Read this page carefully

WA Pharmacy Quality Assurance Commission

Pharmacy Self-Inspection Worksheet

2023/2024 USP <795> – Nonsterile Compounding Addendum

Attention: Responsible Pharmacy Manager or Equivalent Manager

Washington law holds the responsible manager (or equivalent manager) and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this report within the month of March and within 30 days of becoming responsible manager (as required by WAC 246-945-005) may result in disciplinary action. **The following addendum is required to be filled out and kept on file with the General Pharmacy or Hospital Pharmacy Self-Inspection Worksheet. Do not send to the commission office.**

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. This worksheet does not replace U.S. Pharmacopeia (USP) <795> Pharmaceutical Compounding – Nonsterile Preparations. (**Note**: Neither the self-inspection nor a commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.)

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write "corrected" and the date of correction by the appropriate question.

Date responsible manager/change of responsible manager inspection was performed: _____

Signature of responsible pharmacy manager: _____

Questions highlighted in **blue** are questions that will be focused on during routine pharmacy inspections.

General Rule Reference - Applies to all questions through worksheet.
RCW 18.64.270(2) “Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products.”

The following practices are **NOT** considered compounding and are **NOT** required to meet the requirements of this chapter.
Handling of nonsterile HDs should additionally comply with ⟨800⟩. Refer to facility SOPs for additional safe practices (e.g., labeling).
Nonsterile radiopharmaceuticals: Compounding of nonsterile radiopharmaceuticals is subject to the requirements in Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging ⟨825⟩.
Reconstitution: Reconstitution of a conventionally manufactured nonsterile product in accordance with the directions contained in the manufacturer approved labeling
Repackaging: Repackaging of conventionally manufactured drug products (see Good Repackaging Practices ⟨1178⟩ for recommendations)
Splitting tablets: Breaking or cutting a tablet into smaller portions
Administration: Preparation of a single dose for a single patient when administration will begin within 4 hours. This includes crushing a tablet(s) or opening a capsule(s) to mix with food or liquids to facilitate patient dosing.

Please Note: When determining compliance with a question that has multiple requirements, if the facility is NOT compliant with any single requirement in the question check the "No" compliance box. Include an explanation of which part is noncompliant in the "Notes/Corrective Actions" column. Checking the "Yes" compliance box indicates compliance with all requirements in a question.

Does the pharmacy engage in compounding with hazardous drugs?
If yes, you must also complete the 2024 USP 800 – Hazardous Drugs Addendum

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Designated Person(s)						
☐	☐	☐	1.	Does the compounding facility have a designated person or persons responsible for the performance and operation of the facility and personnel? ***Enter the name of the designated person(s) in the Notes/Corrective Actions field	**USP <795> - 1.1.4 Oversight by designated person(s)** “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.”	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	2.	Does the designated person maintain oversight of SOPs, personnel training, component selection, compounding activities, handling and storage?	**USP <795> - 1.1.4 Oversight by designated person(s)** The responsibilities of the designated person(s) include but are not limited to: -Overseeing a training program to ensure competency of personnel involved in compounding, handling, and preparing CNSPs -Selecting components -Monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed -Ensuring that standard operating procedures (SOPs) are fully implemented. The designated person(s) must ensure that follow-up is carried out if problems, deviations, or errors are identified -Establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs	
Personnel Training and Evaluation						
☐	☐	☐	3.	Is the handling of hazardous drugs compliant with USP <800>?	**USP <795> 1. Introduction and Scope** Handling of nonsterile hazardous drugs (HDs) must additionally comply with Hazardous Drugs—Handling in Healthcare Settings <800>.	
☐	☐	☐	4.	Is initial and ongoing training completed and documented for personnel who compound and those who have direct oversight of compounding personnel?	**USP <795> - 2. PERSONNEL TRAINING AND EVALUATION** All personnel who compound or have direct oversight of compounding CNSPs must be initially trained and qualified by demonstrating knowledge and competency according to the requirements in this section (2. Personnel Training and Evaluation) before being allowed to perform their job functions independently. Personnel who compound or have direct oversight of compounding personnel must complete training initially and at least every 12 months in appropriate compounding principles and practices as described in this section. Other personnel, who do not compound and only perform functions such as in-process checks, final verification, or dispensing of CNSPs, must undergo training as required by the facility's SOPs. Training and competency of personnel must be documented as described in 14. Documentation	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	5.	Does training include all required elements?	**USP <795> 2. PERSONNEL TRAINING AND EVALUATION** 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. Knowledge and competency must be demonstrated initially and at least every 12 months in at least the following core competencies: • 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**	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Personal Hygiene and Garbing						
☐	☐	☐	6.	Do personnel follow appropriate hand hygiene and garbing procedures throughout compounding activities?	**USP <795> 3. PERSONAL HYGIENE AND GARBING** Individuals entering the compounding area must maintain appropriate personal hygiene. Individuals must evaluate whether they have a personal risk of potentially contaminating the compounding environment and CNSP (e.g., personnel with rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infection). Individuals must report these conditions to the designated person(s). Because of the risk of contaminating the CNSP and the environment, the designated person(s) is responsible for evaluating whether these individuals should be excluded from working in compounding areas until their conditions have resolved. 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 (e.g., bandanas, coats, hats, and jackets) -Remove all hand, wrist, and other exposed jewelry, including piercings that could interfere with the effectiveness of garbing or hand hygiene (e.g., watches or rings that may tear gloves) -Remove earbuds or headphones	
☐	☐	☐	7.	Is garb replaced if it is contaminated or if its integrity is compromised?	**USP <795> 3.3 Garb and Glove Requirements** Garb must be replaced immediately if it becomes visibly soiled or if its integrity is compromised. All gloves must be inspected for holes, punctures, or tears and must be replaced immediately if such defects are detected.	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Compounding Facilities						
☐	☐	☐	8.	Is the designated compounding area appropriately equipped and maintained?	**USP <795> 4.1 Compounding Area** An area must be designated for nonsterile compounding. Other activities must not be occurring in the compounding area at the same time as compounding. The compounding area must provide for the orderly placement of equipment and materials to prevent mix-ups among components, containers, labels, in-process materials, and finished CNSPs.	
☐	☐	☐	9.	Are daily temperatures monitored and documented using calibrated equipment?	**USP <795> 4.2 Storage Area** Compounding personnel must monitor temperatures in the storage area(s) either manually at least once daily on days that the facility is open, or continuously with a temperature recording device to ensure the temperature remains within the appropriate range for the CNSPs and components. The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s). The results of the temperature readings must be documented on a temperature log or stored in the continuous temperature recording device and must be retrievable. All temperature monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer.	
☐	☐	☐	10.	Are CNSPs and components stored appropriately?	**USP <795> 4.2 Storage Area** When it is known that a CNSP or component has been exposed to temperatures either below or above the storage temperature limits for the CNSP or component, personnel must determine whether the CNSP or component integrity or quality has been compromised, and, if so, the CNSP or component must be discarded. All CNSPs, components, equipment, and containers must be stored off the floor in a manner that prevents contamination and permits inspection and cleaning of the storage area(s).	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	11.	Does the compounding area have an accessible sink with hot and cold water?	**USP <795> 4.3 Water Sources** A source of hot and cold water and an easily accessible sink must be available. 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 nonsterile compounding. The plumbing system must be free of defects that may contribute to the contamination of any CNSP.	
Cleaning and Sanitizing						
☐	☐	☐	12.	Is cleaning and sanitizing of the compounding area performed and documented as required?	**USP <795> 5. CLEANING AND SANITIZING** Cleaning and sanitizing the surfaces in the nonsterile compounding area(s) must occur on a regular basis at the minimum frequencies specified in Table 1 or, if compounding is not performed daily, cleaning and sanitizing must be completed before initiating compounding. Table 1. Minimum Frequency for Cleaning and Sanitizing in Nonsterile Compounding Area(s)--Surfaces Work surfaces -At the beginning and end of each shift on days when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected -Between compounding CNSPs with different components Floors -Daily on days when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected Walls -When visibly soiled, after spills, and when surface contamination (e.g., from splashes) is known or suspected Ceilings -When visibly soiled and when surface contamination (e.g., from splashes) is known or suspected Storage shelving -Every 3 months, after spills, and when surface contamination (e.g., from splashes) is known or suspected Applicable cleaning and sanitizing must be documented daily on days when compounding occurs. Cleaning and sanitizing agents must be selected and used with consideration of compatibilities, effectiveness, and minimal potential to leave residues. If cleaning and sanitizing are performed as separate steps, cleaning must be performed first.	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Equipment and Components						
☐	☐	☐	13.	Are BSC and CVE devices cleaned and sanitized as required and at minimum frequencies?	**USP <795> 6.1 Equipment** If a BSC, CVE, or other nondisposable device is used, it must be cleaned as described in Table 2. Table 2. Minimum Frequency for Cleaning and Sanitizing in Nonsterile Compounding Area(s)—Equipment CVE -At the beginning and end of each shift on days when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected -Clean and sanitize the horizontal work surface of the CVE between compounding CNSPs with different components BSC -At the beginning and end of each shift on days when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected -Clean and sanitize the horizontal work surface of the BSC between compounding CNSPs with different components -Clean and sanitize under the work surface at least monthly Other devices and equipment used in compounding operations -Before first use and thereafter in accordance with the manufacturer's recommendations -If no recommendation is available, between compounding CNSPs with different components	
☐	☐	☐	14.	Are SDSs accessible to and understood by compounding personnel?	**USP <795> 6.2 Components** 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.	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	15.	Do APIs and components other than APIs selected for use in compounding meet minimum quality standards?	**USP <795> 6.2.1 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: - 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	
☐	☐	☐	16.	Is purified water or better quality used in compounding of nonsterile preparations?	**USP <795> 6.2.1 Component selection** 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	
☐	☐	☐	17.	Are required elements of component receipt documented in accordance with facility SOPs?	**USP <795> 6.2.2 Component receipt** The following information must be documented (see 14. Documentation) according to the facility's SOPs: receipt date, quantity received, supplier name, lot number, expiration date, and results of any in-house or third-party testing performed. **For all components that lack a vendor expiration date, the date of receipt by the compounding facility must be clearly and indelibly marked on each packaging system. Packaging systems of components (i.e., API and added substances) that lack a vendor's expiration date must not be used by the compounding facility after 3 years from the date of receipt. A shorter expiration date must be assigned according to Pharmaceutical Compounding—Sterile Preparations ⟨797⟩, 9.3.2 Component receipt if the same component container is also used in sterile compounding or if the ingredient is known to be susceptible to degradation.**	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	18.	Are unacceptable components rejected and segregated from useable stock?	**USP <795> 6.2.2 Component Receipt** Any component found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal. Any other lots of that component from the same vendor must be examined to determine whether the other lots have the same defect.	
☐	☐	☐	19.	Are components re-inspected prior to use?	**USP <795> 6.2.3 Component Evaluation Before Use** Before use, compounding personnel must visually re-inspect all components. Each packaging system must be inspected to detect any container breakage, looseness of the cap or closure, or deviation from the expected appearance or texture of the contents that might have occurred during storage. If the identity, strength, purity, and quality of components intended for preparation of CNSPs cannot be verified (e.g., containers with damaged or incomplete labeling), the components must be immediately rejected. Any component found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	
☐	☐	☐	20.	Are components appropriately handled to minimize contamination, mix-ups or deterioration?	**USP <795> 6.2.4 Component Handling** All components must be handled in accordance with the manufacturer's instructions or per laws and regulations of the applicable regulatory jurisdiction. The handling must minimize the risk of contamination, mix-ups, and deterioration (e.g., loss of identity, strength, purity, or quality). For each use, the lot must be examined for evidence of deterioration and other aspects of unacceptable quality.	
☐	☐	☐	21.	Is management of nonhazardous component spills and disposal documented in accordance with facility SOPs?	**USP <795> 6.2.5 Component spill and disposal** The management and documentation of nonhazardous component spills and disposal must be described in the facility's SOPs.	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	22.	Does spill clean up and disposal meet minimum requirements?	**USP <795> 6.2.5 Component Spill and Disposal** The facility must have a readily accessible spill kit in the compounding area. All personnel who may be required to remediate a spill must receive training in spill management of chemicals used and stored at the compounding facility. Training must be conducted at least every 12 months and documented for all personnel who may be required to clean up a spill. Waste of any component must be disposed of in accordance with laws and regulations of the applicable regulatory jurisdiction.	
Master Formulation and Compounding Records						
☐	☐	☐	23.	Do master formulation records contain all required elements?	**USP <795> 7.1 Creating Master Formulation Records (MFR)** Box 2. Master Formulation Record An MFR must include at least the following information: -Name, strength or activity, and dosage form of the CNSP -Identities and amounts of all components; if applicable, relevant characteristics of components (e.g., particle size, salt form, purity grade, solubility) -Container closure system(s) -Complete instructions 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)	
☐	☐	☐	24.	Are compounding records created for all CNSPs? ****Note: This does not include reconstitution.*	**USP <795> 7.2 Creating Compounding Records (CR)** A CR must be created for all CNSPs. Each CR must be reviewed for completeness before the CNSP is released. The name or other unique identifier of the person completing the review and the date of the review must be documented on the CR. The CR must permit traceability of all components in the case of a recall or known quality issue.	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	25.	Do compounding records contain all required elements?	**USP <795> 7.2 Creating Compounding Records** Box 3. Compounding Record 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	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Release Inspections and Testing						
☐	☐	☐	26.	Are CNSPs visually inspected prior to release?	**USP <795> 8.1 Visual Inspection** At the completion of compounding, before releasing and dispensing, the CNSP must be visually inspected to determine whether the physical appearance of the CNSP is as expected (e.g., color, texture, physical uniformity). Some CNSPs, as noted in their MFR, also must be visually checked for certain characteristics (e.g., emulsions must be checked for phase separation). The CNSP must be visually inspected to confirm that the CNSP and its labeling match the CR and the prescription or medication order. The inspection also must include a visual inspection of container closure integrity (e.g., checking for leakage, cracks in the container, or improper seals). 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 to make sure that the CNSP does not exhibit any defects (e.g., leakage) that could develop during storage. Any CNSP found to be of unacceptable quality (e.g., observed defects) must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	
Labeling						
☐	☐	☐	27.	Do CNSP labels contain all required elements?	**USP <795> 9. Labeling** The label on each container of the prepared CNSP must, at a minimum, display prominently and legibly the following information: -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	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	28.	Are CNSP labels verified for accuracy following facility SOPS?	**USP <795> 9. Labeling** Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups. The label of the CNSP must be verified to ensure that it conforms with the following: -Prescription or medication order; -MFR (see 7.1 Creating Master Formulation Records); and -CR (see 7.2 Creating Compounding Records).	
Beyond Use Dating						
☐	☐	☐	29.	Are required parameters considered when establishing a BUD?	**USP <795> 10.2 Parameters to Consider in Establishing a BUD** When establishing a BUD for a CNSP, compounders must consider parameters that may affect quality, including but not limited to the following: -Chemical and physical stability properties of the API and any added substances in the preparation (e.g., if the API and added substances in the preparation are known to rapidly degrade over time and/or under certain storage conditions, reduce the strength of the preparation, or produce harmful impurities) -Compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, adsorption, and storage conditions) -Degradation of the container closure system, which can lead to a reduction in integrity of the CNSP -Potential for microbial proliferation in the CNSP -Significant deviations from essential compounding steps and procedures; changes to essential compounding steps may have an impact on the stability of the formulation	
☐	☐	☐	30.	Are BUDs assigned not to exceed the shortest expiration date of any commercially available component used in the CNSP?	**USP <795> 10.4 CNSPs Requiring Shorter BUDs** The BUDs in Table 4 are the BUD limits for CNSPs in the absence of specific stability information. This does not absolve the designated person(s) from performing due diligence to determine if there is existing stability data that would require a shorter BUD. Additionally, -The BUD of the CNSP must not exceed the shortest remaining expiration date of any of the commercially available starting components.	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	31.	When compounded products are used in a CNSP, is the BUD assigned in a manner that does not negatively impact the final CNSP?	**USP <795> 10.4 CNSPs Requiring Shorter BUDs**-For CNSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CNSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CNSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CNSP must not be negatively impacted.	
☐	☐	☐	32.	Are assigned BUDs limited based on the type of preparation in the absence of USP-NF monograph?	**USP <795> 10.4 CNSPs Requiring Shorter BUDs** Table 4. BUD Limit by Type of Preparation in the Absence of a USP−NF Compounded Preparation Monograph or CNSP-Specific Stability Information Aqueous Dosage Forms (aw ≥ 0.60) -Nonpreserved aqueous dosage forms--14 day BUD--storage: refrigerator -Preserved aqueous dosage forms--35 day BUD--storage: controlled room temperature or refrigerator Nonaqueous Dosage Forms (aw < 0.60) -Oral liquids (nonaqueous)--90 day BUD--storage: controlled room temperature or refrigerator -Other nonaqueous dosage forms--180 day BUD--storage: controlled room temperature or refrigerator	
☐	☐	☐	33.	Do BUDs for CNSPs follow a USP-NF monograph or appropriate stability studies if available?	**USP <795> 10.5 Extending BUDs for CNSPs** CNSPs with a USP–NF monograph: When compounding from a USP–NF compounded preparation monograph for the CNSP, the BUD must not exceed the BUD specified in the monograph. CNSPs with stability information: If there is a stability study using a stability-indicating analytical method for the API(s), CNSP formulation, and material of composition of the 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.	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	34.	Are CNSPs with extended BUDs tested for antimicrobial effectiveness?	**USP <795> 10.5 Extending BUDs for CNSPs** If the BUD of the CNSP is extended beyond the BUDs in Table 4, an aqueous CNSP must be tested for antimicrobial effectiveness (see Antimicrobial Effectiveness Testing ⟨51⟩). The designated person(s) 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. Alternatively, the designated person(s) 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). When a bracketing study is performed, antimicrobial effectiveness testing may be performed on a low concentration and on a high concentration of the active ingredient in the formulation to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives) must fall within the bracketed range.	
Standard Operating Procedures						
☐	☐	☐	35.	Does the facility have SOPs on all aspects of compounding operations that are fully implemented?	**USP <795> 11. SOPS** Facilities preparing CNSPs must develop SOPs on all aspects of the compounding operation. 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. One or more person(s) must be designated to ensure that the facility's SOPs are fully implemented. The designated person(s) must ensure that follow-up occurs if problems, deviations, or errors are identified.	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Quality Assurance and Quality Control						
☐	☐	☐	36.	Does the facility have a written QA/QC program that is reviewed every 12 months by the designated person(s)?	**USP <795> 12. QUALITY ASSURANCE AND QUALITY CONTROL** Designated person(s) must ensure that the facility has formal, written QA and QC programs that establish a system of 1. Adherence to procedures, 2. Prevention and detection of errors and other quality problems, 3. Evaluation of complaints and adverse events, and 4. Appropriate investigations and corrective actions. The overall QA and QC program must be reviewed at least once every 12 months by the designated person(s). The results of the review must be documented, and appropriate action must be taken if needed.	
☐	☐	☐	37.	Does the facility have recall procedures in place?	**USP <795> 12.1 Notification About and Recall of Dispensed CNSPs** The facility must have procedures in place to -Determine when recalls must be initiated, which should include procedures to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (e.g., strength, purity, or other quality attributes) -Recall any unused dispensed CNSPs and quarantine any stock remaining in the pharmacy -Investigate if other lots are affected and recall if necessary	
☐	☐	☐	38.	Does the designated person(s) review all complaints?	**USP <795> 12.2 Complaint Handling** A designated person(s) must review all complaints to determine whether the complaint indicates a potential quality problem with the CNSP.	
☐	☐	☐	39.	Are investigations completed and corrective actions implemented for all potentially affected CNSPs?	**USP <795> 12.2 Complaint Handling** If it does, a thorough investigation into the cause of the problem must be initiated and completed. The investigation must consider whether the quality problem extends to other CNSPs. Corrective action, if necessary, must be implemented for all potentially affected CNSPs.	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	40.	Are complaint records readily retrievable and do they include all required elements?	**USP <795> 12.2 Complaint Handling** A readily retrievable written or electronic record of each complaint must be kept by the facility, regardless of the source of the complaint (e.g., email, telephone, or mail). The record must contain the name of the complainant or other unique identifier, the date the complaint was received, the nature of the complaint, and the response to the complaint. In addition, to the extent that the information is known, the following should be recorded: the name and strength of the CNSP and the assigned internal identification number (e.g., prescription, order, or lot number). The record must also include the findings of any investigation and any follow-up. Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained in accordance with the record-keeping requirements in 14. Documentation. A CNSP that is returned in connection with a complaint must be quarantined until it is destroyed after completion of the investigation and in accordance with laws and regulations of the applicable regulatory jurisdiction.	
☐	☐	☐	41.	Are adverse events potentially associated with CNSP quality reported in accordance with SOPs?	**USP <795> 12.3 Adverse Event Reporting** Adverse events potentially associated with the quality of CNSPs must be reported in accordance with the facility's SOPs and all laws and regulations of the applicable regulatory jurisdiction.	
☐	☐	☐	42.	If an adverse event is associated with a quality problem are patients and prescribers informed?	**USP <795> 12.3 Adverse Event Reporting** If the investigation into an adverse event reveals a quality problem with a CNSP that is likely to affect other patients, those patients and prescribers potentially affected must be informed.	
Packaging and Transporting						
☐	☐	☐	43.	Does packaging protect the CNSP from damage while protecting personnel from exposure?	**USP <795> 13.1 Packaging of CNSPs** Packaging materials must protect CNSPs from damage, leakage, contamination, and degradation, while simultaneously protecting personnel from exposure.	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Documentation						
☐	☐	☐	44.	Is documentation maintained for all required records?	**USP <795> 14. 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 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)	

Standard Operating Procedure Locations

Please provide the physical location of the document in the pharmacy, or file pathway if policies are maintained in electronic format. Please be as specific as possible, there can be many file cabinets and binders.

45.	Title or SOP number: Location or file pathway:	**USP <795> 2. PERSONNEL TRAINING AND EVALUATION** Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel.	
46.	Title or SOP number: Location or file pathway:	**USP <795> 3.3 Garb and Glove Requirements** Garbing requirements and frequency of changing garb must be determined by the facility and documented in the facility's SOPs.	
47.	Title or SOP number: Location or file pathway:	**USP <795> 3.3 Garb and Glove Requirements** The facility's SOPs must describe cleaning and sanitization procedures for reusing goggles, respirators, and other reusable equipment.	
48.	Title or SOP number: Location or file pathway:	**USP <795> 4.1 Compounding Area** An area must be designated for nonsterile compounding. The method of designation must be described in the facility's SOPs.	
49.	Title or SOP number: Location or file pathway:	**USP <795> 6.2 Components** The compounding facility must have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP.	
50.	Title or SOP number: Location or file pathway:	**USP <795> 12. QUALITY ASSURANCE AND QUALITY CONTROL** A facility's QA and QC programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (⟨795⟩) and the laws and regulations of the applicable regulatory jurisdiction.	
51.	Title or SOP number: Location or file pathway:	**USP <795> 12. 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. Designated person(s) responsible for the QA program must have the training, experience, responsibility, and authority to perform these duties.	

Standard Operating Procedure Locations			
52.	Title or SOP number: Location or file pathway:	**USP <795> 12.1 Notification About and Recall of Dispensed CNSPs** 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 data 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	
53.	Title or SOP number: Location or file pathway:	**USP <795> 12.2 Complaint Handling** Compounding facilities must develop and implement SOPs for handling complaints.	
54.	Title or SOP number: Location or file pathway:	**USP <795> 13.1 Packaging of CNSPs** The facility's SOPs must describe packaging of CNSPs.	
55.	Title or SOP number: Location or file pathway:	**USP <795> 13.2 Transporting of CNSPs** If transporting CNSPs, the facility must have written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed.	