Kansas	**STATE BOARD OF PHARMACY** 800 SW Jackson, Suite 1414 Topeka, Kansas 66612-1244 www.pharmacy.ks.gov (785)296-4056	**INSPECTION:** **Compounding Pharmacy** Form I-02C

Clear Answers

INSPECTION INFORMATION

Pharmacy Name:_____ Registration Number:_____

Inspector Name: _____ Date: _____

PRACTICE SETTING

C-Compliant N/I-Needs Improvement N/C-Not Compliant
U-Unassessed N/A-Not Applicable
Asterisk * denotes Pharmacist in Charge responsibility

Compounder(s) on duty: _____

Facility compounds nonsterile products: ☐Yes ☐No

Compounding observed: ☐Yes ☐No

Facility compounds sterile products: ☐Yes ☐No

Compounding observed: ☐Yes ☐No

Sterile risk levels: ☐High ☐Medium ☐Low ☐Immediate Use

Type of compounding area: ☐Cleanroom Suite ☐HD Cleanroom Suite ☐SCA ☐C-SCA ☐other _____

Type of primary engineering controls (PEC): ☐LAFW ☐CAI ☐CACI ☐BSC ☐CVE ☐IVLFZ ☐other _____

Compounded products shipped out of Kansas: ☐Yes ☐No

If yes, what states: _____

GENERAL COMPOUNDING INFORMATION

C N/I N/C U N/A Compounding components meet standards (FDA, monograph, compendium) —K.A.R. 68-13-3(d) & K.A.R. 68-13-4(p)

Component suppliers: _____

C N/I N/C U N/A Advance compounding limited to routine prescribing patterns—K.A.R. 68-13-3(e) & 68-13-4(j)

C N/I N/C U N/A Veterinary compounds meet same requirements as human compounds—K.A.R. 68-13-3(f) & 68-13-4(k)

C N/I N/C U N/A Compounding with bulk chemicals for food-producing animals does not occur —K.A.R. 68-13-3(f) & 68-13-4(k)

C N/I N/C U N/A Office use compounds labeled: "For Office Use Only – Not for Resale" —K.A.R. 68-13-3(g)&(h) & K.A.R. 68-13-4(l)

RECORDS

C N/I N/C U N/A Documentation maintained showing preparations of products that are commercially available are compounded in accordance with allowed conditions—K.A.R. 68-13-2(r), K.A.R. 68-13-3(c) & K.A.R. 68-13-4(o)

C N/I N/C U N/A UFR maintained at the pharmacy for 5 years—K.A.R. 68-13-3(n) & 68-13-4(t)

C N/I N/C U N/A Compounding record maintained at the pharmacy for 5 years—K.A.R. 68-13-3(n)

C N/I N/C U N/A Certificates of analysis maintained at the pharmacy for 5 years—K.A.R. 68-13-4(x)(3)

C N/I N/C U N/A Certification documents maintained at the pharmacy for last 5 years—K.A.R. 68-13-4(q)(1)

C N/I N/C U N/A Environmental documents maintained at the pharmacy for 5 years—K.A.R. 68-13-4(ee)

Self-Inspection

○C ○N/I ○N/C ○U ○N/A Documentation of daily checks and recordings of cleanroom suite pressures—K.A.R. 68-13-4(cc)

○C ○N/I ○N/C ○U ○N/A HEPA filter maintenance and installation records for past 5 years—K.A.R. 68-13-4(q)(1)

○C ○N/I ○N/C ○U ○N/A Cleaning and disinfecting documented & records maintained for the past year —K.A.R. 68-13-4(q)(1)&(bb)

○C ○N/I ○N/C ○U ○N/A Compounding training documented and maintained at the pharmacy for 5 years—K.A.R. 68-13-4(aa)

○C ○N/I ○N/C ○U ○N/A Invoices for office use sale to practitioner documented (name/address, drug name, lot, BUD, quantity, & date) and readily retrievable—K.A.R. 68-13-3(i)

UNIFORM FORMULATION RECORD (UFR) INFORMATION—K.A.R. 68-13-3(l) & 68-13-4(r) & 68-13-4(u)*

○C ○N/I ○N/C ○U ○N/A UFR for each compounded preparation (procedural document)

○C ○N/I ○N/C ○U ○N/A Medical care facilities have UFR for batch compounds or when assigning sterile BUD>7d

○C ○N/I ○N/C ○U ○N/A Ingredients, quantities, strength and dosage form for drug to be compounded

○C ○N/I ○N/C ○U ○N/A Equipment to be used

○C ○N/I ○N/C ○U ○N/A Mixing instructions

○C ○N/I ○N/C ○U ○N/A Container to be used for dispensing

○C ○N/I ○N/C ○U ○N/A Storage requirements

○C ○N/I ○N/C ○U ○N/A Beyond-use date to be assigned

○C ○N/I ○N/C ○U ○N/A Source of formulation (person, entity, publication)

○C ○N/I ○N/C ○U ○N/A Name of pharmacist verifying UFR and date established

○C ○N/I ○N/C ○U ○N/A Quality control procedures with allowable variances (uniformity, clarity, color, pH, etc.)

○C ○N/I ○N/C ○U ○N/A Sterilization method – if applicable

COMPOUNDING RECORD INFORMATION—K.A.R. 68-13-3(m) & 68-13-4(s) & 68-13-4(u)*

○C ○N/I ○N/C ○U ○N/A CR for each compounded preparation

○C ○N/I ○N/C ○U ○N/A Medical care facilities have CR for batch compounds or when assigning sterile BUD>7d

○C ○N/I ○N/C ○U ○N/A Name and strength of preparation

○C ○N/I ○N/C ○U ○N/A Reference UFR documented

○C ○N/I ○N/C ○U ○N/A Components documented - manufacturer/repackager, lot number, and expiration date

○C ○N/I ○N/C ○U ○N/A Total number of dosage units or quantity compounded

○C ○N/I ○N/C ○U ○N/A Name of each person involved in the compounding procedure

○C ○N/I ○N/C ○U ○N/A Name of pharmacist who verified the preparation

○C ○N/I ○N/C ○U ○N/A Date of compounding

○C ○N/I ○N/C ○U ○N/A Prescription number or internal number – if assigned

Self-Inspection

○C ○N/I ○N/C ○U ○N/A Quality control results

○C ○N/I ○N/C ○U ○N/A Documentation of beyond-use date (BUD) assigned

NON-STERILE COMPOUNDING—K.A.R. 68-13-3

○C ○N/I ○N/C ○U ○N/A Compounding with components meeting requirements of the official compendium

○C ○N/I ○N/C ○U ○N/A Purified water is used for compounding

○C ○N/I ○N/C ○U ○N/A Assignment of appropriate beyond-use dates

○C ○N/I ○N/C ○U ○N/A Documentation of stability information for use of extended BUD's

○C ○N/I ○N/C ○U ○N/A Support personnel trained and can successfully demonstrate compounding techniques

○C ○N/I ○N/C ○U ○N/A Policy and procedure manual with standard operating procedures of non-sterile compounding

DESIGNATED COMPOUNDING AREA—K.A.R. 68-13-3(j)

○C ○N/I ○N/C ○U ○N/A Well-lighted

○C ○N/I ○N/C ○U ○N/A Well-ventilated

○C ○N/I ○N/C ○U ○N/A Clean and sanitary

○C ○N/I ○N/C ○U ○N/A Free of food and beverages

○C ○N/I ○N/C ○U ○N/A Provides protections to maintain drug integrity and security

○C ○N/I ○N/C ○U ○N/A Provides refrigeration, if required

○C ○N/I ○N/C ○U ○N/A Sink with hot and cold running water for hand and equipment washing

STERILE COMPOUNDING—K.A.R. 68-13-4

CERTIFICATION & ENVIRONMENTAL TESTING OF ISO AREAS

○C ○N/I ○N/C ○U ○N/A Antearea - ISO 8 or better – certification up to date

○C ○N/I ○N/C ○U ○N/A Buffer area - ISO 7 or better – certification up to date

○C ○N/I ○N/C ○U ○N/A PEC - ISO 5 or better – certified within last 6 months—K.A.R. 68-13-4 (q)(1)

Certification date: _____

○C ○N/I ○N/C ○U ○N/A Air pressure of the antearea maintained at 5 pascals—K.A.R. 68-13-4(cc)*

○C ○N/I ○N/C ○U ○N/A Air flow of the antearea maintained at 0.2 meters per second—K.A.R. 68-13-4(cc)*

○C ○N/I ○N/C ○U ○N/A Environmental sampling is performed at least every 6 months—K.A.R. 68-13-4(dd)*

○C ○N/I ○N/C ○U ○N/A Environmental sampling performed in PEC, buffer area, and antearea—K.A.R. 68-13-4(dd)*

○C ○N/I ○N/C ○U ○N/A Viable air sampling within acceptable range for PEC (1CFU), buffer area (10CFU), & antearea (100CFU)—K.A.R.68-13-4(ff)

○C ○N/I ○N/C ○U ○N/A Viable surface sampling within acceptable range for PEC (3CFU), buffer area (5CFU) and antearea (100CFU)—K.A.R.68-13-4(ff)

Self-Inspection

○C ○N/I ○N/C ○U ○N/A Nonviable particle counts were performed for PEC, buffer area and antearea—K.A.R.68-13-4(ff)

○C ○N/I ○N/C ○U ○N/A Investigation, triple cleaning, and reevaluation of ISO areas occur for microbial growth above acceptable levels—K.A.R.68-13-4(ff)

FACILITES

○C ○N/I ○N/C ○U ○N/A PEC has unidirectional airflow—K.A.R. 68-13-4(e)

○C ○N/I ○N/C ○U ○N/A Clean room suite/area void of all extraneous activities and materials—K.A.R. 68-13-4(e)

○C ○N/I ○N/C ○U ○N/A Segregated compounding area is designated, demarcated, void of extraneous materials, and restricted to compounding activities—K.A.R. 68-13-2(oo)

○C ○N/I ○N/C ○U ○N/A SCA restricted to compounding of low risk or immediate use preparations—K.A.R. 68-13-2(oo)

○C ○N/I ○N/C ○U ○N/A Sink with hot and cold running water—K.A.R. 68-13-4(q)(2)

○C ○N/I ○N/C ○U ○N/A Refrigerator/freezer with temperatures recorded daily or electronic monitoring system —K.A.R. 68-13-4(q)(3) & 68-13-2(b)

Refrigerator temperature: _____ (36° to 46°F or 2° to 8°C)

Freezer temperature: _____ (32° to -4°F or 0° to -20°C or colder)

○C ○N/I ○N/C ○U ○N/A Medium and low risk, if frozen are maintained at -20°C or colder—K.A.R. 68-13-4(b)

○C ○N/I ○N/C ○U ○N/A High risk, if frozen, are maintained at 0°C to -20°C or colder—K.A.R. 68-13-4(b)

○C ○N/I ○N/C ○U ○N/A Reference material (incompatibilities, stabilities) or electronic access to reference—K.A.R. 68-13-4(q)(4)

POLICY AND PROCEDURES—K.A.R. 68-13-4(q)(5)*

○C ○N/I ○N/C ○U ○N/A Sanitation

○C ○N/I ○N/C ○U ○N/A Storage

○C ○N/I ○N/C ○U ○N/A Dispensing

○C ○N/I ○N/C ○U ○N/A Labeling

○C ○N/I ○N/C ○U ○N/A Destruction and return of controlled substances

○C ○N/I ○N/C ○U ○N/A Recordkeeping

○C ○N/I ○N/C ○U ○N/A Recall procedures

○C ○N/I ○N/C ○U ○N/A Responsibilities and duties of support personnel

○C ○N/I ○N/C ○U ○N/A Aseptic compounding techniques

○C ○N/I ○N/C ○U ○N/A Ongoing evaluation of all staff compounding sterile preparations

○C ○N/I ○N/C ○U ○N/A Supplies necessary for compounding sterile preparations—K.A.R. 68-13-4(q)(6)

○C ○N/I ○N/C ○U ○N/A Storage and delivery methods maintain product stability and sterility—K.A.R. 68-13-4(w)

○C ○N/I ○N/C ○U ○N/A Non-sterile components for sterile compounding have a certificate of analysis—K.A.R. 68-13-4(x)(3)

Self-Inspection

○C ○N/I ○N/C ○U ○N/A Policy and procedure manual updated at least every 2 years—K.A.R. 68-13-4(q)(5)*

TRAINING OF PERSONNEL—K.A.R. 68-13-4(z) & K.A.R. 68-13-2(t)*

○C ○N/I ○N/C ○U ○N/A Required personnel have practical or academic training in sterile compounding techniques, clean room & laminar flow technology, quality assurance techniques, standard operating procedures, and documentation requirements

○C ○N/I ○N/C ○U ○N/A Initial media fill test documented for each sterile compounder

○C ○N/I ○N/C ○U ○N/A Annual media fill test documented for each sterile compounder

○C ○N/I ○N/C ○U ○N/A Media fill test documented for each sterile compounder every 6 months if compounding high risk

○C ○N/I ○N/C ○U ○N/A Initial glove fingertip tests documented for each sterile compounder (3 separate tests with 0CFU)

○C ○N/I ○N/C ○U ○N/A Annual glove fingertip test documented for each sterile compounder (no more than 3CFU)

○C ○N/I ○N/C ○U ○N/A Glove fingertip test documented for each sterile compounder every 6 months if compounding high risk

○C ○N/I ○N/C ○U ○N/A All personnel are trained before performing any sterile compounding

GARBING (excludes CAI compounding)—K.A.R. 68-13-4(v)

○C ○N/I ○N/C ○U ○N/A Garbing policy and procedure follows required order

○C ○N/I ○N/C ○U ○N/A Staff appropriately garbed (direct observation of garbed staff or garbing procedure)

○C ○N/I ○N/C ○U ○N/A Garbing is required and occurs for entry into SCA, anteareas, buffer areas, and PEC

○C ○N/I ○N/C ○U ○N/A Outer garments, cosmetics, jewelry, and artificial nails are removed

○C ○N/I ○N/C ○U ○N/A Shoe covers or dedicated shoes are used

○C ○N/I ○N/C ○U ○N/A Head (hair/mask) and facial hair covers are used

○C ○N/I ○N/C ○U ○N/A Hands are washed for 20 seconds with soap and water or antiseptic hand scrub is used

○C ○N/I ○N/C ○U ○N/A Non-shedding/low-linting gown is used

○C ○N/I ○N/C ○U ○N/A Alcohol-based surgical hand scrub is applied upon entry into work area

○C ○N/I ○N/C ○U ○N/A Sterile, power-free gloves are used

○C ○N/I ○N/C ○U ○N/A Gloves are disinfected after touching any nonsterile area

ISO 5 ENVIRONMENT CLEANING AND DISINFECTING—K.A.R. 68-13-4(bb)*

○C ○N/I ○N/C ○U ○N/A PEC cleaning observed for adherence to facility procedures

○C ○N/I ○N/C ○U ○N/A At the beginning of each shift

○C ○N/I ○N/C ○U ○N/A Every 30 minutes during continuous periods of individual sterile preparations

○C ○N/I ○N/C ○U ○N/A Before each batch

○C ○N/I ○N/C ○U ○N/A After a spill or known contamination

CLEAN ROOM SUITE & SCA CLEANING AND DISINFECTING—K.A.R. 68-13-4(bb)*

○C ○N/I ○N/C ○U ○N/A Cleaning observed for adherence to facility procedures

Self-Inspection

○C ○N/I ○N/C ○U ○N/A Exterior walls and surfaces of PEC cleaned monthly

○C ○N/I ○N/C ○U ○N/A All counters, work surfaces and floor cleaned daily in buffer area, antearea & SCA

○C ○N/I ○N/C ○U ○N/A Walls, ceilings, and storage shelves cleaned monthly in buffer area, antearea & SCA

PRESCRIPTION LABELS—K.A.R. 68-7-14 & K.A.R. 68-13-4(y)

○C ○N/I ○N/C ○U ○N/A Name, address, and telephone number of the dispensing pharmacy

○C ○N/I ○N/C ○U ○N/A Name of the prescriber

○C ○N/I ○N/C ○U ○N/A Full name of the patient

○C ○N/I ○N/C ○U ○N/A Identification number – prescription number

○C ○N/I ○N/C ○U ○N/A Date the prescription was filled or refilled

○C ○N/I ○N/C ○U ○N/A Adequate directions for use of the drug

○C ○N/I ○N/C ○U ○N/A Beyond-use date

○C ○N/I ○N/C ○U ○N/A Brand or generic name, strength, and quantity of each component

○C ○N/I ○N/C ○U ○N/A Name of manufacturer or distributor for generic products

○C ○N/I ○N/C ○U ○N/A Total quantity dispensed

○C ○N/I ○N/C ○U ○N/A Auxiliary labels if necessary

○C ○N/I ○N/C ○U ○N/A Flow rate

○C ○N/I ○N/C ○U ○N/A Name or initials of every person participating in the compounding of the prescription

○C ○N/I ○N/C ○U ○N/A Special storage instructions

ASSIGNMENT OF APPROPRIATE BEYOND-USE-DATES (BUD)—K.A.R. 68-13-4(s)(12)*

○C ○N/I ○N/C ○U ○N/A Maximum BUDs are not exceeded without sterility testing—K.A.R. 68-13-4(b)

○C ○N/I ○N/C ○U ○N/A Immediate use sterile product—K.A.R. 68-13-4(c)

○C ○N/I ○N/C ○U ○N/A Sterile, low risk—K.A.R. 68-13-4(b)

○C ○N/I ○N/C ○U ○N/A Sterile, medium risk—K.A.R. 68-13-4(b)

○C ○N/I ○N/C ○U ○N/A Sterile, high risk—K.A.R. 68-13-4(b)&(gg)

○C ○N/I ○N/C ○U ○N/A Segregated compounding area not more than 12 hours—K.A.R. 68-13-4(f)

○C ○N/I ○N/C ○U ○N/A During re-testing for above acceptable levels of microbial growth—K.A.R. 68-13-4(ff)&(gg)

○C ○N/I ○N/C ○U ○N/A Multi-dose containers with preservatives (28 days or per mfg)—K.A.R. 68-13-4(d)

○C ○N/I ○N/C ○U ○N/A Single-dose containers not used in ISO 5 environment (1 hour)—K.A.R. 68-13-4(h)

○C ○N/I ○N/C ○U ○N/A Single-dose containers used in ISO 5 environment (6 hours)—K.A.R. 68-13-4(j)

COMMENTS

Self-Inspection