Illinois Department of Financial and Professional Regulation
Division of Professional Regulation
Drug Compliance Unit
9511 Harrison Street, Suite 300, Des Plaines, IL 60016
320 W. Washington Street, 2nd Floor, Springfield, IL 62786

Email: fpr.drugcomplianceunit@illinois.gov

(Read this Page Carefully)

NON-STERILE COMPOUNDING

Pharmacy Self-Inspection Form-Admin Code 1330.640
Pharmaceutical Compounding Standards

Illinois Law holds the Pharmacist-in-Charge (PIC) and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy.

The primary objective of this report, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. The inspection report also serves as a necessary document used by the Drug Compliance investigators during an inspection to evaluate a pharmacy's level of compliance. When a Drug Compliance investigator discovers an area of non-compliance, he or she may issue either a Deficiency Notice or a Notice of Non-Compliance. Both require a written response from the PIC. Identifying or correcting an area of non-compliance prior to a Drug Compliance investigator inspection may eliminate the receipt of a Deficiency Notice/Notice of Non-Compliance for that item.

Failure to complete this report by December 31st of each year may result in Disciplinary Action. (Section 1330.800)
Every licensed pharmacy shall conduct an annual self-inspection using forms provided by the Division. The annual self-inspection shall be conducted during the same month, annually, as determined by the pharmacy. Documentation of the self-inspection shall be maintained at the pharmacy for 5 years. The primary objective of the self-inspection is to create an opportunity for a pharmacy to identify and correct areas of noncompliance with State and federal law. This includes, but is not limited to, recordkeeping, inventory, labeling and sanitation requirements.

NOTE: Neither the self-inspection nor a Drug Compliance investigator inspection evaluates your complete compliance with all Laws and Rules of the practice of pharmacy. Further, nothing herein shall constitute a waiver of IDFPR enforcement discretion or constitute compliance with all applicable Laws and Rules governing the practice of pharmacy. This report is not final agency action and is intended as guidance. This report is not intended, nor can it be relied upon to create any rights enforceable by any party in litigation or in any enforcement action brought by IDFPR.

STATE OF ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
DRUG COMPLIANCE UNIT
9511 HARRISON STREET, SUITE 300, DES PLAINES, IL 60016
320 W. WASHINGTON STREET, 2ND FLOOR, SPRINGFIELD, IL 62786

Email: fpr.drugcomplianceunit@illinois.gov

(KEEP CURRENT THROUGHOUT THE YEAR, AS NEEDED)

NON-STERILE COMPOUNDING

BUSINESS NAME	HOURS		DEA REGISTRATION NUMBER	EXPIRES	DATE OF INSPECTION
	M				
	T				
	W				
ADDRESS	TH		ICSA LICENSE NUMBER	EXPIRES	PHARMACY LICENSE NUMBER
	F				
	SAT				
	SUN				
CITY ZIP CODE	OTHER HOURS EXCEP		TELEPHONE ( )		
OWNERSHIP ☐ Individual pharmacist ☐ Individual Non-pharmacist ☐ Partnership ☐ Corporation ☐ LLC	OWNERS		TELEPHONE AFTER HOURS ( )	PHARMACY E-MAIL ADDRESS	
	PERSON IN CHARGE		OWNER'S E-MAIL ADDRESS	COUNTY	

NAME OF LICENSEE R Ph IN CHARGE	LICENSE NUMBER

If the Pharmacist in charge listed above is the PIC in other pharmacies, list here			
	NAME	ADDRESS	PHONE NUMBER
1.			
2.			

Pharmaceutical Compounding Standards (Section 1330.640)				
REQUIREMENTS	**YES**	**NO**	**N/A**	**AUTHORITY**
All nonsterile pharmaceutical compounding shall be governed by the USP Chapter 795				68 Administrative Code Section 1330.640
The pharmacist-in-charge shall ensure that records are maintained for 5 years, are readily retrievable and in a format that provides enforcement agents an accurate and comprehensive method of monitoring distribution via an audit trail. The records shall include at least the following information: • Purchase records • Patient profile or medication				68 Administrative Code Section 1330.640(e)(8)(D)
The pharmacist-in-charge shall ensure the environmental control of all preparations shipped or delivered off site. Therefore, any compounded pharmaceutical must be shipped or delivered to a patient in temperature controlled (as defined by USP Standards) delivery containers				68 Administrative Code Section 1330.640(e)(9)
Sales of compounded drugs to other pharmacies not under common ownership, or to clinics, hospitals or manufacturers, other than as provided in subsection (d), are not allowed, except for sales provided by pharmacies contracted to provide centralized prescription filling services pursuant to Section 25.5 of the Act, including compounding in anticipation of receiving a prescription or order based on routine, readily observed dispensing patterns.				68 Administrative Code Section 1330.640(e)(10)
Must have the current edition of the USP Compounding compendium. Can be electronic or available as a subscription via the internet.				68 Administrative Code Section 1330.640(e)(5)
If engaged in veterinary drug compounding, must have "Plumb's Veterinary Drug Handbook" or any other similar publication approved by the Division				68 Administrative Code Section 1330.640(e)(6)
A logbook or record keeping system to track each compounded drug, which must include the lot number, expiration date of components used, and beyond-use date of compounded drug. This applies to each nonsterile compounded drug and each sterile compounded drug with a beyond-use date greater than 24 hours;				68 Administrative Code Section 1330.640(e)(4)
Consumable materials, as appropriate to the pharmacy services provided at that specific pharmacy, including but not limited to: filter paper, powder papers, empty capsules, ointment jars, bottles, vials, safety closures, powder boxes, labels and distilled water;				68 Administrative Code Section 1330.640(e)(7)

Must have a pharmacy generated patient profile or medication record system that shall be maintained in addition to the prescription file that contains at a minimum: • Patient's name • Date of birth • Gender • Compounded drug dispensed • Date dispensed • Date compounded • Drug content and quantity • Patient directions • Other drugs or supplements the patient is receiving if provided by the patient or his or her agent • Known Drug sensitivities and allergies to drugs and foods				68 Administrative Code Section 1330.640(e)(8)(A)
Each compounded drug dispensed to patients shall be labeled with the following information, using a permanent label: • Name address and telephone number of the licensed pharmacy • Date dispensed and identifying number • Name of each drug component, strength, amount, and dosage form • Directions for use • Prescriber's name • Required controlled substance transfer warnings • Beyond-use-Date • Identity of compounding and dispensing pharmacist or other authorized individual • Auxiliary label with storage requirements • On the label or an auxiliary label the following: "This prescription was specifically compounded in our pharmacy for you at the direction of your prescriber."				68 Administrative Code Section 1330.640(e)(8)(B)
It shall be the ongoing responsibility of the pharmacist-in- charge to ensure that all pharmacists, student pharmacists, registered certified pharmacy technicians, and registered pharmacy technicians who participate in compounding activities are adequately trained for the type of compounding in which they participate. **Documentation of this training shall be maintained by the pharmacy at all times.**				68 Administrative Code Section 1330.640(h)
A pharmacy may only dispense compounded drugs pursuant to a valid patient-specific prescription, except as provided in this Section.				68 Administrative Code Section 1330.640(a)

Pharmacy is compliant with providing compounded non-sterile drug to a practitioner for office use				68 Administrative Code Section 1330.640(d)
The pharmacy maintains readily retrievable records of all compounded drugs ordered by practitioners for office use that include: • Name, address and phone number of practitioner supplied and date of order. • Name Strength, quantity, and dosage form of compounded drug • The date the drug was compounded. • The date the drug was provided to the practitioner • The lot number and beyond-use-date (BUD)				68 Administrative Code Section 1330.640(d)(4)
The pharmacy affixes a label to any compounded drug that is provided for office use. The label shall include: • Name, address and phone number of the compounding pharmacy • Name, strength and dosage of the compounded drug and a list of active ingredients and strengths • The pharmacy's lot number and beyond-use- date • The quantity of amount in the container • The appropriate ancillary instructions such as storage instructions, cautionary statements, hazardous drug warning labels when appropriate • The statement "For Office Use Only- Not for Resale"				68 Administrative Code Section 1330.640(d)(5)
Compounded drugs dispensed to patients shall have on the label or an auxiliary label the following: "This prescription was specifically compounded in our pharmacy for you at the direction of your prescriber."				68 Administrative Code Section 1330.640(e)(8)(C)
A separate storage area for materials used in compounding;				68 Administrative Code Section 1330.640(e)(1)
Scales or measuring devices with sufficient accuracy for the products to be compounded;				68 Administrative Code Section 1330.640(e)(2)
An area of the pharmacy used exclusively for compounding				68 Administrative Code Section 1330.640(e)(3)

Non-Sterile Compounding Standards (USP Chapter 795)				
REQUIREMENTS	**YES**	**NO**	**N/A**	**AUTHORITY**
PERSONNEL TRAINING AND EVALUATION				
The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of CNSPs. The designated person(s) must be identified in the facility's SOPs				USP 795 section 1.1.4
The responsibilities of the designated person(s) include but are not limited to: • Overseeing a training program • Selecting components • Monitoring and observing compounding activities • Ensuring that standard operating procedures (SOPs) are fully implemented. • Establishing, monitoring, and documenting procedures for the handling and storage of CNSPs their components				USP 795 section 1.1.4
All personnel who compound or have direct oversight of compounding CNSPs must be initially trained and qualified by demonstrating knowledge and competency				USP 795 section 2
Designated person(s) are responsible for creating and implementing a training program that describes the required training, the frequency of training, and the process for evaluating the competency of personnel.				USP 795 section 2
Training and competency of personnel must be documented as described in 14. Documentation.				USP 795 section 2
Before beginning to compound CNSPs independently or have direct oversight of compounding personnel, personnel must complete training and be able to demonstrate knowledge of principles and competency of skills for performing nonsterile manipulations as applicable to their assigned tasks.				USP 795 section 2
Knowledge and competency must be demonstrated initially and at least every 12 months in at least the following core competencies:				USP 795 section 2

• Hand hygiene • Garbing • Cleaning and sanitizing • Handling and transporting components and CNSPs • Measuring and mixing • Proper use of equipment and devices selected to compound CNSPs • Documentation of the compounding process (e.g., 7. Master Formulation and Compounding Records) Steps in the training procedure must include the following: • Understand the requirements in this chapter • Understand and interpret safety data sheets (SDSs) and, if applicable, certificates of analysis (COA) • Read and understand procedures related to their compounding duties				
The designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed.				USP 795 section 2
PERSONAL HYGIENE AND GARBING				
Individuals entering the compounding area must maintain appropriate personal hygiene. Before entering the compounding area, compounding personnel must remove any items that are not easily cleanable and that might interfere with garbing. At a minimum, personnel must: • Remove personal outer garments (bandanas, coats, hats, and jackets. • Remove all hand, wrist and exposed jewelry including piercings (watches and rings etc.) • Remove earbuds or headphones. • All accommodations should be documented				USP 795 section 3
Personnel must perform procedures necessary for appropriate hand hygiene when entering the compounding area to compound. The use of alcohol-based hand rub alone is not sufficient.				USP 795 section 3.1
Hand Hygiene Procedures: • Wash hands with soap and water for at least 30 seconds • Dry hands completely with disposable towels or wipes • Don gloves				USP 795 section 3.2

Gloves must be worn for all compounding activities. Other garb (e.g., shoe covers, head or hair covers, facial hair covers, face masks, and gowns) must be appropriate for the type of compounding performed				USP 795 section 3.3
Garb should be removed when leaving the compounding area. If gowns are to be reused, they must remain in the compounding area, and should only be reused. during the same shift.				USP 795 section 3.3

FACILITIES				
An area must be designated for nonsterile compounding. The method of designation must be described in the facility's SOPs				USP 795 section USP 795 4.1
The compounding area **must** be well lit and **must** be maintained in a clean, orderly, sanitary condition and in a good state of repair.				USP 795 section 4.1
There **should** not be carpet in the compounding area				USP 795 section 4.1
Waste disposed in a sanitary manner				USP 795 section 4.1
The compounding area must be organized to prevent mix-ups among components, containers, and labels. The area should be designed, arranged, and used to minimizes cross contamination.				USP 795 section 4.1
Temp monitored and documented at 20 C or 68 F or cooler, calibrated Q 12 Months				USP 795 section 4.2
All components, containers and equipment are stored off the floor.				USP 795 section 4.2
Water Sources: A source of hot and cold water and an easily accessible sink must be available.				USP 795 section 4.3
The sink must be emptied of all items unrelated to compounding and must be cleaned if visibly soiled before being used to clean any equipment used in non-sterile compounding.				USP 795 section 4.3
The plumbing must be free from defects that may contribute to the contamination of any CNSP				USP 795 section 4.3
Purified Water, distilled water, or reverse osmosis water should be used for rinsing equipment and utensils.				USP 795 section 4.3

CLEANING AND SANITIZING				
Cleaning and sanitizing must be completed before initiating compounding. Cleaning and sanitizing must be repeated when spills occur and when surfaces are visibly soiled.				USP 795 section 5
Cleaning and sanitizing must be documented daily on days when compounding occurs.				USP 795 section 5

Surfaces should be resistant to damage by cleaning and sanitizing agents.				USP 795 section 5
Floors in the compounding area should be easily cleanable and should not be porous or particle generating.				USP 795 section 5
If cleaning and sanitizing are performed as separate steps, cleaning must be performed first.				USP 795 section 5
Cleaning and sanitizing minimum frequencies. Work surfaces: • At the beginning and end of each shift on days when compounding occurs, after spills, and when surface is contaminated. • Between compounding CNSPs with different components. Floors: • Daily on days when compounding occurs, after spills and when surface is contaminated. Walls & Ceilings: • When visibly soiled or after spills				USP 795 section 5
Containment Ventilated Isolator (CVE): • At the beginning and end of each shift on days when compounding occurs, after spills, and when surface is contaminated. • Clean and sanitize the horizontal work surface of the CVE between compounding CNSPs with different components. Biological Safety Cabinet (BSC) • At the beginning and end of each shift on days when compounding occurs, after spills, and when surface is contaminated. • Clean and sanitize the horizontal work surface of the BSC between compounding CNSPs with different components.				USP 795 section 6.1

• Clean and sanitize under the work surface at least monthly				
EQUIPMENT AND COMPONENTS				
The equipment and components used for compounding a CNSP **must** be suitable for the specific compounding process.				USP 795 section 6.1
Equipment **must** be stored in a manner that minimizes the risk of contamination and must be located to facilitate equipment use, maintenance, and cleaning.				USP 795 section 6.1
After compounding, the equipment must be cleaned to prevent cross contamination of the next preparation.				USP 795 section 6.1
Equipment must be verified for accuracy as recommended by the frequency recommended by the manufacturer or at least every 12 months.				USP 795 section 6.1
Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs.				
If a CVE or BSC is used, it must be certified at least every 12 months according to manufacturer specifications.				USP 795 section 6.1

Components				
The compounding facility must have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP.				USP 795 section 6.2
SDSs must be readily accessible to all personnel working with components located in the compounding facility. Personnel must be instructed on how to retrieve and interpret needed information.				USP 795 section 6.2

Component Selection: **APIs:** • Must comply with the criteria in the USP–NF monograph, if one exists • Must have a COA that includes specifications (e.g., compendial requirements for quality) and test results for the component that show the API meets expected quality • In the United States, must be manufactured by an FDA-registered facility. • Outside of the United States, must comply with the laws and regulations of the applicable regulatory jurisdiction **All components other than APIs:** • Should be accompanied by a COA that verifies that the component meets the criteria in the USP–NF monograph, if one exists. • In the United States, should be manufactured by an FDA-registered facility (If a component cannot be obtained from an FDA-registered facility, the designated person(s) must select a component that is suitable for the intended use.) • Outside of the United States, must comply with the laws and regulations of the applicable regulatory jurisdiction. **Water:** Purified Water or better quality, e.g., Sterile Water for Irrigation, must be used for compounding nonsterile drug preparations when formulations indicate the inclusion of water.				USP 795 section 6.2.1
Component receipt: Upon receipt of components other than conventionally manufactured products, the COA must be reviewed to ensure that the component has met the acceptance criteria in an appropriate USP–NF monograph, if one exists. The following information must be documented: receipt date, quantity received, supplier name, lot number, expiration date, and results of any in-house or third-party testing performed.				USP 795 section 6.2.2
For all components that lack a vendor expiration date, the date of receipt must be marked on each container and not used after 3 years from the date of receipt.				USP 795 section 6.2.2

Component evaluation before use: Before use, compounding personnel must visually re-inspect all components. Compounding personnel must ascertain before use that components are of the correct identity and have been stored under required conditions in the facility.				USP 795 section 6.2.3
Component handling: Once removed from the original container, a component not used in compounding should be discarded and not returned to the original container				USP 795 section 6.2.4
Component spill and disposal: The facility must have a readily accessible spill kit in the compounding area. Training must be conducted at least every 12 months				USP 795 section 6.2.5
MASTER FORMULATION AND COMPOUNDING RECORDS				
A master formulation record (MFR) must be created for each unique formulation of a CNSP.				USP 795 section 7.1
Details of each preparation are documented on a compounding record				USP 795 section 7.1
Any changes or alterations to the MFR must be approved and documented according to facility's SOP				USP 795 section 7.1
An MFR **must** include at least the following: • Name, strength, or activity, and dosage form • Identities and amounts of all components. • Container closure system • Complete instruction for preparing the CNSP including equipment, supplies and description of compounding steps. • Physical description of the final CNSP • Beyond-use date (BUD) and storage requirements • Reference source to support the assigned BUD • If applicable, calculations to determine and verify quantities and/or concentrations of components and strength or activity of the API(s) • Labeling requirements (e.g., shake well) • Quality control (QC) procedures (e.g., pH testing, visual inspection) and expected results • Other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature)				USP 795 section 7.1

A compounding record (CR) document the compounding of each CNSP. A CR must be created and reviewed for completeness for all CNSP's. The unique identifier of the person checking the CNSP CR must permit traceability of all components in the case of a recall or known quality issue.				USP 795 section 7.2
A CR must include at least the following information: • Name, strength or activity, and dosage form of the CNSP • Date—or date and time—of preparation of the CNSP • Assigned internal identification number (e.g., prescription, order, or lot number) • A method to identify the individuals involved in the compounding process and individuals verifying the final CNSP • Name, vendor or manufacturer, lot number, and expiration date of each component • Weight or measurement of each component • Total quantity of the CNSP compounded • Assigned beyond-use date (BUD) and storage requirements • If applicable, calculations to determine and verify quantities and/or concentrations of components and strength or activity of the API(s) • Physical description of the final CNSP • Results of quality control procedures (e.g., pH testing and visual inspection) • MFR reference for the CNSP				USP 795 section 7.2
RELEASE INSPECTIONS AND TESTING				
All release inspections must be included in the facility's documentation				USP 795 section 8
Visual Inspection: The CNSP must be visually inspected to determine whether the physical appearance of the CNSP is as expected (e.g., color, texture, physical uniformity).				USP 795 section 8.1
The CNSP must be visually inspected to confirm that the CNSP and its labeling match the CR and the prescription or medication order.				USP 795 section 8.1

The inspection also must include a visual inspection of container closure integrity.				USP 795 section 8.1
When a CNSP will not be released or dispensed on the day of preparation, a visual inspection **must** be conducted immediately before it is released or dispensed.				USP 795 section 8.1
LABELING				
The term **labeling** designates all labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except any outer shipping container				USP 795 section 9
The term **label** designates the part of the labeling on the immediate container.				USP 795 section 9
The label on each container of the prepared CNSP must, at a minimum, display prominently and legibly the following: • Assigned internal identification number (e.g., barcode, prescription, order, or lot number) • Active ingredient(s), and their amount(s), activity(ies), or concentration(s) • Storage conditions if other than controlled room temperature • BUD • Dosage form • Total amount or volume if it is not obvious from the container				USP 795 section 9
The labeling on the dispensed CNSP should display the following information: • Route of administration • Indication that the preparation is compounded • Any applicable special handling instructions • Any applicable warning statements • Compounding facility name, and contact information if the CNSP is to be sent outside of the facility or healthcare system in which it was compounded				USP 795 section 9
The label of the CNSP **must** be verified to ensure that it conforms with the following: 1. Prescription or medication order 2. Master Formulation Record 3. Compounding Record				USP 795 section 9

ESTABLISHING BEYOND-USE DATES (BUD)				
Terminology Each CNSP label must state the date, or the hour and date, beyond which the preparation cannot be used and must be discarded (i.e., the BUD). BUDs for CNSPs are calculated in terms of hours, days, or months. BUDs and expiration dates are not the same.				USP 795 section 10.1
BUDs for CNSPs should be established conservatively				USP 795 section 10.2
Aqueous dosage forms with water activity > 0.6 • Non-preserved aqueous dosage forms 14 days BUD Refrigerated • Preserved aqueous dosage forms 35 days BUD controlled room temp				USP 795 section 10.3
Non-aqueous dosage forms with water activity < 0.6 • Oral liquids (nonaqueous) 90 days BUD controlled room temperature • Other non-aqueous dosage forms 180 days BUD controlled room temp				USP 795 section 10.3
The BUD of the CNSP must not exceed the shortest remaining expiration date of any of the commercially available starting components				USP 795 section 10.4
When compounding from a USP–NF compounded preparation monograph for the CNSP, the BUD must not exceed the BUD specified in the monograph				USP 795 section 10.5
If there is a stability study using a stability-indicating analytical method for the **API(s),** CNSP **formulation**, and **container closure** that will be used, then the BUD indicated by the study may be used in lieu of the BUDs specified in Table 4 for aqueous and nonaqueous dosage forms, up to a maximum of 180 days.				USP 795 section 10.5
The compounder may rely on antimicrobial effectiveness testing that is conducted (or contracted for) once for each formulation in the particular container closure system—including materials of composition of the container closure system—in which it will be packaged				USP 795 section 10.5
The compounder may rely on antimicrobial effectiveness testing results provided by an FDA-registered facility or published in peer-reviewed literature as long as the CNSP formulation (including any preservative) and container closure materials of composition are the same as those tested (unless a bracketing study is performed)				USP 795 section 10.5

When a bracketing study is performed, the concentration of all ingredients (including preservatives) must fall within the bracketed range.				USP 795 section 10.5
Standard Operating Procedures (SOPs)				
Facilities preparing CNSPs must develop SOPs on all aspects of the compounding operation				USP 795 section 11
One or more person(s) must be designated to ensure that the facility's SOPs are fully implemented.				USP 795 section 11
All personnel who conduct or oversee compounding activities must be trained in the facility's SOPs and be responsible for ensuring that they are followed.				USP 795 section 11
QUALITY ASSURANCE AND QUALITY CONTROL				
The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program				USP 795 section 12
Designated person(s) responsible for the QA program must have the training, experience, responsibility, and authority to perform these duties				USP 795 section 12
The compounding facility must have documentation that it has reviewed the overall QA and QC program must be reviewed at least once every 12 months by the designated person(s).				USP 795 section 12
The facility must have procedures in place to • Determine when recalls must be initiated, which should include procedures to immediately notify the prescriber. • Recall any unused dispensed CNSPs and quarantine any stock remaining in the pharmacy. • Investigate if other lots are affected and recall if necessary				USP 795 section 12.1

An SOP for recall of dispensed CNSPs must contain: • Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall. • Procedures to determine the distribution of any affected CNSP, including the date and quantity of distribution. • Procedures to identify patients who have received the CNSP. • Procedures for disposal and documentation of the recalled CNSP. • Procedures to investigate and document the reason for recall.				USP 795 section 12.1
Compounding facilities must develop and implement SOPs for handling complaints.				USP 795 section 12.2
Compounding facilities must develop and implement SOPs for reporting adverse events potentially associated with the quality of a CNSP.				USP 795 section 12.3
CNSP PACKAGING AND TRANSPORTING				
The facility's SOPs must describe packaging of CNSPs. Personnel should select and use packaging materials that will maintain the physical and chemical integrity and stability of the CNSPs				USP 795 section 13.1
The facility must have written SOPs to describe the mode of transportation, any special handling, instructions, and whether temperature monitoring devices are needed.				USP 795 section 13.2
DOCUMENTATION				
All facilities where CNSPs are prepared must have and maintain written or electronic documentation to demonstrate compliance with the requirements in this chapter. This documentation must include, but is not limited to, the following: • Personnel training, competency assessments, and qualification records including corrective actions for any failures. • Equipment records (e.g., calibration, verification, and maintenance reports) • COAs and all documentation required for components not conventionally				USP 795 section 14

manufactured • Receipt of components • SOPs, MFRs, and CRs • Release inspection and testing records • Information related to complaints and adverse events including corrective actions taken • Results of investigations and corrective actions • Records of cleaning and sanitizing the designated compounding area • Temperature logs • Accommodations to personnel compounding CNSPs Any required routine review (e.g., yearly review of QA and QC programs, yearly review of chemical hazard and disposal information)				

DO NOT SEND ANY PART OF THIS REPORT TO THE DEPARTMENT!

KEEP IN THE PHARMACY FOR DRUG COMPLIANCE INVESTIGATOR'S REVIEW. COPIES SENT TO THE DEPARTMENT WILL BE DISCARDED.

I hereby certify that I have verified that this pharmacy is in compliance with all laws and rules related to the practice of pharmacy in the State of Illinois and the answers marked on this report are true and correct to the best of my knowledge.

PIC NAME: _____ LICENSE NUMBER: _____

PIC SIGNATURE: _____ DATE: _____