Washington State Department of Health

Read this page carefully

WA Pharmacy Quality Assurance Commission

Pharmacy Self-Inspection Worksheet

2023 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 – Sterile 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."

Compliant Yes	Compliant No	Compliant N/A	#		Rule Reference	Notes/Corrective Actions
Training & Training Procedures						
☐	☐	☐	1.	Are all licensed pharmacy personnel involved in compounding properly trained for the type of compounding they perform? *USP recommends annual evaluations of personnel training.*	**USP <795> - Categories of Compounding** - "Compounders shall acquire and maintain knowledge and skills in all areas (e.g. dosage, form, patient population, and medical specialty) for which they compound." **USP <795> - Training** - "All personnel involved in the compounding, evaluation, packaging, and dispensing of compounded preparations shall be properly trained for the type of compounding conducted. It is the responsibility of the compounder to ensure that a training program has been implemented and that it is ongoing." ***Compounder in this reference can be either a pharmacist or a pharmacy technician.***	
☐	☐	☐	2.	Do training procedures require all pharmacy personnel who compound to read and be familiar with <USP 795>?	**USP <795> -** "Steps in the training procedure include the following: • All employees involved in pharmaceutical compounding shall read and become familiar with this chapter. They should also be familiar with the contents of the USP Pharmacists' Pharmacopeia and other relevant publications, including how to read and interpret MSDSs."	
☐	☐	☐	3.	Do training procedures require all pharmacy personnel who compound to read and be familiar with your pharmacy's procedures related to compounding?	**USP <795> -** "Steps in the training procedure include the following: • All employees shall read and become familiar with each of the procedures related to compounding, including those involving the facility, equipment, personnel, actual compounding, evaluation, packaging, storage, and dispensing."	
☐	☐	☐	4.	Do training procedures include hazardous drug training if hazardous drugs are handled in the pharmacy?	**USP <795> -** "Steps in the training procedure include the following: • All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur before preparing or handling hazardous drugs."	

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	5.	Do training procedures require all training activities to be documented by the responsible manager?		**USP <795> -** "Steps in the training procedure include the following: • All training activities shall be documented. The compounder shall meet with employees to review their work and answer any questions the employees may have concerning compounding procedures."	
			6.	Do training procedures include the Following:		**USP <795> - Training -** "Steps in the training procedure include the following:	
☐	☐	☐	6.	a	Demonstration and observation of proper procedures and knowledge of procedures.	**USP <795> - Training -** "The compounder shall demonstrate the procedures for the employee and shall observe and guide the employee throughout the training process. The employee will then repeat the procedure without any assistance from, but under the direct supervision of, the compounder. 1) When the employee has demonstrated to the compounder a verbal and functional knowledge of the procedure, then and only then will the employee be permitted to perform the procedure without direct supervision. However, the compounder should be physically present and shall approve all ingredients and their quantities and the final preparation." ***Compounder in this reference can be either a pharmacist or a pharmacy technician.***	
☐	☐	☐	6.	b	Requiring signatures on training documentation.	**USP <795> - Training -** "When the compounder is satisfied with the employee's knowledge and proficiency, the compounder will sign the documentation records to show that the employee was appropriately trained." ***Compounder in this reference can be either a pharmacist or a pharmacy technician.***	
☐	☐	☐	6.	c	Pharmacist monitoring of employee's work.	**USP <795> - Training "**Steps in the training procedure include the following: 2) The compounder shall continually monitor the work of the employee and ensure that the employee's calculations and work are accurate and adequately performed." ***Compounder in this reference means a pharmacist.***	
☐	☐	☐	6.	d	Pharmacist responsibility for final preparation.	**USP <795> - Training** "Steps in the training procedure include the following: 3) The compounder is solely responsible for the finished preparation." ***Compounder in this reference means a pharmacist.***	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Compounding Process						
In the Rule References for Questions 7 -18 "compounder" can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.						
☐	☐	☐	7.	Do employees engaged in compounding check to ensure that the dose, safety, and intended use of the product or preparation has been evaluated for suitability?	**USP <795> -** The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **1.** The dose, safety, and intended use of the preparation or device has been evaluated for suitability in terms of: • the chemical and physical properties of the components • dosage form • therapeutic appropriateness and route of administration, including local and systemic biological disposition • legal limitations, if any.	
☐	☐	☐	8.	Do employees engaged in compounding check ingredients to be used in the preparation have their expected identity, quality, and purity?	**USP <795> - Compounding Process -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **3.** Ingredients used in the formulation have their expected identity, quality, and purity. If the formulation is for humans, ingredients are not on a list of federally recognized drugs or specific drug products that have been withdrawn or removed from the market for safety or efficacy reasons (see www.FDA.gov) "	
☐	☐	☐	9.	Do employees engaged in compounding verify that formulations intended for human use or food producing animals are checked to ensure they are not on a list of prohibited items for use in these formulations?	**USP <795> - Compounding Process -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **3.** If the formulation is for food-producing animals, ingredients are not on a list of components prohibited for use in food-producing animals. Certificates of Analysis, when applicable, and MSDSs have been consulted for all ingredients used."	
☐	☐	☐	10.	Is the compounding area appropriately clean and sanitized?	**USP <795> -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **4.** Compounding is done in an appropriately clean and sanitized area dedicated to this activity (see the section Compounding Facilities)."	
☐	☐	☐	11.	Are compounds prepared one at a time in a specific or dedicated workspace?	**USP <795> -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **5.** Only one preparation is compounded at one time in a specific workspace."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	12.	Is compounding equipment inspected for cleanliness and proper functioning?	**USP <795> -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **6.** Appropriate compounding equipment has been selected and inspected for cleanliness and correct functioning and is properly used."	
☐	☐	☐	13.	Are appropriate BUDs assigned to finished preparations?	**USP <795> -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **7.** A reliable BUD is established to ensure that the finished preparation has its accepted potency, purity, quality, and characteristics, at least until the labeled BUD."	
☐	☐	☐	14.	Do employees engaged in compounding properly wash hands and wear the proper PPE based on the type of compounding performed?	**USP <795> -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **8.** Personnel engaged in compounding maintain good hand hygiene and wear clean clothing appropriate to the type of compounding performed (e.g., hair bonnets, coats, gowns, gloves, facemasks, shoes, aprons, or other items) as needed for protection of personnel from chemical exposures and for prevention of drug contamination."	
☐	☐	☐	15.	Are critical processes verified by a pharmacist during compounding to ensure expected qualities of the finished preparation?	**USP <795> -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **10.** Critical processes (including but not limited to weighing, measuring, and mixing) are verified by the compounder to ensure that procedures, when used, will consistently result in the expected qualities in the finished preparation."	
☐	☐	☐	16.	Is the final preparation assessed by a pharmacist using factors such as weight, adequacy of mixing, clarity, odor, color, consistency, pH, and analytical testing, as appropriate?	**USP <795> -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **11.** The final preparation is assessed using factors such as weight, adequacy of mixing, clarity, odor, color, consistency, pH, and analytical testing as appropriate; and this information is recorded on the Compounding Record."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	17.	Is the final preparation properly labeled?	**USP <795> -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **13.** The preparation container is labeled according to all applicable state and federal laws. The labeling shall include the BUD and storage and handling information." ***See RCW 18.64.246***	
Compounding Facilities						
☐	☐	☐	18.	Is there adequate space in the compounding facility that is also designated specifically for compounding to occur?	**USP <795> -** "Compounding facilities shall have an adequate space that is specifically designated for compounding of prescriptions."	
☐	☐	☐	19.	Do compounding facilities provide for placement of equipment and materials to avoid mix-ups among ingredients, containers, labels, in-process materials, and finished preparations and cross-contamination?	**USP <795>** - "This space shall provide for the orderly placement of equipment and materials to prevent mix-ups among ingredients, containers, labels, in-process materials, and finished preparations and is designed, arranged, and used to prevent adventitious cross-contamination."	
☐	☐	☐	20.	Are areas for nonsterile compounding and sterile compounding separate from each other?	**USP <795>** - "Areas used for sterile preparations shall be separated and distinct from the nonsterile compounding area."	
☐	☐	☐	21.	Is purified water used in compounding of nonsterile preparations?	**USP <795> -** "Purified Water (see Purified Water monograph) shall be used for compounding nonsterile drug preparations when formulations indicate the inclusion of water."	
☐	☐	☐	22.	Are adequate hand and equipment washing facilities easily accessible to the compounding area?	**USP <795> -** "Adequate hand and equipment washing facilities shall be easily accessible to the compounding areas. Such facilities shall include, but are not limited to, hot and cold water, soap or detergent, and an air-drier or single-use towels."	
☐	☐	☐	23.	Are all your compounding areas kept clean, and in good repair?	**USP <795> -** "The areas used for compounding shall be maintained in clean, orderly, and sanitary conditions and shall be maintained in a good state of repair."	
☐	☐	☐	24.	Is waste handled in accordance with local, state, and federal guidelines?	**USP <795> -** "Waste shall be held and disposed of in a sanitary and timely manner and in accordance with local, state, and federal guidelines."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	25.	Are heating, ventilation, and air conditioning systems controlled to avoid decomposition and contamination of chemicals?	**USP <795> -** "Heating, ventilation, and air conditioning systems shall be controlled to avoid decomposition and contamination of chemicals (see the General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Storage Temperature and Humidity; and the manufacturers' labeled storage conditions)."	
☐	☐	☐	26.	Are all compounding components, equipment, and containers stored in accordance with the manufacturer or other specified conditions, off of the floor?	**USP <795> -** "All components, equipment, and containers shall be stored off the floor and in a manner to prevent contamination and permit inspection and cleaning of the compounding and storage area."	
☐	☐	☐	27.	Are hazardous drugs stored, prepared, and handled by trained personnel under conditions that protect all personnel?	**USP <795> -** "Hazardous drugs shall be stored, prepared, and handled by appropriately trained personnel under conditions that protect the healthcare workers and other personnel."	
☐	☐	☐	28.	Does disposal of hazardous drugs comply with all applicable federal and state regulations?	**USP <795> -** "Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations."	
☐	☐	☐	29.	Are all personnel who perform routine custodial waste removal and cleaning in hazardous drug preparation areas trained in appropriate procedure to protect themselves and prevent contamination?	**USP <795>** - "All personnel who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedures to protect themselves and prevent contamination."	
Compounding Equipment						
☐	☐	☐	30.	Is equipment appropriate for use in compounding?	**USP <795> -** "The equipment and utensils used for compounding of a drug preparation shall be of appropriate design and capacity…. The equipment shall be of suitable composition that the surfaces that contact components are neither reactive, additive, nor sorptive and therefore will not affect or alter the purity of the compounded preparations."	
☐	☐	☐	31.	Is all equipment stored to protect it from contamination and located to facilitate use, maintenance and cleaning?	**USP <795> -** "Equipment shall be stored to protect it from contamination and shall be located to facilitate its use, maintenance, and cleaning."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	32.	Are automated, mechanical, electronic, or other technology used in compounding routinely tested, inspected, and calibrate to ensure proper performance?	**USP <795> -** "Automated, mechanical, electronic, and other types of equipment used in compounding or testing of compounded preparations shall be routinely inspected, calibrated as necessary, and checked to ensure proper performance."	
☐	☐	☐	33.	Is equipment checked by employees engaged in compounding to determine its suitability for use in compounding?	**USP <795> -** "Immediately before compounding operations, the equipment shall be inspected by the compounder to determine its suitability for use." ***Compounder in this reference can be either a pharmacist or a pharmacy technician.***	
☐	☐	☐	34.	Is equipment used during compounding cleaned after use?	**USP <795>** - "After use, the equipment shall be appropriately cleaned."	
☐	☐	☐	35.	If the same equipment is being used for all drug products, are there procedures in place that allow meticulous cleaning of equipment before use with other drugs?	**USP <795> -** "… when the same equipment is being used for all drug products, appropriate procedures shall be in place to allow meticulous cleaning of equipment before use with other drugs."	
Component Selection, Handling, and Storage						
☐	☐	☐	36.	Are components used in compounding manufactured by FDA-registered facilities?	**USP <795> -** "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **2.** Compounders shall first attempt to use components manufactured in an FDA-registered facility." ***Compounder in this reference can be either a pharmacist or a pharmacy technician.***	
☐	☐	☐	37.	If components are not available from FDA-registered facilities, is professional judgment used when selecting components and to establish purity and safety by reasonable means?	**USP <795> -** "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **2.** When components cannot be obtained from an FDA-registered facility, compounders shall use their professional judgment in selecting an acceptable and reliable source and shall establish purity and safety by reasonable means, which should include Certificate of Analysis, manufacturer reputation, and reliability of source." ***Compounder in this reference can be either a pharmacist or a pharmacy technician.***	

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	38.		Do ingredients used in preparations meet the requirements of compendial monographs for those ingredients? *See point 4 in rule reference column to the right, for when compendial quality components are not obtainable.*	**USP <795> -** "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **3.** Official compounded preparations are prepared from ingredients that meet requirements of the compendial monograph for those individual ingredients for which monographs are provided. These preparations may be labeled USP or NF as appropriate. **4.** When components of compendial quality are not obtainable, components of high quality such as those that are chemically pure, analytical reagent grade, or American Chemical Society–certified may be used."	
			39.		When components are transferred from an original container to a different container, is that container identified with:	**USP <795> -** "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **5.** For components in containers that have an expiration date from the manufacturer or distributor, the material may be used in compounding before that expiration date **(a)** when the material is stored in its original container under conditions to avoid decom-position of the chemicals ... **(b)** when there is minimal exposure of the remaining material each time material is withdrawn from the container, and **(c)** when any withdrawals from the container are performed by those trained in the proper handling of the material. If the component has been transferred to a different container, that container shall be identified with the component name, original supplier, lot or control number, transfer date, and expiration date and shall provide integrity that is equivalent to or better than that of the original container."	
☐	☐	☐	39.	a	Component Name		
☐	☐	☐	39.	b	Original Supplier		
☐	☐	☐	39.	c	Lot or Control Number		
☐	☐	☐	39.	d	Transfer Date, and		
☐	☐	☐	39.	e	Expiration Date		
☐	☐	☐	40.		When components do not have an expiration date assigned by the manufacturer/supplier, is the container labeled with date of receipt, and assigned a conservative expiration date that does not exceed 3 years from receipt?	**USP <795> - "**The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **6.** For components that do not have expiration dates assigned by the manufacturer or supplier, the compounder shall label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt, to the Component (see the General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Labeling, Expiration Date and Beyond-Use Date) based on the nature of the component and its degradation mechanism, the container in which it is packaged, and the storage conditions."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	41.	Are manufactured drug products used by your pharmacy as the source of active ingredient manufactured by FDA-registered facilities and is appropriately labeled with a batch control number and expiration date?	**USP <795> -** The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **7.** If a manufactured drug product is used as the source of active ingredient, the drug product shall be manufactured in an FDA-registered facility, and the manufacturer's product container shall be labeled with a batch control number and expiration date.	
☐	☐	☐	42.	Does the compounder consider all ingredients, including excipients, present in the drug product relative to the intended use of the compounded preparation and the effect of manipulating the drug product on the therapeutic appropriateness and stability of the components?	**USP <795> -** "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **7.** When compounding with manufactured drug products, the compounder shall consider all ingredients, including excipients, present in the drug product relative to the intended use of the compounded preparation and the effect of manipulating the drug product on the therapeutic appropriateness and stability of the components."	
☐	☐	☐	43.	Do ingredients used for dietary or nutritional supplements meet USP, FCC or NF standards?	**USP <795> -** "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **8.** If the preparation is intended for use as a dietary or nutritional supplement, then the compounder must adhere to this chapter and must also comply with any federal and state requirements. Generally, dietary supplements are prepared from ingredients that meet USP, FCC, or NF standards. Where such standards do not exist, substances may be used in dietary supplements if they have been shown to have acceptable food-grade quality using other suitable procedures."	
☐	☐	☐	44.	Does your pharmacy receive written assurance from suppliers that components derived from ruminant animals are in compliance with federal laws?	**USP <795> -** "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **9.** When a component is derived from ruminant animals (e.g., bovine, caprine, ovine), the supplier shall provide written assurance that the component is in compliance with all federal laws governing processing, use, and importation requirements for these materials."	
☐	☐	☐	45.	Are components used in compounding stored properly per manufacturer?	**USP <795> -** "All components used in the compounding of preparations must be stored as directed by the manufacturer, or according to USP, NF, or FCC monograph requirements, in a clean area, and under appropriate temperature and humidity conditions."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	46.	Are components used in compounding stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first?	**USP <795> -** "All components shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first."	
Stability Criteria and Beyond-Use Dating						
☐	☐	☐	47.	Is the BUD determined from when the preparation is compounded?	**USP <795> -** "The BUD is the date after which a compounded preparation shall not be used and is determined from the date when the preparation is compounded."	
☐	☐	☐	48.	When assigning a BUD, are drug specific and general stability documents and literature consulted?	**USP <795> -** "When assigning a BUD, compounders shall consult and apply drug-specific and general stability documentation and literature when available …"	
☐	☐	☐	49.	When a manufactured product is used as the source of the API for a nonsterile compounded preparation, does the compounder refer to the manufacturer, literature and stability factors to assign a beyond use date?	**USP <795> -** "When a manufactured product is used as the source of the API for a nonsterile compounded preparation, the product expiration date cannot be used solely to assign a BUD for the compounded preparation. The compounder shall refer to and consider the following: **1.** Manufacturer for stability information **2.** literature for applicable information on stability, compatibility, and degradation of ingredients **3.** stability factors in USP <1191> All stability data shall be carefully interpreted in relation to the actual compounded formulation."	
☐	☐	☐	50.	Are preparations, at all steps in compounding, dispensing, and storage, observed for signs of instability and deterioration?	**USP <795> -** "At all steps in the compounding, dispensing, and storage process, the compounder shall observe the compounded drug preparation for signs of instability."	
Packaging and Drug Preparation Containers						
☐	☐	☐	51.	Do containers and closures used for packaging preparations meet USP requirements?	**USP <795> -** "The compounder shall ensure that the containers and container closures used in packaging compounded preparations meet USP requirements (see <659>; Containers—Glass <660>; Plastic Packaging Systems and their Materials of Construction <661>; Plastic Materials of Construction <661.1>; Plastic Packaging Systems for Pharmaceutical Use <661.2>; Containers—Performance Testing <671>; <1136>); and when available, compounding monographs Container suppliers shall supply, upon request, verification of USP container compliance." ***Compounder in this reference can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.***	

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	52.		Are the containers and closures used for packaging preparations made of suitable clean material?	**USP <795> -** "The containers and closures shall be made of suitable clean material in order not to alter the quality, strength, or purity of the compounded drug preparation. The container used depends on the physical and chemical properties of the compounded preparation."	
☐	☐	☐	53.		Are the containers and closures used for packaging preparations stored appropriately off the floor in way to prevents contamination and rotated?	**USP <795> -** "The containers and closures shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first."	
☐	☐	☐	54.		Are the containers and container closures stored in such a way as to permit inspection and cleaning of the storage area?	**USP <795> -** "The containers and container closures shall be stored in such a way as to permit inspection and cleaning of the storage area."	
Compounding Documentation							
☐	☐	☐	55.		Does the compounder compound preparation in any other way than the manufacture's labeling instructions?	**USP <795> - "**When the compounder compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described below. This includes a master formulation and compounding record." ***Compounder in this reference can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.***	
			56.		If yes to Question 55, does the **Master Formula** contain:	**USP <795> - "**When the compounder compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described below. This includes a master formulation and compounding record." ***Compounder in this reference can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.***	
☐	☐	☐	56.	a	Official or assigned name, strength, and dosage form of the preparation?	**USP <795> -** "this record shall include: Official or assigned name, strength, and dosage form of the preparation."	
☐	☐	☐	56.	b	Calculations needed to determine and verify quantities or components and doses of active pharmaceutical ingredients?	**USP <795> -** "this record shall include; calculations needed to determine and verify quantities or components and doses of active pharmaceutical ingredients."	

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	56.	c	Description of all ingredients and their quantities?	**USP <795> -** "this record shall include: description of all ingredients and their quantities."	
☐	☐	☐	56.	d	Compatibility and stability information, including references when available?	**USP <795> -** "this record shall include: compatibility and stability information, including references when available."	
☐	☐	☐	56.	e	Equipment needed to prepare the preparation, when appropriate?	**USP <795> -** "this record shall include: equipment needed to prepare the preparation, when appropriate."	
☐	☐	☐	56.	f	Mixing instructions?	**USP <795> -** "this record shall include: Mixing instructions that should include order of mixing, mixing temperatures and environmental controls, duration of mixing, other factors pertinent to the replication of the preparation as compounded.	
☐	☐	☐	56.	g	Container used in dispensing?	**USP <795> -** "this record shall include: container used in dispensing."	
☐	☐	☐	56.	h	Packaging and storage requirements?	**USP <795> -** "this record shall include: packaging and storage requirements."	
☐	☐	☐	56.	i	A description of the final preparation?	**USP <795> -** "this record shall include: description of the final preparation."	
☐	☐	☐	56.	j	Quality control procedures and expected results?	**USP <795> -** "this record shall include: Quality control procedures and expected results."	
			57.		If yes to Question 55, does the **Compounding Formula** contain:	**USP <795> - "**When the compounder compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described below. This includes a master formulation and compounding record." ***Compounder in this reference can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.***	
☐	☐	☐	57.	a	Official or assigned name, strength, and dosage of the preparation?	**USP <795> -** "this record shall include: official or assigned name, strength, and dosage of the preparation."	
☐	☐	☐	57.	b	Master formula Record reference for the preparation?	**USP <795> -** "this record shall include: Master formula Record reference for the preparation."	
☐	☐	☐	57.	c	Names and quantities of all components?	**USP <795> -** "this record shall include: names and quantities of all components."	
☐	☐	☐	57.	d	Sources, lot numbers, and expiration dates of all components?	**USP <795> -** "this record shall include: sources, lot numbers, and expiration dates of all components."	

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	57.	e	Total quantity compounded?	**USP <795> -** "this record shall include: total quantity compounded."	
☐	☐	☐	57.	f	Name of the person who prepare the preparation, name of the person who performed the quality control procedures, and the name of the compounder who approved the preparation?	**USP <795> -** "this record shall include: Name of the person who prepare the preparation, name of the person who performed the quality control procedures, and the name of the compounder who approved the preparation."	
☐	☐	☐	57.	g	Date of preparation?	**USP <795> -** "this record shall include: date of preparation."	
☐	☐	☐	57.	h	Control or prescription number?	**USP <795> -** "this record shall include: assigned control or prescription number."	
☐	☐	☐	57.	i	Assigned BUD?	**USP <795> -** "this record shall include: assigned BUD.	
☐	☐	☐	57.	j	Duplicate label described in the Master Formulation Record?	**USP <795> -** "this record shall include: duplicate label as described in the Master Formulation Record."	
☐	☐	☐	57.	k	Description of final preparation?	**USP <795> -** "this record shall include: description of the final preparation."	
☐	☐	☐	57.	l	Results of the quality control procedures?	**USP <795> -** "this record shall include: results of the quality control procedures (e.g., weight range of filled capsules, pH of aqueous liquids)"	
☐	☐	☐	57.	m	Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or the caregiver?	**USP <795> -** "this record shall include: documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or the caregiver."	
☐	☐	☐	58.		Are Safety Data Sheets readily accessible to all employees working with drug substances or bulk chemicals located on the compounding facility?	**USP <795> -** "Material Safety Data Sheets (MSDSs) shall be readily accessible to all employees working with drug substances or bulk chemicals located on the compounding facility premises."	
Quality Control							
☐	☐	☐	59.		Do pharmacists supervising compounding activities perform a final check that reviews each procedure used in the compounding process and observe the finished preparation to ensure it appears as expected?	**USP <795> -** "As a final check, the compounder shall review each procedure in the compounding process. To ensure accuracy and completeness, the compounder shall observe the finished preparation to ensure that it appears as expected and shall investigate any discrepancies and take appropriate corrective action before the prescription is dispensed to the patient." ***Compounder in this reference means a pharmacist.***	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	60.	Are controls in place to ensure compounding accuracy?	**USP <795> - Compounding Controls** "**1.** The Master Formulation Record, the Compounding Record, and associated written procedures shall be followed in execution of the compounding process. Any deviation in procedures shall be documented. **2.** The compounder shall check and recheck each procedure at each stage of the process. If possible, a trained second person should verify each critical step in the compounding process. **3.** The compounder shall have established written procedures that describe the tests or examinations conducted on the compounded preparation (e.g., the degree of weight variation among capsules) to ensure their uniformity and integrity. **4.** Appropriate control procedures shall be established to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations." ***Compounder in this reference can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.***	
Compounding for Animal Patients						
☐	☐	☐	61.	Do you compound products for animal patients? ***If no, you do not need to answer the questions below***		
☐	☐	☐	62.	Is the intended use by the animal determined prior to compounding preparation?	**USP <795> -** "Intended use of any animal patient (e.g., companion, performance, food) shall be determined before compounding for that patient."	
☐	☐	☐	63.	Do employees engaged in compounding for animals have knowledge of drug regulation and disposition for animal patients?	**USP <795> -** "All compounders preparing formulations for animals shall possess a functional knowledge of drug regulation and disposition in animal patients." ***Compounder in this reference can be either a pharmacist or a pharmacy technician.***	
☐	☐	☐	64.	Do labels include withdrawal time lengths for animals that are food-producing?	**USP <795> -** "Veterinarians are required by law to provide food-producing animal caregivers with an accurate length of time to withhold treated animal tissues (e.g., meat, milk, eggs) from the human food supply. This length of time is referred to as a withdrawal time (WDT) and must also, by law, be included on the dispensing label of every prescription prepared for a food-producing species."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	65.	Do your pharmacists have knowledge of individual species' limitations in physiology and metabolic capacities? What are your resources?	**USP <795> -** "The pharmacist shall be knowledgeable about the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used in compounded preparations."	