Kentucky Board of Pharmacy
125 Holmes St.
Frankfort, KY 40601

Report

Pharmacy

Name: *Demo Pharmacy* **Permit No.**: *P0DEMO*

Address: *State Off. Bldg.Annex Ste 300, Frankfort, KY 40601*

Phone: *(859) 246-2820* **Fax**: *(859) 246-2823* **Email**: *steve.hart@ky.gov*

Inspection

Date: *06/10/2019* **Time In**: *8:04 AM* **Time Out**:

Type: *Routine*

Notes: *None*

Pharmacist and Interns

Policies and Procedures

Description of test or examinations conducted on CNSP to ensure uniformity and integrity.	*N/A*
Recommended all significant procedures performed in the compounding area should be covered by P&Ps.	*N/A*
Recommended P&P for facility, equipment, personnel, preparation, packaging and storage of NSCP to ensure accountability, accuracy, quality, safety, and uniformity in compounding.	*N/A*
Policies and procedures for handling hazardous waste, if applicable.	*N/A*
Policies and procedures manual reviewed and revised on an annual basis.	*N/A*

Training

Documented training of all technician(s) performing nonsterile compounding, signed by Trainer.	*N/A*
Documented training of all pharmacist(s) performing and/or supervising nonsterile compounding, signed by Trainer.	*N/A*
Training is appropriate to category of compounding, simple, moderate and/or complex.	*N/A*
Read USP 795 and familiarity with USP.	*N/A*
Familiar with all compounding procedures, including facility, equipment, personnel, actual compounding, evaluation, packaging, storage, and dispensing.	*N/A*
Trained on hazardous drugs procedures prior to use, including waste removal and cleaning storage and prep areas.	*N/A*

Training *(continued)*

Trainer demonstration of each procedure employee will be performing.	*N/A*
Employee observed demonstration of each procedure employee will be performing.	*N/A*
Training is ongoing.	*N/A*
Compounder continually monitoring the work of the employee, ensuring accuracy.	*N/A*

Components

Consideration of excipients and effect of manipulating manufactured product on therapeutic appropriateness and stability of NSCP.	*N/A*
APIs purchased from an FDA-registered facility, if cannot may use a reliable source as determined by compounder.	*N/A*
API components USP, NF or FCC substance, when available.	*N/A*
If API is not USP/NF, identity, purity and safety established by professional judgment, reliability of source, and/or testing.	*N/A*
API: Certificate of Analysis available.	*N/A*
Components stored to USP or manufacturer specifications in a clean area off the floor.	*N/A*
Components stored in appropriate controlled room temperature of 68 to 77 F or 20 to 25 C.	*N/A*
Components stored in appropriate controlled cold temperature of 36 to 46 F or 2 to 8 C.	*N/A*
Components stored in appropriate controlled freezer temperature of -13 to 14 F or -15 to -10 C.	*N/A*
Components store in appropriate humidity, recommended 35% to 60%.	*N/A*
Hazardous components stored separately. Appropriate hazardous waste disposal system.	*N/A*
Components have manufacturer assigned expiration date.	*N/A*
For facility assigned expiration date: receipt date on package and expiration date is not greater than 3 years from the date of receiving.	*N/A*
If transfer APIs into different containers, is appropriately labeled with component name, original supplier, lot number, transfer date, and expiration date.	*N/A*
Transfer container integrity shall be equivalent to or better than the original container.	*N/A*
Bulk component containers OSHA labeled.	*N/A*
SDSs available for all components.	*N/A*

Components *(continued)*

Components not listed on FDA's withdrawn list.	*N/A*

Equipment

Equipment is appropriate for compound.	*N/A*
Equipment contact components are not reactive, additive, or sorptive.	*N/A*
Equipment stored to prevent contamination.	*N/A*
Equipment routinely inspected.	*N/A*
Equipment routinely calibrated.	*N/A*
Equipment routinely checked to ensure proper performance.	*N/A*
Equipment is inspected immediately prior to use.	*N/A*
Equipment is appropriately cleaned after use, recommended to rinse equipment and utensils with purified water.	*N/A*
Recommended certification of powder containment hood annually.	*N/A*
Designated equipment for hazardous drugs or antibiotics or have procedures for cleaning shared equipment.	*N/A*

Compounding Facility

Compounding area restricted to authorized personnel.	*N/A*
Adequate space recommended that is well lighted.	*N/A*
Space is clean, orderly and sanitary.	*N/A*
Nonsterile compounding area is separate and distinct from sterile compounding area.	*N/A*
Washing facilities easily accessible to the compound area with hot and cold water and soap/detergent to wash with.	*N/A*
Use air-drier or single-use towels.	*N/A*
Waste is disposed of in sanitary and timely manner.	*N/A*
HVAC controlled to prevent decomposition and contamination.	*N/A*
Appropriate temperature monitored for controlled room temperature of 68 to 77 F or 20 to 25 C.	*N/A*

Compounding Facility *(continued)*

Appropriate temperature monitored for controlled cold temperature of 36 to 46 F or 2 to 8 C.	*N/A*
Appropriate temperature monitored for controlled freezer temperature of -13 to 14 F or -15 to -10 C.	*N/A*
Appropriate humidity monitored, recommended 35% to 60%.	*N/A*
Hazardous drugs disposed of in a manner that complies with all Federal and State laws.	*N/A*

Compounding Process

Personnel maintain good hand hygiene.	*N/A*
Personnel wear clean clothing.	*N/A*
Appropriate PPE for compound: gloves, shoe covers, hair covers, facemasks, etc.	*N/A*
One preparation at a time compounded in a specific area.	*N/A*
Critical process verified, including but not limited to weighing, measuring and mixing.	*N/A*
Pharmacist reviewing each procedure in compounding process to include assurance of correct ingredients.	*N/A*
Pharmacist reviewing each procedure in compounding process to include assurance of correct calculations.	*N/A*
Pharmacist reviewing each procedure in compounding process to include accurate measurements.	*N/A*
Pharmacist reviewing each procedure in compounding process to include appropriate conditions.	*N/A*
Pharmacist reviewing each procedure in compounding process to include professional judgment.	*N/A*
Master Formulation Record followed.	*N/A*
Compounding Record created.	*N/A*
Purified water used in preparations requiring water.	*N/A*
Dose, safety, and intended use of the NSCP has been evaluated for suitability of chemical and physical properties of the components.	*N/A*
Dose, safety, and intended use of the NSCP has been evaluated for suitability of dosage form.	*N/A*

Compounding Process *(continued)*

Dose, safety, and intended use of the NSCP has been evaluated for suitability of therapeutic appropriateness and route of administration.	*N/A*
Dose, safety, and intended use of the NSCP has been evaluated for suitability of legal limitations, if any.	*N/A*
Final preparation assessed appropriately for weight, clarity, odor, color, consistency, pH, as appropriate.	*N/A*
Assigned appropriate BUD for nonaqueous NSCPs: earliest expiration date of component used or 6 months, at controlled room temperature, from date of compounding, whichever is less.	*N/A*
Assigned appropriate BUD for aqueous oral NSCPs: earliest expiration date of component used or 14 days at controlled cold temperature, from date of compounding, whichever is less.	*N/A*
Assigned appropriate BUD for aqueous topical/dermal/semi-solid NSCPs: earliest expiration date of component used or 30 days, at controlled room temperature, from date of compounding, whichever is less.	*N/A*
If extend BUD, documented stability data for specific drug and preparation (testing).	*N/A*
Recommended potency testing performed.	*N/A*
Compounding Record reviewed by pharmacist.	*N/A*
Preparation labeled with BUD.	*N/A*
Preparation labeled with storage instructions.	*N/A*
Recommended preparation labeled with statement, “this is a compounded preparation.”	*N/A*
Nonsterile compounded preparation dispensed to a patient labeled with name, address, and telephone number of the licensed pharmacy, if preparation will leave the premises.	*N/A*
Nonsterile compounded preparation dispensed to a patient labeled with date dispensed.	*N/A*
Nonsterile compounded preparation dispensed to a patient labeled with identifying number.	*N/A*
Nonsterile compounded preparation dispensed to a patient labeled with patient's full name.	*N/A*
Nonsterile compounded preparation dispensed to a patient labeled with name of each drug, strength, and amount.	*N/A*
Nonsterile compounded preparation dispensed to a patient labeled with directions for use.	*N/A*
Nonsterile compounded preparation dispensed to a patient labeled with required controlled substances transfer warnings, where applicable.	*N/A*

Compounding Process *(continued)*

Nonsterile compounded preparation dispensed to a patient labeled with identity of dispensing pharmacist.	*N/A*
Nonsterile compounded preparation dispensed to a patient labeled with auxiliary labels, when applicable.	*N/A*
Finished product dispensed in suitable container.	*N/A*

Compounding Documentation

Master formulation includes preparation name, strength, dosage form.	*N/A*
Master formulation includes required calculations.	*N/A*
Master formulation includes ingredients description and quantity.	*N/A*
Master formulation includes compatibility and stability information, including reference when available.	*N/A*
Master formulation includes necessary equipment.	*N/A*
Master formulation includes mixing instructions: with the following recommended to be documented: order, temperature, environment, duration and factors pertinent to replication.	*N/A*
Master formulation includes labeling information: generic name and quality /concentrations, assigned BUD, storage conditions, prescriptions or control numbers.	*N/A*
Master formulation includes dispensing container.	*N/A*
Master formulation includes packaging and storage requirements.	*N/A*
Master Formulation includes description of final preparation.	*N/A*
Master formulation includes quality control procedures and expected results.	*N/A*
Compounding Record includes assigned name, strength, and dosage of preparation.	*N/A*
Compounding Record includes Master Formulation Record reference.	*N/A*
Compounding Record includes names and quantities of all components.	*N/A*
Compounding Record includes component sources, lot numbers and expiration dates.	*N/A*
Compounding Record includes total quantity compounded.	*N/A*
Compounding Record includes name of person compounding.	*N/A*
Compounding Record includes name of person performing quality checks.	*N/A*

Compounding Documentation *(continued)*

Compounding Record includes name of pharmacist verifying preparation.	*N/A*
Compounding Record includes date of preparation.	*N/A*
Compounding Record includes assigned prescription number or control number.	*N/A*
Compounding Record includes assigned BUD.	*N/A*
Compounding Record includes duplicate label.	*N/A*
Compounding Record includes description of final preparation.	*N/A*
Compounding Record includes results of quality check.	*N/A*
Compounding Record includes quality control issues documented.	*N/A*
Compounding Record includes deviations from procedures documented.	*N/A*
Compounding Record includes preparation problems documented.	*N/A*

Quality Control

Quality control issues discovered after dispensing documented.	*N/A*
Adverse reactions discovered after dispensing documented.	*N/A*
Adequate procedures to investigate and correct problems in compounding, testing, or the preparation itself.	*N/A*
Any non-sterile compounded product nonsterile compounded preparation that is frozen or requires refrigeration shall be shipped or delivered to a patient in appropriate temperature controlled delivery containers, if the product preparation leaves the premises.	*N/A*

Counseling

Counsel about proper use, storage, handling and disposal of NSCP.	*N/A*
Instruct patient/caregiver to report adverse reactions.	*N/A*
Instruct patient/caregiver to report physical changes in NSCP.	*N/A*
Documented investigation and corrective action of reported problem with NSCP.	*N/A*

Animal

Determine type of animal: companion, performance, food.	*N/A*
If food-producing animal, must include withdrawal time (WDT) on label of NSCP.	*N/A*

Animal *(continued)*

Knowledge of drug regulation and disposition in animals.	*N/A*
Knowledge of species' limitation when metabolizing drugs that could result in toxicity.	*N/A*
Use formulation specifically for animals.	*N/A*
If animal formulation unavailable, pharmacist conducts literature search of components to determine toxicity to animal.	*N/A*

Board Approved Waivers

Board has approved a waiver for nonsterile compounding.	*Compliant*

Section Waived: *Section 2*

Inspector's Signature

I have completed this inspection in accordance with the statutes and administrative codes.

Inspector: *Katie Busroe*

Pharmacist's Signature

I have read and understand the statutes and administrative codes. I acknowledge that the items noted in this report have been discussed with me. I understand that if I disagree with any of the deficiencies cited, that I have the right to refute them on this report or and other form that I choose to send to the department.

Pharmacist: *B. Steven Hart*