-7b(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. 68-14-7b(a)(2)

○C ○N/I ○N/C ○U ○N/A Quarantine areas—K.A.R. 68-14-7b(a)(3) & K.A.R. 68-14-7b(a)(4)

○C ○N/I ○N/C ○U ○N/A Maintained in a clean and orderly condition—K.A.R. 68-14-7b(a)(5)

○C ○N/I ○N/C ○U ○N/A Free from infestation by insects, rodents, birds, or vermin of any kind—K.A.R. 68-14-7b(a)(6)

○C ○N/I ○N/C ○U ○N/A Drugs and devices stored per manufacturer——K.S.A. 65-657(b) & K.A.R. 68-14-7b(c)

○C ○N/I ○N/C ○U ○N/A Documentation of appropriate temperature—K.A.R. 68-14-7b(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. 68-14-7b(g)

○C ○N/I ○N/C ○U ○N/A Procedures for distribution of oldest approved stock first—K.A.R. 68-14-7b(g)(1)

○C ○N/I ○N/C ○U ○N/A Procedure for handling recalls and withdrawing drugs and devices—K.A.R. 68-14-7b(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. 68-14-7b(g)(3)

○C ○N/I ○N/C ○U ○N/A Procedure for outdated, mislabeled, or adulterated drugs and devices to be removed from stock — 21 U.S.C. 501(a)(2)(B) K.S.A. 65-1634, K.S.A. 65-657(a) & K.A.R. 68-14-7b(g)(4)

○C ○N/I ○N/C ○U ○N/A Patient specific compounding—K.S.A. 65-1655b(g)

○C ○N/I ○N/C ○U ○N/A Compounding with bulk drug substances meets requirements —21 U.S.C. 353b(a) and K.A.R. 68-14-7b(i)(3)

○C ○N/I ○N/C ○U ○N/A Bulk drug substances are accompanied by a valid certificate of analysis —21 U.S.C. 353b(a) and K.A.R. 68-14-7b(i)(3)

○C ○N/I ○N/C ○U ○N/A Compounding components comply with monographs, are not withdrawn, and are not otherwise prohibited by FDA—21 U.S.C. 353b(a) and K.A.R. 68-14-7b(i)(3)

○C ○N/I ○N/C ○U ○N/A Facility utilizes appropriate controls for drugs subject to REMS —21 U.S.C. 353b(a) and K.A.R. 68-14-7b(i)(3)

**SECURITY**

○C ○N/I ○N/C ○U ○N/A Secure when pharmacist is not on premises—21 U.S.C. 353b(a) and K.A.R. 68-14-7b(i)(3)

○C ○N/I ○N/C ○U ○N/A Secure from unauthorized entry—21 C.F.R. 1301.71 thru 1301.76 & K.A.R. 68-14-7b(b)(1)

○C ○N/I ○N/C ○U ○N/A Perimeter of premises well lighted—K.A.R. 68-14-7b(b)(1)

○C ○N/I ○N/C ○U ○N/A Alarm and security systems—21 C.F.R. 1301.71 thru 1301.76 & K.A.R. 68-14-7b(b)(2)&(3)

○C ○N/I ○N/C ○U ○N/A Controlled drugs locked—K.A.R. 68-20-15a & 21 C.F.R. 1301.71 thru 1301.7 6

**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. 68-14-7b(h)

○C ○N/I ○N/C ○U ○N/A Documentation of examination of materials—K.A.R. 68-14-7b(d)

○C ○N/I ○N/C ○U ○N/A Records of ALL transactions in the receipt and distribution of prescription-only drugs, devices & bulk active pharmaceutical ingredients—K.A.R. 68-14-7b(f)

○C ○N/I ○N/C ○U ○N/A Duration of record keeping—K.A.R. 68-20-16(a) & K.A.R. 68-14-7b(f)(2)

○C ○N/I ○N/C ○U ○N/A Central record keeping—K.A.R. 68-14-7b(f)(3) & 21 C.F.R. 1304.04(b)(3)

Location: _____

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

**DRUG LABEL—21 U.S.C. 353b(a)**

○C ○N/I ○N/C ○U ○N/A Statement "This is a compounded drug"

○C ○N/I ○N/C ○U ○N/A Facility name, address, and phone number

○C ○N/I ○N/C ○U ○N/A Lot or batch number

○C ○N/I ○N/C ○U ○N/A Name of drug

○C ○N/I ○N/C ○U ○N/A Dosage form and strength

○C ○N/I ○N/C ○U ○N/A Statement of quantity or volume

○C ○N/I ○N/C ○U ○N/A Date compounded

○C ○N/I ○N/C ○U ○N/A Expiration date

○C ○N/I ○N/C ○U ○N/A Storage and handling instructions

○C ○N/I ○N/C ○U ○N/A NDC, if available

○C ○N/I ○N/C ○U ○N/A Statement "Not for resale"

○C ○N/I ○N/C ○U ○N/A Statement "Office Use Only", if applicable

○C ○N/I ○N/C ○U ○N/A List of inactive and active ingredients and quantities, if not found on container label

**CONTAINER LABEL—21 U.S.C. 353b(a)**

○C ○N/I ○N/C ○U ○N/A List of inactive and active ingredient and quantities, if not found on drug label

○C ○N/I ○N/C ○U ○N/A Adverse event reporting information

○C ○N/I ○N/C ○U ○N/A Directions for use, including, as appropriate, dosage and administration

**COMMENTS**