COMPLIANCE – NON-Sterile Compounding[1], [2]

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure

Board of Registration in Pharmacy
250 Washington Street, Boston, MA 02108-4619
(617) 973-0800
(617) 973-0988 TTY

DATE(S) OF INSPECTION:				INSPECTION #:	ISP-						
PHARMACY DBA NAME:											
STREET ADDRESS:											
CITY / STATE / ZIP:											
TELEPHONE:											
FAX:											
EMAIL:											
PHARMACY LIC. NUMBERS:											
PHARMACY LIC. EXPIRATION:											
DEA REG. NUMBER:											
DEA REG. EXPIRATION:											
PURPOSE OF INSPECTION:	☐ NEW STORE			☐ RELOCATION			☐ COMPLIANCE				
MANAGER OF RECORD (MOR):											
MOR REG. NUMBER:											
PHARMACY HOURS:	MON		TUE		WED		THU		FRI		
	SAT				SUN						
PRACTICE SETTING:	☐ COMMUNITY CHAIN			☐ COMMUNITY INDEPENENT			☐ LONG TERM CARE				
DAILY PHARMACY VOLUME (RXs):	☐ LESS THAN 100			☐ 100 TO 500			☐ ABOVE 500				
PROCEDURAL:	☐ PATIENT SPECIFIC ☐ ANTICIPATORY			☐ HAZARDOUS ☐ COMPLEX			☐ VETERINARY ☐ INVESTIGATIONAL DRUGS				
SECURITY CAMERAS:	☐ YES ☐ NO										
OUT OF STATE LICENSE(S)?	☐ YES ☐ NO										

	White – Compliance Statement	**USP <795> Standards**	Question #s: 1.00 - 61.4
	Blue – Compliance Criteria	**USP <800> Standards**	Questions #s: HD 1.00 – HD 89.00
	Gray – Recommended "Best Practices"		

[1] MA Board of Registration in Pharmacy: Non-Sterile Compounding Pharmacy Practice Resources - https://www.mass.gov/lists/pharmacy-practice-resources (accessed 11.29.23)

[2] 247 CMR 18.00 – Non-Sterile compounding DRAFT regulations approved by Board of Registration in Pharmacy. Pharmacy to assess current operations with draft regulations. https://www.mass.gov/lists/draft-regulations-for-the-board-of-registration-in-pharmacy (last accessed 1/2/2024)

Item #	Requirement	Y/N/N/A	Comment
A	**Standard Operating Procedures for Compounded Nonsterile Preparations (CNSPs)**		
1.0	Does the pharmacy have standard operating procedures (SOPs) on all aspects of the compounding operation that cover the minimum topic requirements in USP <795> standards? These topics include at least the following; (Buildings and Facilities, Personnel Training and Evaluation, Personal Hygiene and Garbing, Components, Temperature Monitoring. Equipment, Safety Data Sheets/Spill Management, Master Formulation Records (MFR), Labeling, Quality Assurance (QA)/Quality Control (QC) Program, Complaint Handling and Adverse Event Reporting, Packaging, Transporting, Recalls)		
B	**Designated Person(s) and Personnel Training Program**		
2.0	Does the pharmacy have a designated person(s) who meets the requirements in USP <795> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CNSPs."*** ***If no, go to the compliance statements.***		**Name of DP(s):**
2.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.		
2.2	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice, and such review is documented. ***Inspector note: Per USP, "The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program... 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."***		
2.3	The designated person(s) is responsible for overseeing a training program to ensure competency of personnel involved in compounding, handling, and preparing CNSPs.		

Item #	Requirement	Y/N/N/A	Comment
B	**Designated Person(s) and Personnel Training Program**		
2.4	The designated person(s) is responsible for selecting components used by the pharmacy.		
2.5	The designated person(s) is responsible for monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed.		
2.6	The designated person(s) is responsible for ensuring SOPs are fully implemented and following up if problems, deviations, or errors are identified.		
2.7	The designated person(s) is responsible for establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs.		
3.0	Has the pharmacy created and implemented a training program that is in compliance with USP <795> standards? ***Inspector note: Per USP, "Training and competency of personnel must be documented."***		
3.1	All personnel who compound CNSPs have been initially trained and qualified before being allowed to independently compound (e.g., perform their job functions). ***Inspector note: Per USP, compounding personnel are defined as "Personnel trained to compound or oversee compounding of preparations."***		
3.2	All personnel who have direct oversight, perform in-process checks, final verification of a CNSP, and/or dispense a CNSP have been initially trained and qualified (according to SOPs) being allowed to independently perform their job functions.		
3.3	All compounding personnel, including those who have direct oversight of compounding personnel, have completed an initial training and at least every 12 months thereafter. ***Inspector note: Per USP, "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."***		

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B	**Designated Person(s) and Personnel Training Program**		
4.0	Does the designated person(s) have a documented (periodic) evaluation of their direct observations for compounding activities and documentation of any deficiencies in the record? ***Inspector note: Per USP, this is a recommendation, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."***		
C	**Compounding Personal Hygiene and Garbing**		
5.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <795> standards? ***If no, go to compliance statements.***		
5.1	Compounding personnel are required to report to the designated person(s)conditions that may contaminate the compounding preparation area. ***Inspector note: Per USP <795>, examples of conditions that have a higher risk of contaminating the CNSP include: rashes, recent tattoos, open sores, conjunctivitis, and active respiratory infection.***		
5.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in the compounding areas before their conditions have resolved.		
5.3	Personnel removes any unnecessary items (outer garments, jewelry that could interfere with garbing, and earbuds/headphones) before entering the compounding area. ***Inspector note: Inspector should also observe compounding area to identify any items stored that do not belong (i.e., dirty garments, jackets, or electronics).***		
5.4	If personnel do not remove an item, the designated person has determined that the quality of the environment and CNSPs are not adversely affected by the accommodation.		

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C	**Compounding Personal Hygiene and Garbing**		
6.0	Do personnel perform hand hygiene, wear required garb and gloves, and follow requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***		
6.1	All personnel entering the compounding area complete hand hygiene procedures.		
6.2	Garb is used for all compounding activities. ***Inspector note: Per USP <795>, gloves are mandatory garb for all compounding activities.***		
6.3	Pharmacy uses SDS to determine other garb requirements for the components and compounding activity.		
6.4	Additional garb (shoe covers, hair and facial hair covers, face masks, gowns) is worn as needed for protection of the personnel/CNSPs. ***If no, please list the garb worn for the type of component and compounding activity.***		
6.5	The garb purchased by the pharmacy is appropriate for the type of compounding being performed.		
6.6	Garb is stored in manner that minimizes risk of contamination (away from sinks to avoid splashing, etc.).		
6.7	Gowns that are reused do not leave the compounding area.		
6.8	Visibly soiled garb or garb with tears or punctures are changed immediately (are not reused).		
6.9	Soiled garb is disposed of or sent for laundering.		
6.10	Shoe covers, hair and facial hair covers, face masks, and head covers are not reused once personnel have left the compounding area.		
7.0	Are non-disposable garb such as goggles cleaned then sanitized with 70% isopropyl alcohol before re-use?		
D	**Buildings and Facilities**		
8.0	Does the compounding area meet the facility requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***		
8.1	The pharmacy has a designated compounding space for nonsterile compounding.		
8.2	The compounding area is well lit.		
8.3	The compounding area is clean and sanitary.		
8.4	The compounding area is orderly (e.g., clutter free, no tripping hazards).		
8.5	The compounding area is in a good state of repair.		

Item #	Requirement	Y/N/N/A	Comment
D	**Buildings and Facilities**		
8.6	The compounding area is designed for orderly placement of equipment and materials to prevent mix- ups among components, containers, labels, in-process materials, and finished CNSPs.		
8.7	The compounding area is not being used for other activities at the same time that it is used for compounding.		
8.8	The compounding area is designed, arranged, and used in a manner that minimizes cross contamination from non-compounding areas.		
9.0	Is the compounding area free of carpet?		***Required: MA DRAFT 247 CMR 18.04 (2) (b)***
10.0	Does the pharmacy's storage area (for CNSPs, components, equipment, and containers) meet requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***		
10.1	The pharmacy records the temperature of the compounding storage area on days when the pharmacy is open. ***Inspector note: Per USP, "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."*** ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***		
10.2	The pharmacy's temperature monitoring records are readily retrievable. ***Inspector note: Per USP, "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."***		
10.3	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Per USP, "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." USP reports that these devices may be verified against a calibrated device.Monitoring devices are typically calibrated or replaced.***		

Item #	Requirement	Y/N/N/A	Comment
D	**Buildings and Facilities**		
10.4	Pharmacy has a process to evaluate temperature excursions. ***Inspector note: Per USP, "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."***		
10.5	CNSPs, components, equipment, and containers are stored off the floor.		
10.6	CNSPs, components, equipment, and containers are stored in a manner that permits inspection and cleaning of the storage area(s).		
10.7	CNSPs, components, equipment, and containers are stored in a clean environment (free of dirt, dust, and debris, and rodent/pest/insect free) to prevent contamination.		
11.0	What is the current temperature of the nonsterile compounding storage area? ***Record in the Inspector Notes.***		
12.0	Are plumbing fixtures, water sources, and cleanliness of sink in compliance with USP <795> standards?***If no, go to compliance statements.***		
12.1	The pharmacy staff can easily access a sink within or nearby the nonsterile compounding area.		
12.2	There is hot and cold running water available at the sink within or nearby the nonsterile compounding area.		
12.3	The sink is emptied of all items unrelated to compounding and before being used to clean any equipment used in nonsterile compounding.		
12.4	The sink is cleaned when visibly soiled (before being used to clean equipment used in nonsterile compounding).		
12.5	The plumbing system is free of any defects that may contribute to contamination of CNSPs.		
13.0	Is purified water, distilled water, or reverse osmosis water used for rinsing equipment and utensils used in nonsterile compounding? ***Inspector note: This is a USP recommendation.***		

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E	**Cleaning and Sanitizing**		
14.0	What agent(s) are used for cleaning and sanitizing the nonsterile compounding area? ***Inspector note: Per USP <795>, "agents must be selected and used with consideration of compatibilities, effectiveness, and minimal potential to leave residues."*** ***List the agents in the Inspector Notes.***		
15.0	Does the pharmacy perform cleaning and sanitizing activities on all surfaces at the minimum frequency per Table 1 and documented in a log or other record in compliance with USP <795> standards? ***Review compounding cleaning logs.*** ***If no, go to compliance statements.***		
15.1	All work surfaces are cleaned and sanitized at the **beginning of each shift** on days when compounding occurs.		
15.2	All work surfaces are cleaned and sanitized at the **end of each shift** on days when compounding occurs.		
15.3	All work surfaces are cleaned and sanitized **between compounding CNSPs with different components**.		
15.4	Floors are cleaned and sanitized daily on days when compounding occurs.		
15.5	Walls and ceilings are cleaned and sanitized when visibly soiled. ***Inspector note: No specific frequency is specified by USP. View compounding area walls and ceilings. If inspector observes soiled walls or ceilings, inspector should answer statement as no.***		
15.6	All work surfaces, floors, walls, ceilings, and storage shelving are cleaned and sanitized when surface contamination (e.g., splashes) or spills are known or suspected.		
15.7	Storage shelving is cleaned and sanitized at least every three months.		
16.0	Are floors in the compounding area easily cleanable, non-porous, and non-particle generating? ***Inspector note: This is a USP recommendation. Per USP, "Surfaces should be resistant to damage by cleaning and sanitizing agents."***		

Item #	Requirement	Y/N/N/A	Comment
F	**Equipment and Components**		
17.0	Does the pharmacy use a closed-system processing device (e.g., CVE, BSC, and single-use containment glove bags)? ***Inspector note: Per USP, examples of closed-system processing devices include: containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags.*** ***If yes, list the type(s) in the Inspector Notes.***		
18.0	Does the pharmacy select, store, clean, and maintain equipment in compliance with USP <795> standards? ***Inspector note: Per USP <795>, "Equipment surfaces that contact components are not reactive, additive, or sorptive, and must not alter the quality of CNSPs."*** ***Review certification reports, calibration records, and cleaning logs.*** ***If no, go to compliance statements.***		
18.1	Equipment and supplies are readily available at the pharmacy for the types of CNSPs prepared. ***Inspector note: For example, if the pharmacy compounds with API as a component, which must be weighed, a scale or balance would be expected.***		
18.2	Pharmacy has evaluated and documented the nonsterile compounding pharmacy activities for weighing, measuring, and otherwise manipulating for an assessment of risk. ***Inspector note: Per USP, "components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) 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 no, inspector should describe observations.***		

Item #	Requirement	Y/N/N/A	Comment
F	**Equipment and Components**		
18.3	The equipment and devices used for compounding CNSPs are clean and stored in a manner and frequency that minimizes the risk of contamination. ***Inspector note: Per USP <795>, "After compounding, the equipment must be cleaned to prevent cross contamination of the next preparation." Additionally, per Table 2:- CVE/BSC are cleaned and sanitized at the beginning and end of each shift when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected;- CVE/BSC horizontal surfaces are cleaned and sanitized between compounding of different components;- Under the work surface of a BSC is cleaned and sanitized at least monthly; and- Other devices and equipment used in compounding are cleaned before initial use, in between compounding CNSPs with different components, and following manufacturer recommendations.If no, inspector should describe observations.***		
18.4	Equipment and devices used in compounding or testing of CNSPs are inspected prior to use (to ensure they are in good working order). ***Inspector note: For example, the pharmacy may need to tare a scale and/or balance prior to use.***		
18.5	Equipment and devices are verified for accuracy as recommended by the manufacturer (at the frequency recommended by the manufacturer or at least every 12 months, whichever is more frequent). ***If the pharmacy does not compound CNSPs that require equipment or devices that must be calibrated for accuracy (such as ones needed for weighing or measuring), the inspector should answer this statement as N/A.***		
18.6	If a CVE or BSC is used by the pharmacy, it is certified at least every 12 months, according to the manufacturer specifications or regulations of the applicable regulatory jurisdiction. ***If the pharmacy does not have the record or documentation of the certification and maintenance of the CVE/BSC, the inspector should answer this statement as no. If the pharmacy does not have a CVE or BSC, the inspector should answer this statement as N/A.***		
19.0	Does the pharmacy compounding CNSPs use APIs?		

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F	**Equipment and Components**		
20.0	Does the pharmacy select APIs that comply with the requirements in USP <795> standards? ***Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products. If no, go to compliance statements.***		
20.1	APIs comply with criteria in the USP-NF monograph, if one exists. ***If the pharmacy does not compound any CSPs that have an available USP monograph, the inspector should answer this statement as N/A.***		
20.2	All APIs used have a COA that includes the specifications (e.g., compendial requirements for quality) and that the test results for the component show the API meets expected quality. ***Inspector note: Per USP, the API should be checked to ensure it is pharmaceutical grade and meets the requirements in the chemical monograph. COA will report an assay has been performed and will include water content (so any corrections/calculations can be performed).***		
20.3	All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Food, Drug, and Cosmetic Act, Section 503A, requirement as well. If the API comes from a repackager, the pharmacy must be able to confirm the manufacturer of the API was registered as an Establishment with FDA.***		
21.0	When formulations indicate the inclusion of water, is purified water or better quality (e.g., sterile water for irrigation) used in compliance with USP <795> standards?		
23.0	Do the pharmacy's component receipt processes comply with the requirements in USP <795> standards? ***If no, go to compliance statements.***		
23.1	For non-conventionally manufactured components, the COA is reviewed upon receipt. ***Inspector note: Per USP, "the COA must be reviewed to ensure that the component has met the acceptance criteria in an appropriate USP–NF monograph, if one exists." Pharmacy's review should be documented. Alternatively, the pharmacy can demonstrate how it's been reviewed (for example, there are notes to show a water content calculation back to 100% based on the specific COA). Inspector can verify the COA is retrievable.***		

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F	**Equipment and Components**		
23.2	The pharmacy documents specific information according to the facility's SOP, including: receipt date, quantity received, supplier name, lot number, expiration date, and the results of any testing performed (whether performed in-house or through a third-party).		
23.3	For all components that lack a vendor expiration date, the pharmacy clearly and indelibly marks on each packaging system received the date the component must no longer be used by the pharmacy. ***Inspector note: Per USP, "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."***		
23.4	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.		
23.5	Any other lots of that (rejected) component from that vendor are examined to determine whether other lots have the same defect.		
24.0	Does the pharmacy re-inspect all components before use and handle them in compliance with USP <795> standards? ***If no, go to compliance statements.***		
24.1	Compounding personnel visually re-inspect each component, including packaging system (any evidence of container breakage, looseness of cap or closure) and deviation from the expected appearance or texture of the contents (that might have changed during storage).		
24.2	Compounding personnel ascertain before use that components are the correct identity based on labeling, that they have been stored under required conditions, and there is no evidence of deterioration or other aspects of unacceptable quality before use of component.		

Item #	Requirement	Y/N/N/A	Comment
F	**Equipment and Components**		
24.3	Components where correct identity, strength, purity, and quality cannot be confirmed (e.g., containers with damaged or incomplete labeling), are immediately rejected and if not immediately discarded, labeled as rejected and segregated from active stock.		
24.4	Compounding personnel handle all components following facility SOPs, manufacturer's instructions/labeling, and laws/regulations of the applicable regulatory jurisdiction.		
24.5	All components are handled in a manner that minimizes the risk of contamination, mix-ups, and deterioration.		
25.0	When components are removed from the original container and not used in compounding (e.g., excess after weighing), are they discarded and not returned to the original container (to minimize risk of contamination of the original component container)? ***Inspector note: This is a USP recommendation.***		
26.0	Does the pharmacy maintain a chemical hazard, spill management, and disposal information program in compliance with USP <795> standards? ***If no, go to compliance statements.***		
26.1	Pharmacy staff have access to safety data sheets (SDS).		
26.2	Pharmacy staff have documented, annual training for those who might have to clean up a spill.		
26.3	The pharmacy has a readily accessible spill kit in the compounding area.		
26.4	The pharmacy has a process to manage and document any nonhazardous spills and disposal.		
26.5	Waste of any component is disposed of in accordance with laws and regulations of the applicable regulatory jurisdiction.		
G	**Master Formulation Records (MFR) and Compounding Records (CR)**		
27.0	Is an MFR created for each unique formulation of a CNSP in compliance with USP <795> standards? ***Inspector note: Per USP, an MFR is a detailed record of procedures that describes how the CNSP is to be prepared.*** ***If no, go to the compliance statements.***		
27.1	An MFR is created for each unique formulation.		
27.2	Any changes or alterations to the MFR are approved and documented.		

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G	**Master Formulation Records (MFR) and Compounding Records (CR)**		
27.3	Does the designated person(s) or designee evaluate CNSP's characteristics when considering the assigned BUD for an MFR? ***Inspector note: Per USP, "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 (and)- Significant deviations from essential compounding steps and procedures; changes to essential compounding steps may have an impact on the stability of the formulation."***		
28.0	Does the pharmacy's MFRs contain all requirements in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and include as an attachment.***		
28.1	MFR includes the name, strength or activity, and dosage form of the CNSP.		
28.2	MFR identifies the identities and amounts of all components and, if applicable, relevant characteristics of components (e.g., particle size, salt form, purity grade, solubility).		
28.3	MFR includes the type of container–closure system(s).		
28.4	MFR has complete instructions for preparing the CNSP, including equipment, supplies, and a description of the compounding steps. ***Inspector note: Per USP, the MFR will also include, "Other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature)." MFRs will include the detailed instructions necessary for an experienced compounder. Some examples of other details to ensure repeatability include, but are not limited to: speed duration, settings on equipment, and specific order of mixing (if applicable).***		

Item #	Requirement	Y/N/N/A	Comment
G	**Master Formulation Records (MFR) and Compounding Records (CR)**		
28.5	MFR has a physical description of the final CNSP.		
28.6	MFR includes the assigned beyond-use date (BUD) and storage requirements.		
28.7	MFR contains the reference source to support the assigned BUD.		
28.8	Labeling requirements (e.g., shake well) are described on the MFR.		
28.9	If applicable, the MFR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of APIs.		
28.10	An MFR has QC procedures (e.g., pH testing, visual inspection) and expected results.		
29.0	Does the pharmacy complete a Compounding Record (CR) for all CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and the CR (no PHI or PII is to be collected).***		
29.1	A CR is completed for each CNSP prepared.		
29.2	The CR includes the name, strength or activity, and dosage form of the CNSP.		
29.3	The CR includes the date (or date and time) the CNSP was prepared.		
29.4	The CR includes the assigned internal identification number (e.g., prescription, order, or lot number).		
29.5	The CR has a method to identify the individuals involved in the compounding process of the CNSP.		
29.6	The CR has a method to identify the individual who completed the review and verified the final CNSP.		
29.7	The CR includes: name, vendor or manufacturer, lot number, and expiration date of each component.		
29.8	The CR includes the weight or measurement of each component.		
29.9	The CR identifies the total quantity compounded.		
29.10	The CR lists the assigned BUD and storage requirements.		
29.11	If applicable, the CR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of API.		
29.12	The CR has a physical description of the final CNSP.		
29.13	The CR includes the results of quality control procedures (e.g., pH testing, visual inspection).		
29.14	The CR contains a MFR reference for the CNSP.		

Item #	Requirement	Y/N/N/A	Comment
G	**Master Formulation Records (MFR) and Compounding Records (CR)** [3]		
29.15	Each CR is reviewed for completeness before the CNSP is released.		
29.16	The CR shows traceability of all components in the case of a recall or known quality issue.		
30.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes. These checks indicate that appropriate procedures for measuring/mixing are followed for each step, including pharmacist verification of steps performed by non-pharmacists and visual inspection of preparation. Inspector should describe their observations in the Inspector Notes***.		
H	**Labeling**		
31.0	Are the pharmacy's labels for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***		
31.1	Information on the label is prominently and legibly displayed. ***Inspector note: Per USP, labeling includes other accompanying materials along with the CSP, which is defined as "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 for any outer shipping container."***		
31.2	The labeling meets any state or federal regulatory requirements.		
31.3	The label on the immediate container includes an assigned internal identification number (e.g., barcode, prescription, order, or lot number).		
31.4	The label on the immediate container includes the active ingredients and their amount(s), activity(ies), or concentration(s).		
31.5	The label on the immediate container includes the storage conditions, if other than controlled room temperature.		
31.6	The label on the immediate container includes the BUD. ***If no, please describe whether the pharmacy instead used the term "expiration date" or similar language or if this information was not included on the label.***		

[3] **Compounding Records** - Each time it prepares a CSP, a pharmacy shall complete and maintain a compounding record that includes all elements as specified in the most recent version of USP and in M.G.L. c. 112, § 39D for "accountability documentation."

Item #	Requirement	Y/N/N/A	Comment
H	**Labeling**		
31.7	The label on the immediate container includes the dosage form.		
31.8	The label on the immediate container includes the total amount or volume, if it is not obvious from the container.		
32.0	Does the labeling on the dispensed CNSP include the route of administration? ***Inspector note: This is a USP recommendation.***		
33.0	Does the labeling contain information identifying the CNSP as a compounded preparation? [4] ***Inspector note: This is a USP recommendation.***		***Required: MA M.G.L. c94c s21***
34.0	Does the labeling on the dispensed CNSP display any applicable special handling instructions or warning statements? ***Inspector note: This is a USP recommendation.***		***Required: MA M.G.L. c94c s21***
35.0	Does the labeling on the dispensed CNSP display the name of the compounding facility and contact information if the CSNP was to be sent outside of the facility or health care system? ***Inspector note: This is a USP recommendation.If the pharmacy only compounds CNSPs for patient use onsite (e.g., a health care facility), inspector should answer this question as N/A***.		***Required: MA M.G.L. c94c s21***
I	**Establishing Beyond Use Dating (BUDs)**		
36.0	Is each CNSP assigned and labeled with a BUD in compliance with USP <795> standards? ***Inspector note: Per USP, the BUD is defined as, "The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded." This is not the same term as "expiration date."*** ***If no, go to compliance statements.***		
36.1	CNSP label has a BUD that specifies the date, or the hour and date, beyond which the preparation cannot be used and must be discarded.		
36.2	CNSP labels do not list an "expiration date" or equivalent language.		
36.3	BUDs are assigned from the date (and time) of preparation.		

[4] **M.G.L c94c s21. Labeling Requirement -** All drug preparations compounded, made or formulated by a pharmacy licensed by the board of registration in pharmacy shall have affixed to their container by the compounding pharmacy a label notifying prescribed users and practitioners that the drug is a sterile compounded drug preparation. Phone number of compounding pharmacy must be on label.

Item #	Requirement	Y/N/N/A	Comment
I	**Establishing Beyond Use Dating (BUDs)**		
36.4	BUDs are assigned based on dispensing in tight, light resistant containers/overpacks. ***Inspector note: Per USP, the Table 4 maximum limits for BUD are, "based on the ability of the CNSP to maintain chemical and physical stability and to suppress microbial growth. These BUDs represent the limit for CNSPs that are packaged in tight, light-resistant containers unless conditions in 10.4 CNSPs Requiring Shorter BUDs or 10.5 Extending BUDs for CNSPs apply."***		
36.5	The BUD assigned to the CNSP does not exceed the shortest remaining expiration date of any of the commercially available starting components.		
37.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest BUD of any individual compounded components? ***Inspector note: Per USP, "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." Another example of these "acceptable instances" (similar to pH-altering components mentioned above) inspectors may see are stock solutions (and other formulas within a formula) such as methocel 1%.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***		
38.0	Does the designated person(s) evaluate a CNSP formulation to establish the maximum BUD? ***If no, who establishes the maximum BUD for an MFR?***		
39.0	Does the pharmacy compound CNSPs with a USP monograph?		
40.0	Does the pharmacy compound CNSPs following the USP monograph precisely? ***If no, go to compliance statements.***		
40.1	Pharmacy staff have access to the USP monograph for reference.		

Item #	Requirement	Y/N/N/A	Comment
I	**Establishing Beyond Use Dating (BUDs)**		
40.2	CNSPs are prepared in accordance with the USP monographs. ***If no, inspector to collect a copy of the compounding record, label; and describe what specific steps of the monograph were not followed.***		
40.3	Components used by the compounder match those listed in the monograph. ***If no, describe the source of the component in monograph and the source that the pharmacy used.***		
40.4	The maximum BUD specified in the USP monograph is not exceeded. ***If no, identify the drug, monograph-stated BUD, and the BUD used by the pharmacy.***		
41.0	Does the pharmacy compound CNSPs that are not available from a USP monograph?		
42.0	Does the pharmacy adhere to the BUD (maximum) limits established in Table 4 for CNSPs in compliance with USP <795> standards? ***Inspector note: This question is for the CNSPs compounded that are <u>not</u> following a USP monograph or those CNSPs where extending BUD requirements were applied (where pharmacy has completed or has access to CNSP-Specific Stability Information). Per USP, the pharmacy is not required to measure water activity (A_w) for a CNSP.If no, go to compliance statements.If <u>all</u> CNSPs compounded at the pharmacy are following a USP monograph or the pharmacy is following a stability study that used a stability-indicating assay analytical method for the API, CNSP formulation, and material of composition of the container closure system, then the inspector should answer this question as N/A.***		

Item #	Requirement	Y/N/N/A	Comment
I	**Establishing Beyond Use Dating (BUDs)**		
42.1	**Non-preserved, Aqueous Dosage Forms**: The non-preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 14 days with refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, e.g., emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound non-preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***		
42.2	**Preserved, Aqueous Dosage Forms:** The preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 35 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, e.g., emulsions, gels, creams, solutions, sprays, or suspensions.If pharmacy does not compound preserved aqueous dosage forms, inspector should answer statement as N/A.If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***		
42.3	**Nonaqueous, Oral Liquid Dosage Forms:** The nonaqueous, oral liquid dosage form CNSP is labeled with a BUD that does not exceed 90 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous oral liquid dosage forms are ones that have an A_w < 0.6. Some examples of oral liquids that are nonaqueous include: oil-based oral solution or suspension. If pharmacy does not compound nonaqueous dosage forms, inspector should answer statement as N/A. If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***		

Item #	Requirement	Y/N/N/A	Comment
I	**Establishing Beyond Use Dating (BUDs)**		
42.4	**Nonaqueous Dosage Forms:** The nonaqueous dosage form CNSP is labeled with a BUD that does not exceed 180 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous (Solid) dosage forms are ones that have an A_w < 0.6. Some examples include capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.If pharmacy does not compound other nonaqueous solid dosage forms, inspector should answer statement as N/A.If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***		
43.0	Does the pharmacy label any CNSPs with BUDs that extend beyond the maximum limits in Table 4 USP <795>?		
44.0	Does the pharmacy follow the requirements for labeling a CNSP with a BUD that exceeds Table 4 in compliance with USP <795> standards? ***If no, go to compliance statements.***		
44.1	The labeled BUD for an aqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***		
44.2	The labeled BUD for a nonaqueous dosage form does not exceed 180 days.***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***		
44.3	Pharmacy is following the results of their own stability study. ***If the pharmacy only follows cited stability studies (does not conduct their own stability studies) for extending BUDs, answer this question as N/A.*** ***If pharmacy is following a bracketed study, inspector may mark this statement as yes if concentrations of CNSPs are at or within the concentrations specified within the study.*** ***If pharmacy is following a bracketed study and is using a concentration outside the study, answer this question as a no and describe observations.***		

Item #	Requirement	Y/N/N/A	Comment
I	**Establishing Beyond Use Dating (BUDs)**		
44.4	The pharmacy has a copy of the cited stability study, which used a stability-indicating analytical method, for extending BUDs. ***Per USP, any stability study that meets the requirements of a stability-indicating assay method can be used (whether it is published or unpublished, such as a study provided by a chemical supplier) to extend BUDs up to 180 days for a CNSP. If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***		
44.5	The cited stability study (which uses a stability-indicating analytical method for extending BUDs) describes the API(s), CNSP formulation, and material composition of the container closure used. ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.If no, please describe the inspector observations.***		
44.6	If the cited stability study (which uses a stability-indicating analytical method for extending BUDs) is bracketed, the pharmacy's CNSP formulation is at or within the low and high concentration of each active ingredient within the stability study. ***If no, describe the concentrations cited in the stability study and the concentration of the CNSP compounded by the pharmacy. If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.***		

Item #	Requirement	Y/N/N/A	Comment
I	**Establishing Beyond Use Dating (BUDs)**		
44.7	Aqueous CNSPs whose labeled BUDs are extended beyond Table 4, have: - been tested for antimicrobial effectiveness at least once for each formulation in the type of (with the same material composition of the) container closure system that will be used;- received study results from an FDA-registered facility (for the same CNSP formulation using the same material composition of the container closure system); or- a study published from peer-reviewed literature (for the same CNSP formulation using the same material composition of the container closure system). ***Inspector note: Pharmacy may rely on a bracketed study from the above options as long as the bracketed study information includes the low and high concentration of each active ingredient in the formulation. Per USP, this is "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.***		
J	**Quality Assurance (QA), Quality Control (QC), and Quality Management (QM)[5]**		
45.0	Does the pharmacy have a QA/QC program to ensure that CNSPs are prepared per the requirements in USP <795> standards and any applicable regulatory requirements? ***If no, go to compliance statements.***		
45.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "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."***		
45.2	The QA/QC programs address adherence to procedures.		
45.3	The QA/QC programs address prevention and detection of errors and other quality problems.		

[5] **Defective Drug Preparation Log:** Per M.G.L. c. 112, § 39D(e), a pharmacy that is licensed with the Board has a legal responsibility to recall a compounded drug preparation if it knows or should have reason to know that a compounded drug preparation dispensed or distributed into, within, or from Massachusetts by the pharmacy is or may be defective in any way.

Item #	Requirement		
J	**Quality Assurance (QA), Quality Control (QC), and Quality Management (QM)**		
45.4	The QA/QC programs address evaluation of complaints and adverse events. ***Review at least one complaint and one adverse event. If there are no complaints or adverse events, review the process that the pharmacy would follow in the event of a complaint or adverse event.***		
45.5	The QA/QC programs address appropriate investigations and corrective actions.		
46.0	Has the pharmacy received any complaints related to CNSPs within the past year?		
47.0	Does the pharmacy follow complaint handling requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***		
47.1	The pharmacy has a complete written or electronic record of each complaint made. ***Inspector note: Per USP, "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, thefollowing 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."***		
47.2	Complaints are reviewed in accordance with SOPs by the designated person for the QA program.		
47.3	Complaints are reviewed to determine whether it indicates a potential quality problem with the CNSP.		
47.4	Complaints are fully investigated.		
47.5	Complaint investigations consider whether the quality problem extends to other CNSPs.		

Item #	Requirement		
J	**Quality Assurance (QA), Quality Control (QC), and Quality Management (QM)**		
47.6	Corrective action, if necessary, is implemented for all potentially affected CNSPs. ***Inspector note: Per USP, the pharmacy is to, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease nonsterile compounding processes until all underlying problems have been identified and corrected."***		
47.7	A CNSP that is returned in connection with a complaint is quarantined until it is destroyed after the completion of the investigation and in accordance with the laws and regulations of the applicable regulatory jurisdiction.		
48.0	Has the pharmacy initiated any recalls of CNSPs within the past two years? ***Inspector note: Per USP <795> requires all records to be readily retrievable for two years, including recalls; However, the state/jurisdictional regulator may require records to be kept for a longer period of time.Review most recent recall and describe in the Inspector Notes.If the pharmacy has not had any recalls within the past two years, inspector should answer the question as No.***		
49.0	Does the pharmacy follow recall and adverse event procedures for CNSPs in compliance with USP <795> standards? [6] ***If no, go to compliance statements.***		
49.1	The pharmacy has procedures to determine when recalls must be initiated.		
49.2	The pharmacy documented the implementation of the recall.		
49.3	Pharmacy reports recalled CNSPs to the appropriate regulatory bodies (as required by laws and regulations of the applicable regulatory jurisdiction).		
49.4	Investigations into an adverse event that reveals a quality problem with a CNSP that is likely to affect other patients are reported to both patients and their prescribers.		

[6] **Serious Adverse Drug Event (SADE):** M.G.L c. 112, § 39D(b)&(c), retail pharmacies licensed by the Massachusetts Board of Registration in Pharmacy (Board) shall report to the Board within seven business days any serious adverse drug event that occurs as a result of any compounded preparation dispensed from a pharmacy (sterile or non-sterile), any improper dispensing of a prescription drug resulting in serious injury or death.

Item #	Requirement		
J	**Quality Assurance (QA), Quality Control (QC), and Quality Management (QM)**		
50.0	Do the pharmacy procedures include a step to immediately notify the prescriber of a failure of specifications with potential to cause harm (e.g., strength, purity, or other quality attributes)? ***Inspector note: This is a USP recommendation.***		***Required: MA 247 CMR 15.03; 247 CMR 6.14 (2): specific situations***
K	**CNSP Packaging**		
51.0	Does the pharmacy's packaging processes and materials meet the requirements in USP <795>? ***If no, go to compliance statements.***		
51.1	The packaging materials protect CNSPs from damage, leakage, contamination, and degradation.		
51.2	The packaging materials used protects personnel from exposure (from the packaged CNSP).		
52.0	The packaging materials selected by the pharmacy maintain the physical and chemical integrity and stability needed for CNSPs (e.g., protect from light).		
L	**Compounding Personnel Work Practices**		
53.0	**Personal Preparation Observation:** Before entering the compounding area, do personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <795> standards? ***If no, go to compliance statements.***		
53.1	Personnel removed all outer garments (e.g., hats, scarves, bandanas, vests, coats, and jackets).		
53.2	Personnel removed all items that are not easily cleanable and that might interfere with garbing.		
53.3	Personnel removed all hand, wrist, and other exposed jewelry, including piercings, that could interfere with the effectiveness of garbing and hand hygiene (e.g., watches, rings that may tear gloves).		
53.4	Personnel removed earbuds or headphones.		
53.5	Any accommodations permitted by the designated person(s) should be documented. ***Inspector note: Per USP <795>, accommodations may be permitted if the quality of the CSP and environment will not be affected.***		

Item #	Requirement		
L	**Compounding Personnel Work Practices**		
54.0	**Hand Hygiene Observation:** Were personnel who enter the compounding area to compound observed performing the appropriate hand washing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***		
54.1	All personnel who enter the compounding area to compound performed hand hygiene.		
54.2	Personnel wash hands with soap and water for at least 30 seconds.		
54.3	Personnel dry their hands completely with disposable towels or wipers.		
54.4	Personnel do not solely rely on the use of alcohol hand sanitizers.		
55.0	***Garbing Observation:*** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***		
55.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).		
55.2	All personnel who perform compounding activities don gloves. ***Inspector note: Per USP, "Gloves must be worn for all compounding activities."***		
55.3	Gloves are inspected periodically for holes, punctures, or tears and replaced immediately if a defect is detected.		
56.0	Are gloves wiped or replaced before beginning compounding a CNSP with a different component or when other objects were touched (e.g., pens, keyboards) to minimize risk of cross contamination with other CNSPs? ***Inspector note: This is a USP recommendation.***		
58.0	**Compounding Observation:** Are compounding personnel using appropriate nonsterile compounding techniques for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***		
58.1	The compounding personnel enter the nonsterile compounding area in accordance with the SOPs.		
58.2	The compounding personnel started with a clean compounding area for CNSPs.		
58.3	The compounding personnel selected the correct MFR for the CNSP to be prepared.		

Item #	Requirement	Y/N/N/A	Comment
L	**Compounding Personnel Work Practices**		
58.4	The compounding personnel performed hand hygiene. ***Inspector note: Per USP <795>, Box 1, personnel are to: wash hands with soap and water for at least 30 seconds, dry hands completely with disposable towels or wipers, and then don gloves.***		
58.5	The compounding personnel are appropriately garbed for the type of CNSP prepared.		
58.6	The compounding personnel obtained the proper ingredients (APIs and/or components). ***Inspector note: All ingredients must be within date and match what is listed in the MFR. If the ingredient is an API, the COA must have already been reviewed and approved for use.***		
58.7	The compounding personnel gathered all necessary materials, equipment, and supplies necessary and/or specified in the MFR and is in good working order prior to use for the CNSP. ***Inspector note: All items must be clean prior to use. If equipment requires calibration and/or certification, compounder must ensure the equipment or device is within proper specifications (e.g.,*** t***are scales and/or balances).***		
58.8	The compounding personnel have knowledge of and access to any SDS.		
58.9	The compounding personnel only compound one CNSP at a time (to proactively prevent mix-ups, errors, and cross contamination).		
58.10	The compounding personnel compound the CNSP according to the MFR. ***If no, inspector needs to describe in detail their observations in the Inspector Notes and collect a copy of the MFR and CR (no PHI or PII to be collected).***		
58.11	The compounding personnel document any required steps listed in the MFR on the CR. ***Inspector note: This would include any weights, volume, and any in-process checks needed.***		
58.12	Documentation in the CR is legible. ***If no, collect copy of record that is illegible. Redact any PHI on record.***		
58.13	The compounding personnel verify the correct BUD in accordance with the MFR requirements in USP <795>.		

Item #	Requirement	Y/N/N/A	Comment
L	**Compounding Personnel Work Practices**		
58.14	The compounding personnel performed any quality control steps specified in the MFR. ***Inspector note: Examples of this include but are not limited to: testing of pH for a suspension, weighing of capsules, and visual inspection against product description specifications.If no, describe observations in Inspector Notes.***		
58.15	The compounding personnel placed the CNSP into the proper container closure system.		
58.16	The compounding personnel labeled the CNSP. ***Inspector note: Storage requirements must be included on the label if refrigerated or frozen (so patient can identify the storage temperature requirements).***		
58.17	The compounding personnel completed any documentation on the CR. ***If no, describe observations of what was missing or omitted in Inspector Notes.***		
58.18	The compounding personnel cleaned and sanitized the compounding area before the next CNSP (with differing ingredients) is prepared.		
59.0	**Final CNSP check observation**: Does the visual inspection of the CNSP by the pharmacist confirm all USP <795> requirements? ***If no, go to compliance statements.***		
59.1	CSNP was visually inspected to determine the physical appearance of the CNSP is as expected (e.g., color, texture, physical uniformity), including any special characteristics listed in the MFR (e.g., emulsions must be checked for phase separation).		
59.2	Visual inspection included checking for container closure integrity (e.g., leakage, cracks, improper seals).		
59.3	CNSP label was verified against the prescription or medication order.		
59.4	CNSP label was verified against the MFR.		
59.5	CNSP label was verified against the CR.		
59.6	If a CNSP will not be released or dispensed on the day the preparation was made, a visual inspection was conducted immediately before it is released or dispensed to make sure the CNSP did not develop any defects during storage.		
59.7	All checks and inspection that are performed are properly documented.		

Item #	Requirement	Y/N/N/A	Comment
L	**Compounding Personnel Work Practices**		
59.8	CSNP that do not meet requirements, are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before disposal.		
60.0	Inspect several different finished compounded nonsterile preparations. Are all the finished compounded preparations free from any evidence of signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined. Report as applicable. Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (e.g., particulates, dirt/debris/(suspected) mold within container closure); number of preparations affected (e.g., two of the five containers on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***		
61.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and sanitizing activities in the compounding area in compliance with USP <795> standards? ***If no, go to compliance statements.***		
61.1	Pharmacy staff starts with a clean and sanitized work surface prior to compounding a CNSP.		
61.2	Pharmacy staff perform cleaning and sanitizing between compounding CNSPs with different components. ***Inspector note: Per USP, "If cleaning and sanitizing are performed as separate steps, cleaning must be performed first."***		
61.3	Pharmacy staff ensure equipment and devices used in compounding activities are clean and sanitized after use (to prevent cross contamination of the next preparation).		
61.4	Pharmacy staff perform cleaning and sanitizing on work surfaces when visibly soiled, after spills, and/or when surface contamination is known or suspected.		

795 Comments:

Item #	Requirement	Yes/No/N/A	Comment
AA	**General Information**		
HD 3.00	The pharmacy maintains a list of any items it handles that are included on the current NIOSH list of antineoplastic and other HDs. Review and attach list. Verify that pharmacy has access to a copy of current NIOSH list.		
HD 4.00	The pharmacy reviews this list at least every 12 months for additions, deletions, or other changes and documents the review. Verify documentation and list date of last change/review.		
HD 5.00	The pharmacy reviews this list whenever the pharmacy adds a new agent or dosage form to the items it handles.		
HD 6.00	The pharmacy has a system in place for the evaluation of new drugs (purchased, stored, handled, and/or dispensed) to determine whether they are considered HD.		
HD 6.01	Pharmacy evaluates the drugs against the current version of the NIOSH list.		
HD 6.02	In the absence of information, the pharmacy treats any new drug as an HD.		
HD 7.00	If the pharmacy handles any HDs not using all containment requirements of, an assessment of risk was performed for each drug and dosage form individually to determine alternative containment strategies, if needed, and work practices for each. Review documentation of assessment and SOPs related to work practices/alternative containment.		
HD 8.00	The assessment of risk evaluation performed by the pharmacy's organization includes all required information, for each drug and dosage form.		
HD 8.01	Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk only);		
HD 8.02	Dosage form;		
HD 8.03	Risk of exposure;		
HD 8.04	Packaging;		
HD 8.05	Manipulation; and		
HD 8.06	If applicable, Table II and III drugs have alternative containment strategies and/or work practices to minimize occupational exposure.		

Item #	Requirement	Yes/No/N/A	Comment
AA	**General Information**		
HD 8.07	The assessment of risk is reviewed at least every 12 months, and the review is documented. Enter date of last review in the notes.		
HD 9.00	The pharmacy has a designated person(s) to oversee the handling of HDs who is qualified and trained for development of standard operating procedures (SOPs); overseeing compliance with standards, laws, and rules; ensuring competency of personnel; and ensuring environmental control.		
HD 9.01	The designated person oversees the monitoring of the facility, including testing/sampling programs, maintaining, and documentation, and acting on results.		
HD 10.00	The assessment of risk and SOPs for handling HDs addresses all potential types of exposure, including all activities occurring within the operation that present an opportunity for exposure:		
HD 10.01	Receiving: Contacting HD residues on packaging, work surfaces, floors		
HD 10.02	Dispensing: Counting or packaging tablets and capsules		
HD 10.03	Compounding/other manipulations: Crushing/splitting tablets, opening capsules, pouring liquids, weighing, or mixing, constituting/reconstituting powdered/lyophilized HDs, expelling air from HD syringes, HD residue on personal protective equipment (PPE), cleaning activities of HD areas, and HD equipment maintenance.		
HD 10.05	Spills: Spill generation, management, and disposal.		
HD 10.06	Transport		
HD 10.07	Waste: Collection and disposal of HD waste and trace contaminated waste		
BB	**Standard Operating Procedures**		
HD 11.00	SOPs are reviewed at least every 12 months by the designated person, and the review is documented		
HD 12.00	SOPs are readily available to all who may need to handle HD or respond to a spill (pharmacy employees, housekeeping, nursing personnel, delivery personnel, etc.). Describe whether P&Ps are available electronically, by paper, or both.		

Item #	Requirement	Yes/No/N/A	Comment
CC	**Hazard Communication Program**		
HD 15.00	The pharmacy's hazard communication program includes, at a minimum, all the following:		
HD 15.06	Personnel of reproductive capability confirm in writing that they understand the risks of handling HDs.		
DD	**Hazardous Drug Training**		
HD 16.00	All personnel handling HDs are trained based on their job function prior to independently handling HDs.		
HD 20.00	After initial HD training, personnel are trained prior to introduction of any new HD or new equipment, or prior to any significant change in process or SOP.		
HD 21.00	All HD training and assessments are documented for each employee who transports, compounds, or administers HDs, and meets Occupational Safety and Health Administration Standard 1910.120 and any other requirements of law or regulation.		
HD 22.00	All personnel who perform custodial HD waste removal and cleaning in HD handling areas are trained in appropriate procedures to protect themselves and the environment.		
HD 23.00	HD training, based on employee file review, all the following are present:		
HD 23.01	Overview of pharmacy's HD list and their risks;		
HD 23.02	Review of the SOPs related to HDs;		
HD 23.03	Proper use of PPE;		
HD 23.04	Proper use of equipment and devices (e.g., engineering controls);		
HD 23.05	Appropriate procedures for deactivation, decontamination, cleaning, and disinfection (if applicable);		
HD 23.07	Spill management;		
HD 23.08	Proper disposal of HDs and trace-contaminated materials; and		
HD 23.09	New HD drug/new equipment or prior to any significant change in process or SOP.		
HD 24.00	If respiratory protection is needed for any HDs handled, personnel are fit tested and trained in the proper use of the respirator.		
HD 26.00	Appropriate PPE is readily accessible where HD is handled, include all the following:		
HD 26.01	Receipt (PPE appropriate to HD as set forth in SOPs, and at a minimum, chemotherapy gloves worn);		
HD 26.02	Storage;		

Item #	Requirement	Yes/No/N/A	Comment
DD	**Hazardous Drug Training**		
HD 26.03	Transport;		
HD 26.07	Deactivation/decontamination, cleaning, and disinfecting (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted/addressed in SOPs);		
HD 26.08	Spill control;		
HD 26.09	Waste disposal; and		
HD 27.00	Disposable PPE is not reused.		
HD 28.00	Reusable PPE is decontaminated and cleaned after each use.		
EE	**Gloves**		
HD 29.00	The pharmacy is using appropriate gloves for the activities conducted (chemotherapy gloves meet ASTM standard D6978 -- or its successor -- and are resistant to cleaning agents used) and are resistant to cleaning agents used.		
HD 29.01	Recommendation: Are chemotherapy gloves worn for handling all HDs including non-antineoplastics and for reproductive risk only HDs?		
HD 29.02	Chemotherapy or hazardous handling gloves are powder-free.		
HD 29.03	Chemotherapy or hazardous handling gloves are inspected for physical defects before use and defective gloves (e.g., pin holes, tears, weak spots) are discarded		
HD 29.05	Chemotherapy or hazardous handling gloves are changed when torn, punctured, or contaminated.		
HD 29.06	Recommendation: Are chemotherapy or hazardous handling gloves changed every 30 minutes (unless otherwise recommended by the manufacturer)?		
HD 29.07	Hands are washed with soap and water after removing chemotherapy or hazardous handling gloves.		
FF	**Gowns & Garb: Personal Protection Equipment (PPE)**		
HD 30.00	The pharmacy is using appropriate gowns for the activities conducted (if required for type of compounding based on standards or assessment of risk).		
HD 30.01	Gowns are disposable.		
HD 30.02	Gowns resist permeability of HDs and are not laboratory coats, surgical scrubs, or isolation gowns (selected based on HDs handled).		
HD 30.03	Gowns close in the back, are long sleeved, and have closed cuffs that are elastic or knit.		

Item #	Requirement	Yes/No/N/A	Comment
FF	**Gowns & Garb: Personal Protection Equipment (PPE)**		
HD 30.04	Gowns do not have seams or closures that will allow HDs to pass through.		
HD 30.05	Gowns are changed in accordance with the manufacturer's instructions, or if no permeation information is available, they are changed every two to three hours or immediately after a spill or splash.		
HD 30.06	Gowns worn in HD areas are not worn in other areas.		
HD 31.00	Head, hair (beard and moustache, if appropriate), and shoe and sleeve covers. The pharmacy is using appropriate head, hair, and shoe and sleeve covers for the type of compounding based on standards or assessment of risk to provide protection from contact with HD residue, if required.		
HD 31.01	When HD compounding, a second pair of shoe covers are donned before entering the C-SEC and doffed when exiting the C-SEC.		
HD 31.02	Shoe covers worn in HD areas are not worn in other areas of the facility.		
GG	**Eye and Face Protection**		
HD 32.00	The pharmacy is using appropriate eye and face PPE protection for the activities conducted (based on assessment of risk that HDs are irritating to the eyes and mucous membranes, where there is risk of spills or splashes when working outside of a C-PEC), if required.		
HD 32.01	If a risk to eyes, goggles (or a full-face respirator) are worn. Eyeglasses or safety glasses with side shields are not substituted for goggles.		
HD 32.02	If a risk to face and eyes, goggles plus a face shield (or a full-face respirator) are worn.		
HH	**Respiratory Protection**		
HD 33.00	The pharmacy is using appropriate respiratory PPE protection for the activities conducted (receiving, transport, compounding, administration, and waste disposal) based on assessment of risk based on type of HD and type of activity, if required. Indicate what type of PPE which is available to employees (and is fit tested, when required		
HD 34.00	Surgical masks are not used as PPE when respiratory protection is needed.		

Item #	Requirement	Yes/No/N/A	Comment
HH	**Respiratory Protection**		
HD 35.00	The pharmacy uses an appropriate respiratory PPE for large HD spills; deactivating, decontaminating, and cleaning underneath the work surface of the C-PEC; and when there is known or suspected airborne exposure to powders or vapors.		
HD 36.00	Surgical masks are not used as PPE when respiratory protection is needed.		
II	**Disposal of Personal Protective Equipment (PPE)**		
HD 37.00	Is all PPE worn during handling of HDs considered contaminated with at least trace quantities?		
HD 37.01	Worn PPE is placed in an appropriate HD waste container.		
HD 37.02	The HD waste container is in reasonable proximity to HD PPE doffing activities.		
HD 37.03	Chemotherapy or hazardous handling gloves, and sleeve covers if worn, are carefully removed, and discarded immediately into an approved HD trace waste container inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC.		
HD 38.00	There are signs prominently displayed before the entrance to all HD handling areas designating the hazard.		
HD 38.01	Access to these areas is restricted to authorized personnel who have been appropriately trained.		
HD 38.02	HD areas are located away from breakrooms/refreshment areas for personnel, patients, and/or visitors.		
HD 39.00	There are designated HD areas for any of the following:		
HD 39.01	Receiving and unpacking of HDs		
HD 39.02	Storage of HDs		
HD 40.00	Recommendation: If there is a requirement for certain designated areas to have negative pressure from surrounding areas, is there an uninterrupted power source (UPS) to the ventilation systems to maintain negative pressure in the case of power loss?		
JJ	**Receipt of Hazardous Drugs**		
HD 41.00	Are HDs received and unpacked (removed from external shipping containers) in an appropriate environment?		
HD 41.01	Antineoplastics and HD APIs are unpacked in an area with air pressure relative to surrounding areas that is either neutral or negative pressure. Indicate the type of environment. If the environment is positive pressure, it is non-compliant.		

Item #	Requirement	Yes/No/N/A	Comment
JJ	**Receipt of Hazardous Drugs**		
HD 42.00	HDs are not unpacked in a sterile compounding area (e.g., no external containers are brought into C-SEC).		
KK	**Storage of Hazardous Drugs**		
HD 43.00	Are HDs stored in a manner to minimize accidental exposure? Describe.		
HD 43.01	HDs are not stored on the floor.		
HD 43.02	HDs are stored in a manner to minimize breakage and spillage.		
HD 43.03	If the facility is in an area prone to specific types of natural disasters, appropriate precautions are taken (e.g., raised front lips on shelving in earthquake prone areas).		
HD 44.00	Antineoplastic HDs that require manipulation (other than counting and repackaging final dosage forms) and HD API are stored separately from non-HDs.		
HD 44.01	These HDs are stored in an externally ventilated, negative pressure room.		
HD 44.02	The HD storage room has at least 12 air changes per hour (ACPH).		
HD 44.03	Refrigerated antineoplastic HDs are stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH (e.g., storage room, buffer room, or containment segregated compounding area [CSCA]).		
HD 45.00	If non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastics are stored with another non-HD inventory, there is a written policy/SOP addressing it.		
LL	**Compounding Environment**		
HD 46.00	There are appropriate engineering controls to protect the HD preparation from cross-contamination, during all phases of the compounding process.		
HD 47.00	All non-sterile HD compounding is performed within a C-PEC designated for non-sterile compounding and located in a designated non-sterile C-SEC room.		
HD 47.01	The C-SEC for non-sterile HD compounding has all the following:		
HD 47.01.01	Has fixed walls;		
HD 47.01.02	Is externally vented;		
HD 47.01.03	Can meet (12) or exceed ACPH requirements;		
HD 47.01.04	Is physically separated (i.e., a different room) from other preparation areas; and		

Item #	Requirement	Yes/No/N/A	Comment
LL	**Compounding Environment**		
HD 47.01.05	Has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to all adjacent areas.		
HD 48.00	The C-PEC operates continuously if it supplies some or all the negative pressure in the C-SEC.		
HD 49.00	There is a sink readily available for handwashing on the hazardous side.		
HD 49.01	There is an eyewash station readily available.		
HD 49.02	Water sources and drains are a minimum of 1 meter away from the C-PEC.		
HD 54.00	The ceilings, walls, floors, fixtures, shelving, counters, and cabinets are smooth, impervious, free from cracks and crevices, and non-shedding. If non-compliant describe.		
MM	**Delivery and Packing/Unpacking of Hazardous Drugs**		
HD 64.00	HDs are delivered to the HD storage area immediately after unpacking.		
HD 65.00	A spill kit is readily accessible in the receiving area.		
HD 66.00	Containers are visually examined for signs of damage or breakage prior to opening.		
HD 67.00	If a shipping container appears damaged and does not need to be opened, it is sealed, enclosed in an impervious container, labeled "hazardous" on the outside, and returned to the supplier after contact or disposed of as hazardous waste.		
HD 67.01	If a damaged shipping container must be opened, it is done so according to SOPs, to include sealing the container in plastic or an impervious container, transporting it to the C- PEC for unpacking, removing, and wiping the outside of the undamaged items with disposable wipes, resealing the damaged items in an impervious container and marking it "hazardous," returning it to the supplier after contact or disposing as hazardous waste, and deactivating, decontaminating, and cleaning the C-PEC.		
HD 68.00	Damaged packages are considered spills and reported to the designated person. List last date of damaged package receipt.		
HD 69.00	HDs requiring special HD handling are always clearly labeled as hazardous during transport and in accordance with any laws related to labeling of HDs.		
HD 70.00	Labeling processes do not introduce contamination into non-HD handling areas.		

Item #	Requirement	Yes/No/N/A	Comment
MM	**Delivery and Packing/Unpacking of Hazardous Drugs**		
HD 71.00	Packaging materials are chosen that protect the HD and healthcare worker against damage, leakage, contamination, and degradation during transport, but also maintains the physical integrity, stability, and sterility of the HD.		
HD 72.00	Pneumatic tubes are not used for transporting any liquid HDs or antineoplastic HDs.		
HD 73.00	Labeling on HDs shipped outside the pharmacy meets all the following requirements:		
HD 73.01	Labeling specified in SDS for transport;		
HD 73.02	Storage and disposal instructions; and		
HD 73.03	Labeled with HD category.		
HD 74.00	Counting of antineoplastics is done by hand (e.g., not placed into automated counting devices).		
HD 75.00	Clean, dedicated (not used for non-HD purposes), or disposable equipment is used for counting, packaging, and compounding of HDs.		
HD 76.00	APIs or other powdered HDs are handled in a C-PEC during particle generating activities, such as crushing, opening capsules, and weighing powders		
NN	**Deactivation, Decontamination, Cleaning and Disinfection (DDCD)**		
HD 77.00	The pharmacy has chosen appropriate oxidizing agent(s) for deactivation and decontamination and proven effective by testing.		
HD 78.00	Wipes or other appropriate delivery mechanisms (e.g., not a spray bottle) are used for deactivation and decontamination.		
HD 79.00	Is the C-PEC decontaminated at the appropriate intervals?		
HD 79.01	Between compounding of different HDs		
HD 79.02	At least daily when used		
HD 79.03	Any time a spill occurs		
HD 79.04	Before and after certification		
HD 79.05	Any time voluntary interruption occurs		
HD 79.06	If the ventilation tool is moved		
HD 80.00	HD containers are wiped down prior to placing them in the C-PEC and the solution used does not alter the product label.		

Item #	Requirement	Yes/No/N/A	Comment
NN	**Deactivation, Decontamination, Cleaning and Disinfection (DDCD)**		
HD 81.00	Areas other than the work surface of the C-PEC, where contamination can build up (such as areas under the work tray), are deactivated, decontaminated, and cleaned at least monthly.		
HD 82.00	Additional PPE (e.g., respirator) is used in accordance with SOPs, to protect the worker if containment airflows are compromised by opening the cabinets to get to these areas.		
HD 83.00	Spills are contained and cleaned immediately.		
HD 84.00	Trained/qualified personnel are always available during operation with HDs to handle spills.		
HD 85.00	Only trained/qualified personnel engage in spill containment and cleanup.		
HD 86.00	There are signs available to restrict access to spill areas.		
HD 87.00	Spill kits, containing all ingredients necessary to clean HD spills, are readily available in all areas where HDs are routinely handled.		
HD 88.00	Spill materials are disposed of as hazardous waste.		
HD 89.00	The circumstances and management of all spills are documented. Review documentation		

USP 800 Comments:

Additional Comments:

Plan of Correction Issued: ☐ Yes ☐ No

If yes, I will provide a plan of correction for all findings within 15 business days. **Due Date**: _____

Inspector: _____ **Date:** _____

Inspector: _____ **Date:** _____

Inspector: _____ **Date:** _____

Inspector: _____ **Date:** _____