National Association of Boards of Pharmacy®	West Virginia Board of Pharmacy
New/Remodel Inspection Form – Indicate type below:	1207 Quarrier Street, Fourth Floor
☐**New** Sterile Compounding Facility Inspection	Charleston, WV 25301
☐Sterile Compounding **Remodel** Inspection* ***Only items marked are required.**	Phone: 304-558-0558 Fax: (304)-558-0573

Pharmacy e-Profile ID: if available			**Inspection Information**
Legal Business Name:		**Day 1:**	
Doing Business As (DBA):		**Start Time: 24-hour format (13:00)**	
Address:		**End Time: 24-hour format (13:00)**	
City:		**Day 2:**	
State:		**Start Time: 24-hour format (13:00)**	
Zip Code:		**End Time: 24-hour format (13:00)**	
Telephone number:		**Inspector Name:**	
Toll free number:		**Inspection Performed by (NABP, State, etc):**	West Virginia Board of Pharmacy
Fax number:		**Observer Name/Affiliation (if applicable):**	
Website:		**Observer Name/Affiliation (if applicable):**	

Pharmacy Hours of Operation	**Check if 24/7 ☐**		
	Open		**Closed**
	Start Time: (24-hour format)	**End Time: (24-hour format)**	**(X)**
Sunday			
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			

Key Pharmacy Personnel	**Name**	**Contact (e-mail)**	**e-Profile ID**
Pharmacist in Charge			
Nonsterile Compounding Supervisor			
Sterile Compounding Supervisor			
Hazardous Compounding Supervisor			

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

If more than 10, list the first 10 above, then list the title and number (e.g.: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc.) for the additional personnel present.

Business Licensure Information for State of Residence and Federal board of pharmacy, state-controlled substance, DEA, FDA, etc.)

License/Registration Agency	Business Name on License/Registration	License Type/Number	Expiration Date
West Virginia Board of Pharmacy			
Drug Enforcement Administration			

Inspector Notes: List states in which Non-Resident licenses are held

Attachments
(NO PHI, including prescription numbers)

Attachment Name	Description

	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail	☐	Telepharmacy	☐
Open to the Public	☐	Central Fill/Processing/Shared Services	☐
Closed Door	☐	Specialty Pharmacy	☐
Drive-through window	☐	Handles Medical Marijuana	☐
Mail/Deliver (in state)	☐	Nuclear Pharmacy	☐
Mail/Deliver (out-of-state list below)	☐	Manufacturer	☐
Veterinary Pharmacy	☐	Wholesale Distributor	☐
Investigational Drugs, Clinical Trials/Research	☐	Provide products for "Office Use"	☐
Institutional	☐	Outsourcing Facility	☐
Long-Term Care	☐	Nonsterile Compounding	☐
HMO/PBM only	☐	Nonsterile Hazardous Drug Compounding	☐
Internet Pharmacy (New Rx)	☐	Sterile Compounding	☐
Internet Pharmacy (Refill Rx)	☐	Sterile Hazardous Drug Compounding	☐
Facility Size in Square Feet and Number of PECs		**Personnel**	
Total Pharmacy size:		Total Pharmacists:	
Nonsterile Compounding Room size:		Number of Compounding Pharmacists	

Nonsterile Compounding powder hoods number:		Total Graduate Students or Residents:	
Nonsterile Hazardous Drugs (HD) Compounding Room size:		Total Student Interns:	
Nonsterile HD Compounding BSC/CACI hoods number:		Total Technicians:	
Sterile Compounding Ante Room size:		Number of Compounding Technicians	
Sterile Compounding Clean/Buffer Room size:		Of technicians, how many are certified?	
Sterile Compounding Number LAFW hoods/areas:		Of technicians, how many are techs-in-training?	
Sterile Compounding Number BSC hoods:		Total Other Licensed Personnel:	
Sterile Compounding Number CAI/CACI hoods:		Total Other Unlicensed Personnel:	
Negative Pressure Sterile HD Room size:		Ratio #tech: #RPh present at time of inspection:	
Sterile HD Compounding Number of BSC hoods:		Total Pharmacist Hours Per Week:	
Sterile HD Compounding Number of CACI hoods:		Total Technician Hours Per Week:	

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Sterile Compounding Inspection for USP <797>

Facility Name:
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	Observation *Remodel questions begin at 2.4 and end at 34.0	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
	Standard Operating Procedures (SOPs) for Compounded Sterile Preparations (CSPs)						
1.0	Does the pharmacy have a designated person(s) who meets the requirements in compliance with USP <797> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals (ie, the designated person(s)) to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and for performing other functions."***	☐	☐	☐	☐		1.1.3, 2
1.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	☐	☐	☐	☐		18
1.2	The designated person(s) is responsible and accountable for the performance and operation of the facility. ***Per USP, "The designated person(s) is responsible for ensuring that each area related to CSP preparation meets the classified air quality standard appropriate for the activities conducted in that area. The designated person(s) must also ensure that the ISO Class 5 areas are located, operated, maintained, monitored, and certified to have appropriate air quality."***	☐	☐	☐	☐		2, 4.2, 4.5
1.3	The designated person(s) is responsible for personnel performing sterile compounding or other related functions (e.g., quality checks and prescription dispensing of compounded preparations).	☐	☐	☐	☐		2, 17
1.4	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented.	☐	☐	☐	☐		2, 17
1.5	The designated person(s) ensures that SOP revisions are implemented.	☐	☐	☐	☐		2, 17

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
1.6	The designated person(s) communicates all SOP revisions to all impacted personnel. ***Inspector note: USP <797> recommends that personnel should also document acknowledgment and communication of SOP changes and revisions.***	☐	☐	☐	☐		2, 17
1.7	The designated person(s) ensures that personnel demonstrate competency in performing every procedure that relates to their job function.	☐	☐	☐	☐		2, 17
1.8	The designated person(s) ensures that corrective actions are taken if problems, deviations, out-of-range results, failures, or errors are identified. ***Inspector note: Per USP, "Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective."***	☐	☐	☐	☐		2, 5, 12
2.0	Has the pharmacy developed and implemented SOPs that describe sterile compounding processes and other support activities in compliance with USP <797> standards? ***Inspector note: In order for this to be answered yes, all topics must be addressed if applicable to their business practices.***	☐	☐	☐	☐		17
2.1	**Scope of Practice:** Types of CSPs that are prepared (e.g., immediate use, allergenic extracts, Category 1, Category 2, Category 3). Roles and responsibilities of the designated person(s).	☐	☐	☐	☐		1.5
2.2	**Personnel Training and Evaluation:** Description of initial and ongoing training and competency for the designated person(s), compounding personnel, personnel with direct oversight of compounding personnel, and personnel who only perform restocking or cleaning, and disinfecting duties outside of the primary engineering control (PEC). Description of media-fill testing procedures, hand hygiene and garbing competency, and aseptic manipulation competency. Training and competency assessment of personnel on all sterilization methods and equipment used by the facility. Frequency of training is defined.	☐	☐	☐	☐		2, 2.2, 10 Box 1, Box 2, Table 2, Table 3

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
2.3	**Personal Hygiene and Garbing:** Description of the required garb, manner of storage, and order of garbing, including disinfection procedures for reusing goggles, respirators, and other reusable equipment. ***Inspector note: Per USP, the RABS (or pharmaceutical isolator) sleeve and glove changes should (not required) be changed per the manufacturer's recommendations and defined in the facility's SOPs.***	☐	☐	☐	☐		3, 3.3
* 2.4	**Facility Design and Engineering Controls:** Description of design requirements to maintain air quality standards and procedures for evaluating, maintaining, and certifying the areas used for compounding.	☐	☐	☐	☐		4, 4.2
* 2.5	**Certification and Recertification:** Description of sampling sites and procedures.	☐	☐	☐	☐		5, 5.1
* 2.6	**Microbiological Air and Surface Monitoring:** Description of the pharmacy's microbiological air and surface monitoring program which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (eg, surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that will trigger corrective actions and documentation requirements.	☐	☐	☐	☐		6, 6.1, 6.2, 6.3
2.7	**Cleaning, Disinfection, and Application of Sporicidal Disinfectants and Sterile 70% IPA:** Description of procedures for cleaning, disinfecting, and applying sporicidal disinfectants and include the frequency, methods, locations of cleaning, and documentation requirements.	☐	☐	☐	☐		7, 7.2 Box 7, Box 8
* 2.8	**Equipment:** Description of procedures for the calibration, maintenance, cleaning, use of the equipment, and documentation requirements.	☐	☐	☐	☐		9.1, 10, 20
2.9	**Components:** Description of procedures that address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components, including all ingredients and container closures.	☐	☐	☐	☐		9.3

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
2.10	**Master Formulation and Compounding Records:** Description of procedures for developing and maintaining MFRs and required information, documentation, and record-keeping requirements for MFRs and CRs.	☐	☐	☐	☐		11.1, 11.2, 20
2.11	**Release Inspections and Testing:** Description of release testing procedures (e.g., visual inspections and/or sterility and endotoxin testing), out-of-specification procedures, corrective action procedures, and documentation requirements.	☐	☐	☐	☐		12, 18, 20
2.12	**Labeling:** Procedures for labeling and label verification (confirming against the prescription or medication order, the MFR, and the CR) in order to prevent errors, CSP mix-ups, and required displayed information.	☐	☐	☐	☐		13
2.13	**CSP handling, storage, packaging, shipping, and transport:** Processes and techniques for handling, storing, packaging, and transporting CSPs that include temperature monitoring, excursions, shipping containers, packaging requirements, and selected transportation modes.	☐	☐	☐	☐		19
2.14	**Documentation:** Record keeping requirements and procedures for documentation maintenance and storage. ***Inspector note: USP requires readily retrievable records for two years; however, it is acknowledged that state or accreditation organizations may require records for a longer period of time.***	☐	☐	☐	☐		20
* 2.15	**Sterilization and Depyrogenation:** Description of methods used for establishing and verifying the effectiveness of the terminal sterilization and depyrogenation methods selected, as well as the methods for maintaining and cleaning the sterilizing and depyrogenation equipment. ***If not applicable to their business practices, Inspector should answer statement as N/A.***	☐	☐	☐	☐		10

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
2.16	**Immediate Use CSPs:** Description of processes followed to meet all conditions of exemption from the requirements for Category 1, Category 2, and Category 3 CSPs. ***If not applicable to their business practices, Inspector should answer statement as N/A.***	☐	☐	☐	☐		1.3
2.17	**Blood/Biological Handling:** Description of processes used to avoid cross-contamination and meet applicable regulatory requirements. ***If not applicable to their business practices, inspector should answer statement as N/A.***	☐	☐	☐	☐		1.1.2
2.18	**Allergenic Extracts:** Description of procedures for training, competency assessments, personnel hygiene and garbing, facility requirements, cleaning and disinfecting, beyond use dates (BUDs), labeling, storage, shipping and transporting, and documentation. ***If applicable to their business practices, please complete the Allergenic Extracts module.*** ***If not applicable to their business practices, inspector should answer statement as N/A.***	☐	☐	☐	☐		21
	CSPs - Immediate Use, Proprietary Vial/Bag Systems, and Blood-Derived						1
3.0	Does the pharmacy prepare and dispense compounded sterile preparations for direct and immediate use?	☐	☐	☐	☐		1.3
4.0	Does the pharmacy meet all conditions specified in USP <797> for CSPs compounded for direct and immediate use? ***Inspector note: Per USP <797>, all conditions must be met to qualify for exemptions of the requirements for Category 1, Category 2, and Category 3 CSPs.***	☐	☐	☐	☐		1.3

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
4.1	Aseptic techniques, processes, and procedures are followed. ***Inspector note: Per USP <797>, facility SOPs must describe procedures followed "to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs."***	☐	☐	☐	☐		1.3
4.2	Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs. ***Review personnel records to verify.***	☐	☐	☐	☐		1.3
4.3	Preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs. ***Inspector note: Examples of this include approved labeling and/or published or unpublished stability and compatibility studies.***	☐	☐	☐	☐		1.3
4.4	Preparation involves not more than three (3) different sterile products (e.g., ingredients and/or components in a single container).	☐	☐	☐	☐		1.3
4.5	Unused components from a single-use container are discarded after the preparation for one individual patient is complete (i.e., single-dose containers are not used for more than one patient).	☐	☐	☐	☐		1.3
4.6	Administration begins within four hours of the start of the preparation, and if not, the preparation is discarded. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***	☐	☐	☐	☐		1.3

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
4.7	Unless the person preparing the preparation is administering or witnessing administration, the preparation is labeled with names and amounts of all active ingredients, name or initials of preparer, and exact four-hour time period in which administration must begin. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***	☐	☐	☐	☐		1.3
5.0	Does the pharmacy prepare proprietary bag and vial systems (ex. addEASE, ADD-Vantage, Mini Bag Plus, Vial2Bag) in compliance with USP <797> standards? ***Inspector note: Docking and activation of proprietary bag and vial systems for immediate administration to an individual patient is out of scope of USP <797> and may be performed outside of an ISO Class 5 environment.*** ***If no, go to the compliance statements.*** ***If the pharmacy does not stock, prepare, and/or dispense any proprietary vial and bag systems, inspector should answer statement as N/A.***	☐	☐	☐	☐		1.4
5.1	Docking for *future activation* and administration is performed in an ISO Class 5 environment and in accordance with requirements of USP <797>, with the exception of BUD assignment.	☐	☐	☐	☐		1.4
5.2	BUD assignment is not longer than specified in the manufacturer's labeling.	☐	☐	☐	☐		1.4
6.0	Does the pharmacy meet the conditions specified in USP <797> for CSPs to be prepared per approved labeling? ***Inspector note: Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's approved labeling is considered outside the scope of the USP chapter.*** ***If the pharmacy only compounds sterile preparations (e.g., does not prepare sterile preparations that strictly adheres to the conventionally manufactured approved labeling for preparation), inspector should answer statement as N/A.***	☐	☐	☐	☐		1.4

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
6.1	The product is prepared as a single dose for an individual patient.	☐	☐	☐	☐		1.4
6.2	The approved labeling includes information for the diluent, the resultant strength, the container closure system, and the storage time.	☐	☐	☐	☐		1.4
7.0	Does the pharmacy perform compounding activities that require the manipulation of a patient's blood-derived or other biological material (e.g., autologous serum)?	☐	☐	☐	☐		1.1.2
8.0	For compounding activities that require the manipulation of a patient's blood-derived or other biological material, does the pharmacy perform manipulations that are clearly separated from other compounding activities and equipment used in CSP preparation activities and are controlled by specific SOPs to avoid any cross-contamination? ***Inspector note: Per USP, a separate cart could be used for blood-derived or other biological materials (a separate area is not required by the chapter). Pharmacy should change garb. Pharmacy to have cleaning processes as part of SOPs to avoid cross-contamination.*** ***If the pharmacy does not compound with blood products or other biological materials, inspector should answer statement as N/A. If the inspector answers the compliance question as "no", please describe your observations.***	☐	☐	☐	☐		1.1.2
	Facility Design and Engineering Controls						**4**
* 9.0	**Segregated Compounding Area (SCA):** Does the pharmacy use an SCA as an SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP, only Category 1 CSPs may be compounded in a SCA.*** ***If pharmacy only uses a cleanroom suite for sterile compounding preparations, inspector should answer question as N/A.***	☐	☐	☐	☐		4.1, 4.1.1, 4.1.2, 4.2.1 Table 5

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
* 9.1	The facility is designed to afford a well-lighted and comfortable working environment.	☐	☐	☐	☐		4.2, 4.2.1
* 9.2	Only Category 1 CSPS are prepared in a SCA. ***If pharmacy is compounding Category 2 or Category 3 CSPs in a SCA, inspector should answer this statement as no and collect photographs and copies of the MFR, CR, and provide a description of their observations in the Inspector Notes.***	☐	☐	☐	☐		4.2.1, 4.2.3 Table 5
* 9.3	The SCA is located away from unsealed windows, doors that connect to outdoors, and traffic flow. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***	☐	☐	☐	☐		4.2.1
* 9.4	The SCA is located away from environmental control challenges and separate from areas not related to compounding (i.e., restrooms, warehouses, food preparation areas).	☐	☐	☐	☐		4.2.1
* 9.5	A visible perimeter establishes the boundaries of the SCA. ***Inspector note: Per USP, the SCA is defined as "a designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only." USP further defines a perimeter as "a visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA." The perimeter will be defined in the pharmacy's SOPs. Tape or an alternative method may be used to define this visible perimeter, since this is not a classified space.***	☐	☐	☐	☐		4.2.1 Glossary
* 9.6	Access to the SCA is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning.***	☐	☐	☐	☐		4.2.1
* 9.7	Free-standing humidifiers/dehumidifiers and air conditioners are not located within the perimeter of the SCA.	☐	☐	☐	☐		4.2

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
* 9.8	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in the compounding area. ***Inspector note: Per USP, these items should be low-shedding, easily cleaned, and disinfected. This applies to items within the perimeter around the Primary Engineering Control (PEC).***	☐	☐	☐	☐		4.5
* 9.9	Shipping cartons or other corrugated or uncoated cardboard are not allowed in the SCA.	☐	☐	☐	☐		4.5
* 9.10	The SCA and all surfaces (walls, floors, counters, equipment) are clean, uncluttered, and dedicated tocompounding.	☐	☐	☐	☐		4.2.1, 4.3.2
* 9.11	The sink is located inside the SCA or in close proximity and is located at least one meter away from thePEC.	☐	☐	☐	☐		4.4
* 9.12	The area within one meter of the PEC is dedicated only for sterile compounding (eg, not storage, hand hygiene, donning and doffing garb, or other highly particle-generating activities, such as patient care).	☐	☐	☐	☐		4, 4.2.1
* 9.13	If overhangs or ledges are present in the SCA, are they easily cleanable? ***If no, describe observations in Inspector Notes.***	☐	☐	☐	☐		4.2.1, 4.3.2
10.0	Are surfaces smooth, impervious, free from cracks and crevices, and non-shedding so they can be cleaned and disinfected? ***Inspector note: this is a recommendation by USP.*** ***If no, describe in comments Inspector Notes (eg, peeling of Formica countertops).***	☐	☐	☐	☐		4.3.2
11.0	Are surfaces resistant to damage from cleaning, sanitizing, and sporicidal agents used? ***Inspector note: this is a recommendation by USP.*** ***If no, describe in comments inspector observations (i.e., observed rust on preparation cart or flaking of particle board on shelving).***	☐	☐	☐	☐		4.2.1, 4.3.2

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
* 12.0	**Cleanroom Suite:** Does the pharmacy use a Cleanroom Suite (ISO-classified anteroom and buffer room) as a SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP <797>, a cleanroom suite is required if compounding any Category 2 and Category 3 CSPs.*** ***If pharmacy only uses an SCA for Category 1 CSPs, inspector should answer question as N/A.***	☐	☐	☐	☐		4.1, 4.1.1, 4.1.2, 4.2.1, 4.3.1 Table 5
* 12.1	Access to the cleanroom suite is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning. Some examples pharmacies may use to demonstrate compliance with this statement (but are not specifically required by the chapter) include posting a sign or creating a badge access point for authorized personnel to enter the cleanroom suite.***	☐	☐	☐	☐		4.2.1
* 12.2	The facility is designed to afford a well-lit environment.	☐	☐	☐	☐		4.2, 4.2.1
* 12.3	The facility provides a comfortable working environment (e.g., temperature and humidity settings so appropriate garb can be donned).	☐	☐	☐	☐		4.2.1
* 12.4	The anteroom and buffer room are separated from surrounding unclassified areas by fixed walls and doors.	☐	☐	☐	☐		4, 4.2.1
12.5	Controls are in place to minimize the flow of lower-quality air into the more-controlled areas. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***	☐	☐	☐	☐		4.2.1
* 12.6	Anterooms providing access to only positive pressure buffer rooms meet at least ISO Class 8 specifications. ***If the pharmacy has a negative pressure room, inspector should answer statement as N/A.***	☐	☐	☐	☐		4.1.2, 4.2.1

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
* 12.7	The anteroom provides access to a negative pressure room and meets at least ISO Class 7 specifications. ***If the pharmacy does not compound hazardous drugs, inspector should answer statement as N/A.***	☐	☐	☐	☐		4.1.2, 4.2.1
* 12.8	The buffer room, where the PEC is placed, meets ISO Class 7 or better air quality specifications. ***Inspector note: If the PEC is a pharmaceutical isolator, the buffer room must be at least ISO Class 8 air quality or better and an anteroom is not required.*** ***Per USP <797>, a pharmaceutical isolator is defined as an enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. A CAI or CACI is not a pharmaceutical isolator.***	☐	☐	☐	☐		4.1.2, 4.2.1, 4.2.3
* 12.9	Air supply to the anteroom and buffer room is introduced through HEPA filters in the ceiling.	☐	☐	☐	☐		4.2.1
* 12.10	Air returns are located low on the wall. ***If the pharmacy has a visual smoke study (as described in the USP chapter and compliance statement below), inspector should answer statement as N/A.***	☐	☐	☐	☐		4.2.1
* 12.11	A visual smoke study demonstrates an absence of stagnant air where particles can accumulate and is repeated if any equipment/placement changes when air returns are not located low on the wall. ***Inspector note: Per USP, "the smoke study, along with environmental monitoring, must be repeated whenever a change is made to the placement of equipment within the room or any other alteration is performed within the cleanroom suite that affects the quality of the air (e.g., HVAC alterations, chapter of HEPA filter units)."*** ***If air returns are low on the wall, inspector should answer statement as N/A.***	☐	☐	☐	☐		4.2.1
* 12.12	The anteroom has a line of demarcation to separate the dirty side from the clean side or has two separate anterooms, a dirty anteroom and a clean anteroom. ***Describe observations for the type of line of demarcation in the Inspector Notes.***	☐	☐	☐	☐		4.2.1

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
* 12.13	Personnel enter the dirty side/room first from the unclassified area and the clean side/room is located closest to the buffer room.	☐	☐	☐	☐		4.2.1
* 12.14	All surfaces (ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets) are smooth, impervious, free from cracks and crevices, and non-shedding.	☐	☐	☐	☐		4.2.1, 4.3.1
* 12.15	Junctures between ceilings and walls and between the walls and floors are sealed.	☐	☐	☐	☐		4.2.1, 4.3.1
* 12.16	If the ceiling consists of inlaid panels, the panels are caulked to seal them to the support frame. ***If the ceiling does not consist of inlaid panels, inspector should answer statement as N/A.***	☐	☐	☐	☐		4.2.1, 4.3.1
* 12.17	Walls are constructed of, or covered with, a durable material (e.g., epoxy paint, heavy gauge polymer) and integrity of surface maintained.	☐	☐	☐	☐		4.2.1, 4.3.1
* 12.18	Walls, if paneled, are joined together and sealed to the support structure. ***If walls are not paneled, inspector should answer statement as N/A.***	☐	☐	☐	☐		4.2.1, 4.3.1
* 12.19	Floors include coving to the sidewall or the juncture between floor and wall is caulked.	☐	☐	☐	☐		4.2.1, 4.3.1
* 12.20	If overhangs or ledges are present, they are easily cleanable. ***If there are no overhangs, ledges, utility pipes, windowsills, etc., inspector should answer statement as N/A.***	☐	☐	☐	☐		4.2.1, 4.3.1
* 12.21	Exterior lens surfaces of the ceiling light fixtures are smooth, mounted flush, and sealed.	☐	☐	☐	☐		4.2.1, 4.3.1
* 12.22	All other penetrations through the ceiling or walls (e.g., camera domes) are sealed.	☐	☐	☐	☐		4.2.1, 4.3.1

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* 12.23	The buffer room does not contain plumbed water sources (e.g., sinks, eyewashes, showers, or floor drains).	☐	☐	☐	☐		4.4
* 12.24	The anteroom does not contain floor drains.	☐	☐	☐	☐		4.4
* 13.0	Are **PECs** used to prepare CSPs located in the appropriate space (e.g., buffer room or SCA) for category types prepared in compliance with USP <797> standards? ***Inspector to review certification reports and observe compounding area(s) to evaluate.***	☐	☐	☐	☐		4.2.1, 4.2.2, 4.2.3 Table 4, Table 5
13.1	All compounded sterile preparations (that are not for immediate use) are compounded in a PEC.	☐	☐	☐	☐		1.3, 4, 4.1.2
* 13.2	PEC is certified to maintain ISO 5 classification or better conditions during dynamic operating conditions. ***The inspector should only answer yes if the PEC has been certified within the past six months.***	☐	☐	☐	☐		4.2.2, 4.2.3, 5
* 13.3	The PEC is located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns inside the PEC. ***Review certification report.***	☐	☐	☐	☐		4, 4.2.2, 4.2.3
* 13.4	Placement of the PEC allows for cleaning around the PEC.	☐	☐	☐	☐		4.2.3
* 13.5	**Category 2 and Category 3**: PEC(s) are located in a cleanroom suite. ***If pharmacy only compounds Category 1 CSPs, inspector should answer this statement as N/A.***	☐	☐	☐	☐		4.2.3 Table 5

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14.0	Does the pharmacy have any CAIs/CACIs used for sterile compounded preparations? ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***	☐	☐	☐	☐		4.2.3 Table 5
* 15.0	Are **CAIs/CACIs** (RABS) used for compounding sterile preparations operated in compliance with manufacturer specifications **and** USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***	☐	☐	☐	☐		4.2.3
* 15.1	The documented recovery time is followed after opening the CAI/CACI transfer chamber to maintain ISO Class 5 air quality. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***	☐	☐	☐	☐		4.2.3
* 15.2	Staff ensure that adequate recovery time is allowed after closing the CAI/CACI during compounding operations. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***	☐	☐	☐	☐		4.2.3
* 15.3	Sterile gloves are worn over the gloves attached to the CAI/CACI sleeve. ***Inspector note: Per USP, if using a RABS (i.e., a CAI or CACI), disposable gloves should be (not required) worn inside the gloves attached to the RABS sleeves.***	☐	☐	☐	☐		3.3
* 16.0	Are there controls in place to minimize the influx of contaminants from materials (supplies and equipment) and personnel as they move from areas of lower quality to those of higher quality in compliance with USP <797> standards? ***Inspector note: An example of material movement from lower quality air to higher quality air includes movement from a non-classified area to an ISO Class 8 anteroom, ISO Class 8 anteroom to an ISO Class 7 buffer room, or from an ISO Class 7 buffer room to an ISO Class 5 PEC.***	☐	☐	☐	☐		4.5

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16.1	Before any item is introduced into the SEC, placed into the pass-through chamber, or brought into the SCA (providing that packaging integrity will not be compromised), it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% isopropyl alcohol (IPA) using low-lint wipers by personnel wearing gloves.	☐	☐	☐	☐		4.5
16.2	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use.	☐	☐	☐	☐		4.5
* 17.0	Does the pharmacy have the appropriate facility design and controls (including the fixtures, types of equipment, materials, and supplies that are stored) in the classified areas in compliance with USP <797> standards?	☐	☐	☐	☐		4, 9.1, 19.1
* 17.1	The sink used for hand hygiene, located outside of the anteroom, is placed in an appropriate area and clean space to minimize the risk of bringing contaminants into the anteroom. ***Inspector note: Inspector should evaluate the sink location in relation to the activities that occur where the sink is located as well as the distance between the sink and the entrance to the compounding suite/SCA. Examples that may not be considered appropriate include but are not limited to: sink is located in the bathroom, an adjacent suite or property, or in an employee breakroom where food is prepared.*** ***If the sink is located in the anteroom, inspector should answer statement as N/A.***	☐	☐	☐	☐		4.4
* 17.2	The sink used for hand hygiene, located inside of the anteroom, is placed in an appropriate area to minimize the risk of bringing contaminants into the buffer room. ***Inspector note: Inspector should evaluate the sink location in relation to the doors and compounding activities. For example, the sink is where compounders perform hand hygiene close to where garb is stored (where it can easily get wet/splashed).*** ***If the sink is located outside the anteroom, inspector should answer statement as N/A.***	☐	☐	☐	☐		4.4

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* 17.3	The doors into the anteroom from the general pharmacy area and from the anteroom into the clean/buffer room are prevented from both being open at the same time (e.g., by interlocking, training of personnel, or signage).	☐	☐	☐	☐		4.2.1
* 17.4	The inside and outside doors of a pass-through are prevented from both being open at the same time (e.g., by interlocking, training of personnel, or signage).	☐	☐	☐	☐		4.2.1
* 17.5	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. ***Inspector note: Per USP, items necessary for performing compounding activities are low-shedding and can be easily cleaned and disinfected.*** ***If no, describe the types of items that are observed. If appropriate, submit a photograph with inspection report.***	☐	☐	☐	☐		4.5, 9.1
* 17.6	Tacky mats are not used in the classified areas. ***Inspector note: Per USP <797>, "Tacky mats must not be placed within ISO-classified areas."***	☐	☐	☐	☐		4.2.1
* 17.7	Shipping cartons or other corrugated or uncoated cardboard are not permitted in the classified areas.	☐	☐	☐	☐		4.5
* 17.8	Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels.	☐	☐	☐	☐		4.5
* 17.9	Carts (including casters) are cleaned and disinfected prior to moving from the dirty side to the clean side of the anteroom.	☐	☐	☐	☐		4.5
* 18.0	Does the pharmacy's facility design for maintaining (e.g., recording, monitoring, and controlling) temperature and humidity (e.g., HVAC) comply with USP <797> standards? ***Inspector note: Compounded preparations that are finished and stored will be addressed in the general pharmacy module. Inspector should be aware that USP cleanroom temperature recommendations may not be harmonized with USP, FDA, or manufacturer/supplier temperature requirements for drug storage.***	☐	☐	☐	☐		4.2, 19.1 USP <659>

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
* 18.1	The compounding area temperature and humidity is maintained by a heating, ventilation, and air conditioning (HVAC) system. ***If inspector finds a free-standing air conditioner, humidifier, or dehumidifier within the classified area or the SCA, the inspector should answer statement as "No." Additionally, inspector should describe what they observed, where the equipment was located, and collect/submit photographs.***	☐	☐	☐	☐		4.2, 9.3.4, 19.1
* 18.2	The pharmacy records the temperature of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	☐	☐	☐	☐		4.2, 9.3.4, 19.1
* 18.3	The pharmacy records the humidity of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of humidity recording in the notes.***	☐	☐	☐	☐		4.2, 9.3.4, 19.1
* 18.4	The pharmacy maintains records of temperature and humidity that are specific to the cleanroom suite. ***Temperature and humidity for drug storage areas will be documented in the general pharmacy module.*** ***If the pharmacy only uses an SCA, inspector should answer statement as N/A.***	☐	☐	☐	☐		4.2, 9.3.4, 19.1
* 18.5	The pharmacy can readily retrieve temperature and humidity records. ***If the electronic monitoring system is only capable of providing text message alerts for excursions alone (e.g., a report cannot be generated for ongoing temperature conditions), inspector should answer statement as "No."***	☐	☐	☐	☐		4.2, 9.3.4, 19.1

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* 18.6	The pharmacy controls temperature and humidity to maintain appropriate working conditions if no overnight drug storage occurs and/or is following the most restrictive drug label. ***Inspector note: Per USP <797>, the cleanroom suite should be maintained at a temperature of 20°C or cooler and a relative humidity of 60% or below to minimize the risk of microbial proliferation and to provide comfortable conditions for compounding personnel attired in the required garb. CRT is defined as 20°C-25°C per USP <659>.***	☐	☐	☐	☐		4.2, 9.3.4, 19.1
* 18.7	The placement of the HVAC unit does not cause cross contamination or interfere with the functioning of the classified area. ***Inspector note: Air streams from the HVAC system(s) can disrupt the unidirectional airflow of an open faced PEC such as a laminar airflow workbench (LAFW).***	☐	☐	☐	☐		4, 4.2
* 18.8	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***	☐	☐	☐	☐		4.2, 9.3.4
* 18.9	Humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***	☐	☐	☐	☐		4.2, 9.3.4
19.0	Does the pharmacy store drugs in the cleanroom suite overnight and/or for long periods of time? ***Inspector note: Long periods of time is not defined as pre-compounding preparation right before compounding activities are commenced.***	☐	☐	☐	☐		4.2, 9.3.4, 19.1
20.0	If the pharmacy is storing drugs inside the cleanroom suite overnight and/or long periods of time, are any of the drugs stored unable to tolerate temperature excursions?	☐	☐	☐	☐		4.2, 9.3.4, 19.1
21.0	What is the current temperature of the cleanroom suite/SCA? ***Record in the Inspector Notes.***	☐	☐	☐	☐		4.2, 9.3.4, 19.1

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22.0	What is the current relative humidity percentage of the cleanroom suite/SCA? ***Record in the Inspector Notes.***	☐	☐	☐	☐		4.2, 9.3.4, 19.1
23.0	Is the humidity maintained at less than 60% relative humidity (RH) in the compounding area to minimize risk of microbial proliferation?	☐	☐	☐	☐		4.2, 9.3.4, 19.1
* 24.0	Is differential positive pressure maintained in compliance with USP <797> standards? ***Inspector note: Per USP <797>, no pressure differential is required between the SCA and the surrounding area.*** ***Inspector should view logs and current status (while observing compounding) to verify.*** ***If the pharmacy uses an SCA for sterile compounding environment, inspector should answer statement as N/A.***	☐	☐	☐	☐		4.2.1, 4.2.5, 5
* 24.1	The facility design creates room separation to allow positive pressure differentials between spaces (rooms) for movement of air from higher quality air to lower quality air. ***Inspector should review a graphic of the airflow contained in the certification report.***	☐	☐	☐	☐		4.2.1, 4.2.5, 5
* 24.2	The facility has a system in place to continuously monitor pressure differentials (e.g., magnehelic gauge). ***Per USP, pressure differentials need to be monitored continuously, but personnel are not specifically required to visually monitor pressure during compounding activities.***	☐	☐	☐	☐		4.2.1, 4.2.5, 5
* 24.3	The facility has a record system to record pressure differentials on days when compounding occurs. ***Inspector note: Per USP, the quantitative results from the pressure monitoring device must be reviewed and documented at least daily on the days when compounding is occurs.***	☐	☐	☐	☐		4.2.1, 4.2.5, 5

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
* 24.4	The differential positive pressure between unclassified and the first space in the compounding suite is at least 0.020 inch water column. ***Inspector note: Per USP, certifiers should confirm (this is a USP recommendation) positive pressure around doorways, pass-throughs and any opening in the cleanroom suite with smoke testing (to confirm positive pressure is maintained) with initial certification of the cleanroom suite.*** ***If no, record the observed pressure differential between the two identified spaces (e.g., ISO Class 8 anteroom and the general pharmacy area).***	☐	☐	☐	☐		4.2.1, 4.2.5, 5
* 24.5	The differential positive pressure between adjacent classified areas is at least 0.020 inch water column. ***If no, record the observed pressure differential between the two identified spaces (e.g., ISO Class 8 anteroom and the ISO Class 7 buffer room).***	☐	☐	☐	☐		4.2.1, 4.2.5, 5
24.6	Pressure differential monitoring and quantitative results are reviewed and documented at least daily on days when compounding occurs.	☐	☐	☐	☐		4.2.1, 4.2.5, 5
25.0	Does the pharmacy have a policy in place to cease compounding when the pharmacy is unable to maintain positive pressure differentials (outside of anticipated variations due to opening and closing of doors)?	☐	☐	☐	☐		4.2.1, 4.2.5, 5
26.0	Are pressure differential monitoring procedures in place that include an alarm or alert when there is an excursion? ***Inspector note: USP <797> does not require there to be an alarm or an alert.***	☐	☐	☐	☐		4.2.5
27.0	Does the facility perform both sterile and nonsterile compounding?	☐	☐	☐	☐		4.2.1
28.0	If the pharmacy performs nonsterile compounding and sterile compounding, are the designated areas separate and distinct from each other?	☐	☐	☐	☐		4.2.1

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* 29.0	If PECs are placed into the same room that are used for both sterile and nonsterile compounding, is the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP <797>, PECs used for both sterile and nonsterile compounding may be placed in the same room only if the PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification.*** ***If the pharmacy does not perform nonsterile compounding in the same room as sterile compounding, inspector should answer this question as N/A.***	☐	☐	☐	☐		4.2.1, 4.2.6
* 29.1	PECs used for nonsterile compounding are placed at least one meter away from PECs used for sterile compounding.	☐	☐	☐	☐		4.2.1
* 29.2	Particle-generating activity must not be performed while sterile compounding is in process.	☐	☐	☐	☐		4.2.1
* 29.3	PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification air quality during nonsterile compounding.	☐	☐	☐	☐		4.2.1
30.0	Does the pharmacy prepare Category 2 and Category 3 CSPs from nonsterile components? ***Inspector note: Category 1 CSPs can be made from nonsterile components.*** ***If the pharmacy does not compound using nonsterile components, the inspector should answer question as N/A.***	☐	☐	☐	☐		4.2.1, 4.2.6
* 31.0	Does the pharmacy's presterilization procedures comply with USP <797> standards?	☐	☐	☐	☐		4.2.6
* 31.1	Presterilization procedures, such as weighing and mixing, are completed in an ISO Class 8 or better environment (e.g., anteroom or buffer room). ***Inspector note: This statement only applies for Category 2 and Category 3.***	☐	☐	☐	☐		4.2.6

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* 31.2	Presterilization procedures, such as weighing and mixing, are performed in a single-use containment glove bag, CVE, BSC, or CACI to minimize the risk of airborne contamination. ***Inspector note: This statement only applies for Category 2 and Category 3. CVEs, BSCs, or CACIs used for presterilization procedures must be certified at least every six months.***	☐	☐	☐	☐		4.2.6
	Certification and Environmental Monitoring Inspector to review past two (2) Certification reports for the SEC and all PECs.						**5**
* 32.0	Does the pharmacy ensure that each area related to CSP preparation is certified to meet the classified air quality standard appropriate for the activities conducted in that area in compliance with USP <797> standards? ***Inspector is to review current certification reports.***	☐	☐	☐	☐		5
* 32.1	The most recent PEC and SEC certification reports are available for review.	☐	☐	☐	☐		4.2, 5, 20
* 32.2	Certification of all classified areas, including PECs, is performed at least every six months.	☐	☐	☐	☐		4.2.3, 5
* 32.3	Certification of all classified areas, including PECs, is performed whenever a device is relocated or a major service to the facility is performed. ***Inspector note: Classified areas must be recertified if there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality.***	☐	☐	☐	☐		5
* 32.4	Certification reports are reviewed by the designated person(s). ***Inspector note: If the designated person(s) review is not documented, describe how it is ensured that the review occurred.***	☐	☐	☐	☐		4.2, 5

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* 32.5	All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, pharmaceutical isolators, IVLFZ, and robotic enclosures) have been certified within the last six months. ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***	☐	☐	☐	☐		4.2.3, 5
* 32.6	All PECs meet ISO Class 5 air quality requirements with (total, nonviable) particle counts documented within the report. ***Inspector note: Per ISO definition, ISO Class 5 areas are certified as having less than 3,520 particles per cubic meter of air under dynamic operating conditions.*** ***If no, describe what occurred and the pharmacy's response to total airborne particle sampling results, data evaluation, and action level (eg, pharmacy took PEC out of service, pharmacy ordered new HEPA filter, PEC was repaired and re-certified).***	☐	☐	☐	☐		4.1.1, 5.1 Table 4
* 32.7	All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last six months. ***Inspector note: Per ISO definition, ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air under dynamic operating conditions and ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air under dynamic operating conditions.*** ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***	☐	☐	☐	☐		4.1.1, 4.1.2, 5.1 Table 4
* 32.8	All SECs meet ISO Class 7 air quality requirements and ISO Class 8 air quality requirements where permitted, with particle counts documented within the report. ***If no, describe what occurred and the pharmacy's response (e.g., pharmacy reduced BUD, pharmacy used an alternative facility, pharmacy followed mitigation strategies, and/or disaster planning processes).***	☐	☐	☐	☐		4.1.1, 5.1 Table 4

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* 33.0	Does the certification report received by the pharmacy have all required elements documented for the pharmacy's designated person(s) to make an informed decision related to functionality of PEC and SEC environments in compliance with USP <797> standards? ***Inspector note: It is recommended that the designated person review the certification report in its entirety.***	☐	☐	☐	☐		5, 20
* 33.1	The certification report includes information about the equipment used for performing each test including last calibration date (or date when next calibration is due). ***Inspector note: Per USP, "total particle count testing must be performed under dynamic operating conditions using calibrated electronic equipment" and "all impaction air samplers must be serviced and calibrated as recommended by the manufacturer."***	☐	☐	☐	☐		5.1, 6.1, 20
* 33.2	The certification report includes the name of the certifier. ***Inspector note: Per USP <797>, a qualified certifier may have received training and education from professional organizations such as the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) and Controlled Environment Testing Association (CETA). Both organizations provide certification (Registered Certification Professional – Sterile Compounding Facilities), education, and resources.***	☐	☐	☐	☐		5
* 33.3	The certification report describes the "dynamic conditions" including the number of personnel in the cleanroom suite. ***Inspector note: Compounders can perform mock compounding activities and/or perform media-fill while the certifier is conducting testing. Number of personnel present in the SEC must be documented.***	☐	☐	☐	☐		5, 20

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
* 33.4	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **air volume and room air exchange rate (ACPH)**. ***Inspector note: Per USP <797>, unclassified SCAs have no ACPH requirement.*** ***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***	☐	☐	☐	☐		4.2.4, 5 Table 6
* 33.5	**SEC:** All of the following ACPH required elements were documented on the certification report: the ACPH from HVAC, the ACPH contributed from the PEC, and the total ACPH. ***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***	☐	☐	☐	☐		4.2.4, 5
* 33.6	**The ISO Class 8 anteroom** is certified and documented as having a minimum of 20 ACPH with at least 15 ACPH of the total air change rate coming from HVAC through HEPA filters located in the ceiling. ***If the pharmacy has an ISO Class 7 anteroom, inspector should mark as N/A.***	☐	☐	☐	☐		4.2.4, 5 Table 6
* 33.7	**The ISO Class 7 buffer room and ISO Class 7 anteroom (if required)** is certified and documented as having a minimum of 30 ACPH with at least 15 ACPH of the total air change rate in a room coming from the HVAC through HEPA filters located in the ceiling. ***Inspector note: If the PEC is used to meet the minimum total ACPH requirements, the PEC must not be turned off, except for maintenance.***	☐	☐	☐	☐		4.2.4, 5 Table 6
* 33.8	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **room pressure differential** in doorways between adjacent rooms.	☐	☐	☐	☐		4.2.5, 5
* 33.9	**SEC:** The differential pressure measured was at least 0.020 inch water column positive from the cleanroom to the anteroom and between the anteroom and all adjacent spaces with the doors closed. ***Inspector note: No pressure differential is required between the SCA and the surrounding area.***	☐	☐	☐	☐		4.2.1, 4.2.5, 5

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
* 33.10	**SEC:** All SEC HEPA filters were leak tested (to confirm **HEPA filter integrity**).	☐	☐	☐	☐		5
* 33.11	**SEC:** All SEC HEPA filters with leaks were repaired. ***If leaks were not repaired, describe what actions pharmacy took (e.g., pharmacy implemented mitigation strategies such as reduced BUD or used alternative pharmacy location).*** ***If no repairs were needed, inspector should answer statement as N/A.***	☐	☐	☐	☐		5
* 33.12	**PEC:** (**Dynamic airflow**) **Smoke pattern tests** are performed for each PEC during dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the CSPs. ***Inspector note: Per USP, "HEPA-filtered air must be supplied by the PEC at a velocity sufficient to sweep particles away from critical sites and maintain unidirectional airflow during operations. Proper design, control, and use minimizes turbulence and creation of eddies or stagnant air in the PEC."*** ***Describe if smoke pattern testing of PEC was documented thoroughly in the report or through video.***	☐	☐	☐	☐		4.2.2, 4.2.3, 5
* 33.13	**PEC: Dynamic airflow smoke pattern** confirms equipment and supplies necessary for performing compounding activities in the PEC do not disrupt unidirectional airflow. ***Inspector note: Per USP, "Proper placement of equipment in a PEC must be initially verified by a dynamic airflow smoke pattern test to demonstrate minimal disruption in airflow. The dynamic airflow smoke pattern test must be repeated if equipment is placed in a different location."***	☐	☐	☐	☐		4.2.2, 4.2.3, 4.5, 5, 9.1

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* 33.14	**PEC: Total (nonviable) particle count** testing was performed under dynamic operating conditions using calibrated electronic equipment. ***Inspector note: Per USP, "Measurements of total airborne particles must be taken in each PEC at locations where there is greatest risk to the exposed CSPs, containers, and closures...Measurements of total airborne particles in other classified areas, including the buffer room(s) and anteroom(s), should be taken at representative locations that reflect the quality of air in the room(s)."***	☐	☐	☐	☐		5, 5.1
* 33.15	**PEC:** All PEC HEPA filters were leak tested (to confirm **HEPA filter integrity**). ***Inspector note: The certification report for each PEC should show air velocities within the PEC.***	☐	☐	☐	☐		5
* 33.16	**PEC:** All PEC HEPA filters with leaks identified were repaired. ***If leaks were not repaired, describe what actions pharmacy took (example: PEC taken out of service until HEPA filter could be replaced).*** ***If no repairs were needed, inspector should answer statement as N/A.***	☐	☐	☐	☐		5

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
* 33.17	**PEC-IVLFZ**: Pharmacy's integrated vertical laminar flow zone (IVLFZ) meets design, functional requirements, and certification requirements under USP <797>. ***Inspector note: Per USP <797>, "Strategic location of air returns in addition to full coverage of HEPA-filters above the work surface is required. Both static and dynamic smoke studies of air returns in addition to full coverage of HEPA-filtered air void of turbulence, dead air zones, and refluxing from the HEPA filters to and across the entire work area and to the air returns must be documented (e.g., with video)."*** ***If pharmacy does not use an IVLFZ, inspector should answer statement as N/A.***	☐	☐	☐	☐		4.2.3
* 33.18	If a **robotic enclosure is used as the PEC**, or placed within the PEC, a dynamic airflow smoke pattern test must be performed initially and at least every 6 months thereafter to ensure that: 1) it is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the direct compounding area(s). ***If pharmacy does not use a robotic enclosure, inspector should answer statement as N/A.***	☐	☐	☐	☐		4.2.3
* 34.0	Was smoke testing performed in SEC to confirm all particle generating equipment (e.g., computers, printers, refrigerators, PECs) do not disrupt airflow? ***Inspector note: This question will be N/A unless the pharmacy is new, has recently completed construction, or equipment has been moved within SEC since last certification.*** ****No further remodel questions after this line item.***	☐	☐	☐	☐		5

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35.0	Does the pharmacy have an established environmental monitoring (eg, microbiological air and surface monitoring) program in compliance with USP <797> standards? ***Inspector note: Per USP, "The goals of a microbiological air and surface monitoring program are to determine whether contamination is present at unacceptable levels and to assess whether proper personnel practices are being followed, cleaning and disinfecting agents are effective, and environmental quality is maintained."***	☐	☐	☐	☐		6, 6.1, 6.2
35.1	Environmental monitoring program (e.g., viable air and/or surface monitoring) is performed initially in the selected sampling sites to establish a baseline level of environmental quality for each classified area, i.e., each ISO Class 5 PEC, each ISO Class 7, and ISO Class 8 room.	☐	☐	☐	☐		6, 6.1, 6.2
35.2	Environmental monitoring program (e.g., viable air and/or surface monitoring) is performed in conjunction with the certification of new facilities and equipment.	☐	☐	☐	☐		6, 6.1, 6.2
35.3	Environmental monitoring program (e.g., viable air and/or surface monitoring) is performed after any servicing of facilities or equipment.	☐	☐	☐	☐		6, 6.1, 6.2
35.4	Environmental monitoring program (e.g., viable air and/or surface monitoring) is performed in response to identified problems (e.g., positive growth in sterility tests of sterile compounded preparation).	☐	☐	☐	☐		6, 6.1, 6.2
35.5	Environmental monitoring program (e.g., viable air and/or surface monitoring) is performed in response to identified trends (e.g., repeated positive gloved fingertip and thumb sampling results, failed media fill testing, or repeated observations of air or surface contamination).	☐	☐	☐	☐		6, 6.1, 6.2

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35.6	Results from the environmental monitoring program (e.g., viable air and/or surface monitoring) are reviewed in response to changes that could impact the sterile compounding environment (e.g., change in cleaning agents) and in conjunction with personnel data (i.e., training records, visual observations, competency assessments) to assess the state of control and to identify potential risks of contamination. ***Inspector note: Per USP, the program is reviewed to "assess risks for contamination, potential routes of contamination, and the adequacy of cleaning and disinfecting agents and procedures. Regular review of the sampling data must be performed to detect trends and the results of the review must be documented."***	☐	☐	☐	☐		6, 6.1, 6.2, 20 Table 4, Table 7, Table 8
35.7	The pharmacy ensures that viable air and surface sampling is performed by a trained and competent individual who is familiar with the methods and procedures for air sampling and surface testing. ***If sampling is conducted by internal personnel, inspector should verify that documented training and competencies are located in the employee file.***	☐	☐	☐	☐		6, 6.1, 6.2
35.8	Environmental monitoring program (e.g., viable air and/or surface monitoring) describes/identifies corrective actions to minimize the risk of CSP contamination and that these corrective actions are documented.	☐	☐	☐	☐		6, 20
36.0	Is surface sampling performed at the end of a compounding activity or shift but before the area has been cleaned and disinfected (to obtain a sample that is representative of the typical compounding conditions at the pharmacy)? ***Inspector note: this is a USP recommendation.***	☐	☐	☐	☐		6.1, 6.3
37.0	Does the pharmacy send out all air quality for viable airborne samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***	☐	☐	☐	☐		6.2.2

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
38.0	Does the pharmacy send out all surfaces for viable particle samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***	☐	☐	☐	☐		6.3
39.0	For any samples that are sent to an external lab (third party), does the pharmacy receive a report from the third-party confirming incubation parameters meet USP <797> requirements (e.g., the correct temperature and the correct length of incubation time are documented in the report)? ***Inspector note: Incubation parameters are the same as seen in statements 40.6-40.7 and 41.4-41.5.*** ***This question applies for any air or surface sample sent to an external lab.*** ***If no, describe observations.***	☐	☐	☐	☐		6.2.2
40.0	Are processes for sampling and monitoring **air quality for viable airborne** particles in compliance with USP <797> standards? ***Inspector note: Per USP <797>, facilities performing any Category 3 compounding must adhere to the increased environmental monitoring requirements for all classified areas where Category 3 CSPs are compounded and increased environmental monitoring requirements apply at all times regardless of whether Category 3 CSPs are being compounded on a given day.*** ***Review six months of air sampling data to verify. If no, go to the compliance statements.***	☐	☐	☐	☐		6.2, 6.2.1, 6.2.2, 6.2.3, 14.4.2 Box 5, Table 7
40.1	All classified areas are sampled using a volumetric active air sampling device (impaction air sampler). ***Inspector note: This sampling must be performed during dynamic operating conditions (to obtain a sample that is representative of the typical compounding conditions at the pharmacy).***	☐	☐	☐	☐		6.1, 6.2.1

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
40.2	All classified areas are sampled at the **frequencies** specified by USP for volumetric active air sampling. ***Inspector note: Per USP <797>, Category 1 and Category 2 compounding frequency is every six months and Category 3 compounding frequency is monthly.*** ***For facilities compounding any Category 3 CSPs, this must be completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.***	☐	☐	☐	☐		6.2.1, 14.4.2
40.3	At least one cubic meter (1000 L) of air is tested using the volumetric active air sampling device from each sample location.	☐	☐	☐	☐		6.2.2 Box 5
40.4	All impaction air samplers are serviced and calibrated as recommended by the manufacturer.	☐	☐	☐	☐		6.1
40.5	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a media that supports the growth of bacteria and fungi (eg, TSA), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements.***	☐	☐	☐	☐		6.2.2 Box 5
40.6	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797> (Box 5), when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C–35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C–25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	☐	☐	☐	☐		6.2.2 Box 5

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
40.7	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797> (Box 5), two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (e.g., malt extract agar [MEA] or sabouraud dextrose agar [SDA]). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	☐	☐	☐	☐		6.2.2 Box 6
40.8	Results for all plates are recorded for each sample and did not exceed USP <797> Table 7 action levels (or internal action levels if more restrictive). **ISO Class 5: >1 cfu/m^3/device** **ISO Class 7: >10 cfu/m^3/device** **ISO Class 8: > 100 cfu/m^3/device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media separately.***	☐	☐	☐	☐		6.2.3 Table 7
40.9	For any air sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***	☐	☐	☐	☐		6.2.3
40.10	For any areas that exceed action levels, an investigation is conducted to attempt to determine cause and a corrective action plan is implemented.	☐	☐	☐	☐		6.2.3

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
41.0	Are processes for sampling and monitoring **surfaces for viable particles** in compliance with USP <797>standards? ***Review six months of surface sampling data to verify. If no, go to the compliance statements.***	☐	☐	☐	☐		6.3
41.1	**Surfaces** and pass-through chambers in the cleanroom suite and SCA are sampled for microbial contamination for each classified area. ***Inspector note: Sampling locations must include work surfaces in each classified room, the interior of each ISO Class 5 PEC, and all pass-through chambers connecting to classified areas. USP recommends samples be taken from: equipment contained within the PEC, staging or working area near the PEC, and frequently touched surfaces.***	☐	☐	☐	☐		6.3, 6.3.1
41.2	**Surfaces** within the cleanroom suite and SCA are sampled at the **frequencies** specified by USP for viable particle surface sampling. ***Inspector note: Category 1 and Category 2 CSP surface sampling frequency is monthly and Category 3 compounding is weekly, regardless of the frequency of compounding Category 3 CSPs.*** ***Additionally, surface sampling is to be performed within the PEC used to prepare Category 3 CSPs, at the end of each batch, before cleaning and disinfection occurs unless a self-enclosed robot is used. If a self-enclosed robot is used, frequency is at least once daily at the end of compounding operations.*** ***For facilities compounding any Category 3 CSPs, a surface sampling must be completed prior to assigning BUDs longer than the limits established in Table 13.***	☐	☐	☐	☐		6.3, 6.3.1, 14.4.2

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
41.3	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a surface sampling device with a raised convex surface for sampling flat surfaces is used that contain general microbial growth media that supports the growth of bacteria and fungi (e.g., TSA supplemented with additives that neutralize effects of any disinfecting agent, e.g., lecithin and polysorbate 80), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements. Per USP, "sterile swabs wetted with sterile water or a sterile neutralizing buffer may be used when sampling irregular surfaces and difficult-to-reach locations such as crevices, corners, and spaces between surfaces."***	☐	☐	☐	☐		6.3.2 Box 6
41.4	The pharmacy incubates all surface samples in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797>, when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C-35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C-25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	☐	☐	☐	☐		6.3.2 Box 6
41.5	The pharmacy incubates all surface samples in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797>, two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (e.g., MEA or SDA). Media must be supplemented with neutralizing additives (e.g., lecithin and polysorbate 80). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	☐	☐	☐	☐		6.3.2 Box 7

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41.6	Results for all plates are recorded for each sample and did not exceed USP <797> Table 8 action levels (or internal action levels if more restrictive). **ISO Class 5: >3 cfu/media device** **ISO Class 7: >5 cfu/media device** **ISO Class 8: > 50 cfu/media device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media device separately.***	☐	☐	☐	☐		6.3.3 Table 8
41.7	For any surface sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***	☐	☐	☐	☐		6.3.3
41.8	For any areas that exceed action levels, an investigation is conducted to determine cause, and a corrective action plan is implemented.	☐	☐	☐	☐		6.3.3
	Compounding Personal Hygiene and Garbing						
42.0	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 <797> standards?	☐	☐	☐	☐		3.1
42.1	Compounding personnel are required to report conditions that may contaminate the sterile preparation and environment to the designated person(s). ***Inspector note: Per USP <797>, examples of conditions that have a higher risk of contaminating the CSP and sterile environment includes: rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections.***	☐	☐	☐	☐		3, 3.1

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42.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in compounding areas before their conditions have been resolved. ***Inspector note: Per USP <797>, the designated person(s) may permit accommodations as long as the quality of the CSP and environment will not be affected.***	☐	☐	☐	☐		3, 3.1
42.3	Any accommodations permitted by the designated person(s) are documented.	☐	☐	☐	☐		3.1
42.4	Food (including mints, gum, etc.) and drinks are not permitted in anterooms, buffer rooms, or segregated compounding areas.	☐	☐	☐	☐		3.1
43.0	Does the pharmacy stock the necessary garb to ensure minimum garbing requirements are continuously met in compliance with USP <797> standards?	☐	☐	☐	☐		3.3
43.1	The pharmacy stocks gowns and/or coveralls that are low lint with sleeves that fit snugly around the wrists and an enclosed neck.	☐	☐	☐	☐		3.3
43.2	The pharmacy stocks shoe covers that are low lint.	☐	☐	☐	☐		3.3
43.3	The pharmacy stocks head covers that are low lint and cover the hair and ears.	☐	☐	☐	☐		3.3

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43.4	The pharmacy stocks facial hair covers (not masks) that are low lint. ***If the pharmacy does not have personnel with beards, inspector should answer this statement as N/A.***	☐	☐	☐	☐		3.3
43.5	The pharmacy stocks masks that are low lint.	☐	☐	☐	☐		3.3
43.6	The pharmacy stocks sterile, powder-free gloves.	☐	☐	☐	☐		3.3
43.7	**Category 1 and Category 2:** All non-disposable garb used to prepare Category 1 and Category 2 CSPs is laundered before reuse. ***If only disposable items are used, inspector should mark as N/A.***	☐	☐	☐	☐		3.3
43.8	**Category 3 only:** The pharmacy stocks low lint face and neck coverings that ensure no skin is exposed. ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***	☐	☐	☐	☐		3.3, 14.4.2
43.9	**Category 3 only:** The pharmacy stocks sterile, low lint outer garb (including sterile sleeves over gauntlet sleeves when a RABS is used). ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***	☐	☐	☐	☐		3.3

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43.10	**Category 3 only:** All non-disposable garb used to prepare Category 3 CSPs is **laundered and resterilized** with a validated cycle before each use. ***Document whether laundering and sterilization is performed in-house or by an outside vendor.*** ***If only disposable items are used, inspector should answer statement as N/A.***	☐	☐	☐	☐		3.3, 14.4.2
	Media-Fill						
44.0	Is the media-fill testing simulation performed by the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP, "When performing a media-fill test, simulate the most difficult and challenging aseptic compounding procedures encountered by the person replacing all the components used in the CSPs with soybean-casein digest media. The simulation must capture elements that could potentially affect the sterility of the CSP."***	☐	☐	☐	☐		2.3
44.1	The simulation captures factors associated with the length of the process that can pose contamination risk (e.g., operator fatigue, quality of equipment).	☐	☐	☐	☐		2.3
44.2	The simulation captures number of aseptic additions or transfers.	☐	☐	☐	☐		2.3
44.3	The simulation captures number, type, and complexity of manipulations.	☐	☐	☐	☐		2.3
44.4	The simulation captures number of personnel in the buffer room or SCA.	☐	☐	☐	☐		2.3

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44.5	Does the facility define "the most difficult and challenging procedures" and the rationale for how they are the most challenging? ***Inspector note: Best practice is for this to be documented in an SOP. Inspectors may also find this information documented on a training/competency assessment checklist. For complex/variety of compounding practices, inspectors may find additional media fills are completed (more than what is required by the USP chapters).***	☐	☐	☐	☐		2.3, 20
45.0	Are the pharmacy's media-fill storage, review, and preparation processes in compliance with USP <797> standards?	☐	☐	☐	☐		2.3
45.1	If pharmacy uses commercial sterile microbial growth media, a COA was obtained. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	☐	☐	☐	☐		2.3
45.2	The COA for the commercial sterile microbial growth media includes statements from the supplier that the lot of the growth media will support the growth of microorganisms. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	☐	☐	☐	☐		2.3
45.3	Storage of commercial sterile microbial growth media is in accordance with manufacturer instructions. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	☐	☐	☐	☐		2.3

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
45.4	Commercial sterile microbial growth media is stored and used before its expiration date. ***Inspector note: Media is to be inoculated by the expiration date, meaning that the test needs to be started (not that incubation needs to be completed before the expiration date).*** ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	☐	☐	☐	☐		2.3
45.5	Sterile-to-sterile media-fill testing microbial growth media (non-commercial) was prepared and growth promotion capability was demonstrated prior to use, following USP <71>. ***If pharmacy only uses commercial sterile microbial growth media, inspector should answer statement as N/A.***	☐	☐	☐	☐		2.3
45.6	Nonsterile starting components (commercially available nonsterile soybean-casein digest powder) are dissolved to make a 3% nonsterile solution, manipulated in a manner that simulates nonsterile-to-sterile compounding activities, with a minimum of one positive control container. ***If pharmacy does not perform sterile compounding using nonsterile ingredients, inspector should answer statement as N/A.***	☐	☐	☐	☐		Box 2
	Cleaning and Disinfection						**7**
46.0	Is the pharmacy equipped with the necessary cleaning and disinfecting equipment and supplies that comply with USP <797> standards?	☐	☐	☐	☐		7, 7.1.1, 7.1.2 <1072>
46.1	All cleaning and disinfecting supplies (e.g., wipers, sponges, pads, and mop heads), with the exception of tool handles and holders, are low lint.	☐	☐	☐	☐		7.1.2
46.2	Reusable cleaning tools are made of cleanable materials (no wood handles or any other porous material).	☐	☐	☐	☐		7.1.2
46.3	Reusable cleaning tools are dedicated for use in the classified areas or SCA and are not removed from these areas except for disposal.	☐	☐	☐	☐		7.1.2

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
46.4	The pharmacy has the appropriate cleaners **EPA-registered disinfecting agent(s)** to adequately perform cleaning and disinfection. ***Inspector note: Examples of EPA-registered disinfectants include, but are not limited to: phenolics; oxidizers, such as peroxyacetic acid and sodium hypochlorite; quaternary ammonium; and hydrogen peroxide. If the agent is EPA-registered, a registration number will be on the label. Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 7, the pharmacy is to ensure the contact time specified by the manufacturer is achieved. Per USP, Inspector should check to see if agent is effective against Clostridium difficile.***	☐	☐	☐	☐		7.1.1 Box 7 <1072>
46.5	The pharmacy has the appropriate **EPA-registered sporicidal agent(s)** to adequately perform sporicidal disinfection. ***Inspector notes: Examples of EPA-registered agents include but are not limited to: oxidizers such as peroxyacetic acid, sodium hypochlorite, and hydrogen peroxide. Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 8, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.***	☐	☐	☐	☐		7.1.1 Box 7 <1072>
46.6	All cleaning and disinfectant agents are appropriately labeled including expiration dates. ***Inspector should verify that no expired agents are present.***	☐	☐	☐	☐		7.1.1
46.7	When used in the PEC, any cleaning and disinfecting agents that are not "ready-to-use" formulations are diluted using sterile water. ***If only ready-to-use formulations are used, inspector should answer statement as N/A.***	☐	☐	☐	☐		7.1.1
47.0	Does the pharmacy's documented **cleaning and disinfection** activities for surfaces in the classified areas and/or SCA comply with the **frequencies** specified in USP <797> Table 10? ***Review cleaning logs to verify.***	☐	☐	☐	☐		7.2 Table 10

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47.1	All interior surfaces of the PEC are cleaned and disinfected on days when compounding occurs.	☐	☐	☐	☐		7.2 Table 10
47.2	All interior surfaces of the PEC are cleaned and disinfected when surface contamination is known or suspected.	☐	☐	☐	☐		7.2 Table 10
47.3	The removable work tray inside the PEC is cleaned and disinfected on days when compounding occurs. ***If the PEC is not equipped with a removeable work tray, inspector should answer statement as N/A.***	☐	☐	☐	☐		7.2 Table 10
47.4	All equipment inside the PEC is cleaned and disinfected on days when compounding occurs.	☐	☐	☐	☐		7.2, 9.1 Table 10
47.5	All work surfaces outside of the PEC (e.g., counters, worktables) are cleaned and disinfected on days when compounding occurs.	☐	☐	☐	☐		7.2 Table 10
47.6	All pass-through chambers are cleaned and disinfected on days when compounding occurs. ***If the pharmacy is not equipped with a pass-through chamber, inspector should answer statement as N/A.***	☐	☐	☐	☐		7.2 Table 10
47.7	Floors in the buffer room, anteroom, and/or SCA are cleaned and disinfected on days when compounding occurs.	☐	☐	☐	☐		7.2 Table 10

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
47.8	Sinks used for hand hygiene are cleaned and disinfected on each day of use.	☐	☐	☐	☐		4.4, 7.2, Table 10
47.9	Walls, doors, and door frames are cleaned and disinfected monthly.	☐	☐	☐	☐		7.2 Table 10
47.10	Storage and shelving bins are cleaned and disinfected monthly.	☐	☐	☐	☐		7.2 Table 10
47.11	All equipment outside the PEC is cleaned and disinfected monthly. ***Inspector note: Equipment in the SEC/SCA may include, but is not limited to: carts, refrigerators, computers, barcode readers, and label printers.***	☐	☐	☐	☐		7.2 Table 10
47.12	Ceilings in the buffer room and anteroom are cleaned and disinfected monthly. ***If the pharmacy performs compounding only in a SCA, inspector should answer statement as N/A.***	☐	☐	☐	☐		7.2 Table 10
47.13	Ceilings in the SCA are required to be cleaned and disinfected only when visibly soiled and when surface contamination is suspected. ***If the pharmacy performs compounding only in a cleanroom suite, inspector should answer statement as N/A.***	☐	☐	☐	☐		7.2 Table 10
47.14	The surface of the removable work tray and the area underneath the removable work tray of the PEC is cleaned and disinfected monthly. ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	☐	☐	☐	☐		7.2 Table 10

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
48.0	Does the pharmacy's documented application of **sporicidal disinfectant** on surfaces comply with the **frequencies** specified for each CSP category in USP <797> Table 10? ***Inspector note: Per USP <797>, if the pharmacy prepares any Category 3 CSPs, the cleaning requirements for Category 3 must be followed at all times regardless of whether a Category 3 CSPs is prepared on any given day.*** ***Review cleaning logs to verify.***	☐	☐	☐	☐		7.2, 14.4.2 Table 10
48.1	**Sporicidal disinfectant** is applied to all interior surfaces of the **PEC** at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	☐	☐	☐	☐		7.2, Table 10
48.2	Sporicidal disinfectant is applied to equipment inside the PEC at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	☐	☐	☐	☐		7.2 Table 10
48.3	Sporicidal disinfectant is applied to work surfaces outside the PEC (e.g., counters, worktables) at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, application frequency is monthly. For any Category 3 compounding, application frequency is weekly.***	☐	☐	☐	☐		7.2 Table 10
48.4	Sporicidal disinfectant is applied to surfaces in the pass-through chambers at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.*** ***If the facility is not equipped with a pass-through chamber, inspector should answer statement as N/A.***	☐	☐	☐	☐		7.2 Table 10

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
48.5	Sporicidal disinfectant is applied to the floors in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	☐	☐	☐	☐		7.2 Table 10
48.6	Sporicidal disinfectant is applied to walls, doors, and door frames at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	☐	☐	☐	☐		7.2 Table 10
48.7	Sporicidal disinfectant is applied to storage shelving and bins at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	☐	☐	☐	☐		7.2 Table 10
48.8	Sporicidal disinfectant is applied to equipment stored outside the PEC at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	☐	☐	☐	☐		7.2 Table 10
48.9	Sporicidal disinfectant is applied to ceilings in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: Per USP <797>, Table 10, the application frequency is monthly for all category types. Per USP, ceilings of the SCA are required to be cleaned, disinfected, and applied with sporicidal disinfectant only when visibly soiled and when surface contamination is suspected. The SCA may not have an accessible ceiling.***	☐	☐	☐	☐		7.2 Table 10
48.10	Sporicidal disinfectant is applied to sinks used for hand hygiene at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	☐	☐	☐	☐		4.4, 7.2 Table 10

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
48.11	Sporicidal disinfectant is applied to the work surface of the removable tray in the PEC and area underneath the removable work tray at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.*** ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	☐	☐	☐	☐		7.2 Table 10
	Components						**9**
49.0	Does the pharmacy compound CSPs using active pharmaceutical ingredients (APIs) and non-API components? ***Inspector note: Per USP <797>, non-API components may include pharmaceutical excipients, sterile containers, and container closure systems.*** ***If the pharmacy does not compound using API or non-API components, inspector should answer this question as N/A.***	☐	☐	☐	☐		9.3
50.0	Is the pharmacy's selection of active API and non-API components in compliance with USP <797> standards? ***Verify by selecting products from the shelf of different suppliers and ask to see the COAs for those products.***	☐	☐	☐	☐		9.3
50.1	**APIs**: APIs used are compliant with the criteria in the USP–NF monograph, if one exists. ***If pharmacy does not compound CSPs that have a USP monograph, inspector should answer this statement as N/A.***	☐	☐	☐	☐		9.3.1
50.2	**APIs:** All APIs used have a COA that includes the specifications (e.g., compendial requirements for quality) and that test results for the component show that the API meets expected quality.	☐	☐	☐	☐		9.3.1

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
50.3	**APIs:** All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Federal 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.***	☐	☐	☐	☐		9.3.1
50.4	All **non-API components** comply with the criteria in the USP–NF monograph, if one exists.	☐	☐	☐	☐		9.3.1
50.5	All **non-API components** are accompanied by documentation (e.g., COA, labeling) that include the specifications and test results and shows that the component meets the specifications.	☐	☐	☐	☐		9.3.1
50.6	All **non-API components** used are manufactured by an FDA-registered facility. ***Inspector note: Per USP <797>, "If a component cannot be obtained from an FDA-registered facility, the designated person(s) must select an acceptable and reliable source (see USP <1197> Good Distribution Practices for Bulk Pharmaceutical Excipients). The compounding facility must establish the identity, strength, purity, and quality of the ingredients obtained from that supplier by reasonable means. Reasonable means may include but are not limited to visual inspections, evaluation of a COA supplied by the manufacturer, and/or verification by analytically testing a sample to determine conformance with the COA or other specifications."***	☐	☐	☐	☐		9.3.1
51.0	Does the pharmacy have processes in place to evaluate API and non-API components upon receipt and before use in compliance with USP <797> standards? ***Inspector note: Non-API components may be defined as excipients, containers, and container closure systems.*** ***If the pharmacy does not compound with API or other non-API components, inspector should answer question as N/A.***	☐	☐	☐	☐		9.3.2, 9.3.3

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
51.1	APIs or other components have been evaluated for use in sterile drug preparation. ***Inspector note: Per USP <797>, "Components labeled with 'not for pharmaceutical use,' 'not for injectable use,' 'not for human use' or an equivalent statement must not be used to compound for these purposes."*** ***If no, photograph and describe in the notes column. Request copies of the invoices for products with these types of labels.***	☐	☐	☐	☐		9.3.2, 9.3.3
51.2	Upon receipt of each lot of a component, personnel verify the labeling and condition of each component and examine the external packaging for evidence of deterioration and other aspects of unacceptable quality (e.g., outer packaging is damaged, temperature-sensing indicators show that the component has been exposed to excessive temperatures).	☐	☐	☐	☐		9.3.2, 9.3.3
51.3	Each lot of commercially available sterile, depyrogenated containers and container-closure systems are accompanied by a COA or other documentation showing conformance with established specifications for sterility and depyrogenation requirements.	☐	☐	☐	☐		9.3.1, 9.3.2, 9.3.3
51.4	The date of receipt by the pharmacy is clearly marked on each API or component package that lacks a vendor expiration date and are assigned and labeled with an expiration date not to exceed one year after receipt by the pharmacy.	☐	☐	☐	☐		9.3.2, 9.3.3
51.5	All components are reinspected before use. ***Inspector note: Per USP <797>, all packages must be inspected to detect container breaks, looseness of the cap or closure, and deviation from the expected appearance, aroma, and/or texture of the contents that might have occurred during storage. Sterile container closures are visually reinspected to ensure that they are free from defects that could compromise sterility and that they are otherwise suitable for their intended use.***	☐	☐	☐	☐		9.3.2, 9.3.3

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
51.6	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.	☐	☐	☐	☐		9.3.2, 9.3.3
51.7	Any other lots of that component from that vendor are examined to determine whether other lots have the same defect.	☐	☐	☐	☐		9.3.2, 9.3.3
	Equipment and Supplies						**9**
52.0	Is the pharmacy equipped with the appropriate supplies and equipment used for compounding in compliance with USP <797> standards?	☐	☐	☐	☐		9, 9.1, 9.2
52.1	Supplies (e.g., beakers, utensils, needles, syringes, filters, and tubing sets) that contact components are not reactive, additive, sorptive, and do not alter the quality of sterile compounded preparation. ***Inspector note: The appropriate supplies are available as applicable to the type of CSPs prepared (e.g., non-PVC, silicone-free, able to withstand high heat, able to be sterilized).***	☐	☐	☐	☐		9.2
52.2	Any supplies that are in direct contact with CSPs are sterile and/or depyrogenated.	☐	☐	☐	☐		9.2
52.3	The equipment must be able to be cleaned using the required agents and tools without damaging the equipment and/or contaminating the compounded preparation. ***Inspector note: Equipment used in compounding are of suitable composition and the surfaces that contact components are not reactive or sorptive.***	☐	☐	☐	☐		9.1

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
52.4	When nonsterile ingredients, products, components, or devices (e.g., non-sterile APIs and nonsterile vials and closures) are used for compounding, the pharmacy has the appropriate equipment to sterilize the finished product. Per USP, "Injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (e.g., containers, tubing) during any phase of the compounding procedure must be sterilized within 6 hours after completing the preparation to minimize the generation of bacterial endotoxins in CSPs." ***If the pharmacy does not perform compounding that requires sterilization, inspector should answer statement as N/A.***	☐	☐	☐	☐		9.1, 9.3.1, 10
53.0	Does the pharmacy operate and maintain records for all equipment used for compounding in accordance with manufacturer specifications and USP <797> standards?	☐	☐	☐	☐		9.1, 20
53.1	Automated, mechanical, or electronic equipment (monitoring equipment, autoclaves, ovens, etc.) are periodically inspected and calibrated yearly or in accordance with the equipment manufacturer guidelines.	☐	☐	☐	☐		9.1, 9.3.4
53.2	Automated compounding devices (ACDs) and other similar equipment (single channel or multi-channel) are assessed for accuracy and calibrated daily, prior to initial use, and a daily record is maintained. ***Inspector note: Per USP, "The precision of the equipment can be monitored based on an assessment of day-to-day variations in its accuracy measures. Compounding personnel must maintain a daily record of the accuracy measurements on the days the equipment is in use. Corrective actions must be implemented if accuracy measurements are outside the manufacturer's specification."***	☐	☐	☐	☐		9.1

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53.3	Incubators used for environmental and personnel monitoring are placed in a location outside of the sterile compounding area and calibrated in accordance with manufacturer's instructions. ***If the pharmacy does not incubate samples and or/media-fills in-house, inspector should answer statement as N/A.***	☐	☐	☐	☐		6.1, 6.2.2, 6.3.2
53.4	Incubators used for environmental and personnel monitoring are monitored for temperature during incubation periods either manually or by use of a continuous recording device. ***Inspector note: Incubators store media at 20˚C-25˚C and 30˚C-35˚C. If the pharmacy has more than one incubator, review records for both incubators.*** ***View incubator temperature records to verify. Evaluate the size of the incubator and volume of media it can store. If the pharmacy does not incubate samples and/or media-fills in-house, inspector should answer statement as N/A.***	☐	☐	☐	☐		6.2.2, 6.3.2 Box 5
	Compounding Personnel Observation - Inspector ***must*** observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. If the inspector is unable to view activities from a window or other observation area, it is expected they will gown/garb into compounding area. It is acceptable for pharmacy staff to perform mock compounding activities (with sterile saline or other drug) as long as all observations can be viewed.						
54.0	**Personnel Preparation Observation:** Before entering the compounding area, do compounding personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <797> standards?	☐	☐	☐	☐		3.1
54.1	All outer garments such as hats, scarves, sweaters, bandanas, vests, coats, and jackets are removed.	☐	☐	☐	☐		3.1
54.2	Makeup and/or cosmetics are removed.	☐	☐	☐	☐		3.1

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54.3	All hand, wrist, and other exposed jewelry, including piercings such as earrings, lip or eyebrow piercings, etc., are removed and any jewelry that cannot be removed is covered.	☐	☐	☐	☐		3.1
54.4	Earbuds or headphones are removed.	☐	☐	☐	☐		3.1
54.5	Electronic devices that are not necessary for compounding or other required tasks are prohibited from entering the compounding areas.	☐	☐	☐	☐		3.1
54.6	Nails are kept clean and neatly trimmed.	☐	☐	☐	☐		3.1
54.7	Any nail polish, artificial nails, or extenders are removed.	☐	☐	☐	☐		3.1
54.8	If worn, eyeglasses are wiped. ***If none of the pharmacy staff wear glasses, inspector should answer statement as N/A.***	☐	☐	☐	☐		3.1
54.9	Any accommodations permitted by the designated person(s) have been documented. ***Inspector note: Per USP <797>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	☐	☐	☐	☐		3.1
55.0	**Hand Hygiene Observation:** Were compounding personnel entering the compounding area observed performing the appropriate hand washing procedures in compliance with USP <797> standards?	☐	☐	☐	☐		3.2 Box 3
55.1	All personnel entering the compounding area performed hand hygiene.	☐	☐	☐	☐		3.2 Box 3

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55.2	The order of hand washing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***	☐	☐	☐	☐		3.2 Box 3
55.3	Fingernails are cleaned under warm running water using a disposable nail cleaner (e.g., nail pick). ***Inspector note: During observations, inspect whether nail picks are available for use when performing hand hygiene.***	☐	☐	☐	☐		3.2 Box 3
55.4	Brushes are not used for hand hygiene.	☐	☐	☐	☐		3.2 Box 3
55.5	Hands and forearms are washed up to the elbows with soap and warm water for at least 30 seconds. ***Inspector note: Compounding personnel describe method for ensuring they have washed for 30 seconds (example: clock or timer is available near the sink).***	☐	☐	☐	☐		3.2 Box 3
55.6	Soap containers are not refilled or topped off.	☐	☐	☐	☐		3.2
55.7	Hands and forearms are completely dried up to the elbows with low-lint disposable towels or wipers.	☐	☐	☐	☐		3.2 Box 3
55.8	Hand dryers are not used for hand hygiene.	☐	☐	☐	☐		3.2 Box 3
56.0	**Garbing Observation:** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <797> standards?	☐	☐	☐	☐		3.3
56.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	☐	☐	☐	☐		3.3

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
56.2	Compounding personnel entering the cleanroom suite and/or SCA adhere to the minimum garbing requirements in USP <797>. ***Inspector note: Per USP <797>, additional garbing requirements must be continuously met in the buffer room where Category 3 CSPs are prepared, regardless of whether Category 3 CSPs are compounded on a given day.***	☐	☐	☐	☐		3.3
56.3	Donning procedures are performed in an order that reduces the risk of contamination. ***Inspector note: USP recommends (not requires) the donning procedure to be performed in the anteroom.*** ***If no, inspector must describe in the notes column why a risk of contamination is a concern.***	☐	☐	☐	☐		3.3
56.4	Doffing procedures are performed in an order that reduces the risk of contamination.	☐	☐	☐	☐		3.3
56.5	The order of garbing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***	☐	☐	☐	☐		3.2, 3.3
56.6	Sterile gloves are donned in a classified room or SCA.	☐	☐	☐	☐		3.2
56.7	Skin is not exposed inside the ISO Class 5 PEC.	☐	☐	☐	☐		3.3
56.8	Garb is replaced immediately if it becomes visibly soiled or if its integrity is compromised.	☐	☐	☐	☐		3.3
56.9	**Category 1 and Category 2 only:** Upon exit of the compounding area, all garb (except for gowns) is discarded or laundered prior to reuse. ***Inspector note: Gowns (disposable and non-disposable) may be reused within the same shift by the same person only if stored appropriately.*** ***If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused, inspector should answer statement as N/A.***	☐	☐	☐	☐		3.3

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Sterile Compounding Inspection for USP <797>

Facility Name: «Name»,«DBA_Name»
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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
56.10	**Category 1 and Category 2 only:** Gowns reused within the same shift and by the same person are maintained in a manner that prevents contamination. ***Inspector note: Per USP <797>, gowns stored for reuse must be maintained in a classified area or adjacent to or within the SCA in a manner that prevents contamination (e.g., away from sinks to avoid splashing).*** ***If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused; inspector should answer statement as N/A.***	☐	☐	☐	☐		3.3
57.0	List the name(s) of the CSPs observed by the inspector as part of live compounding demonstration.						
58.0	**Compounding Observation:** Are compounding personnel observed using the appropriate aseptic technique that ensures the quality of the CSP and the environment is maintained in compliance with USP <797> standards?	☐	☐	☐	☐		1, 2.1, 2.3
58.1	All sterile compounding is performed in a PEC with ISO Class 5 conditions or better. ***If the pharmacy only performs immediate use compounding, inspector should answer this statement as N/A.***	☐	☐	☐	☐		4.1.2
58.2	**Category 2 and Category 3 only:** All PECs are placed in a cleanroom suite. ***Inspector note: Per USP, "If compounding only Category 1 CSPs, the PEC may be placed in an unclassified SCA."*** ***If the pharmacy only prepares Category 1 CSPs, inspector should answer this statement as N/A.***	☐	☐	☐	☐		4.1.2
58.3	Compounding personnel ascertain before use that components are of the correct identity, appropriate quality, within the expiration date, and have been stored under the proper conditions.	☐	☐	☐	☐		9.3.3

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
58.4	All items are wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA prior to being introduced into the clean side of the anteroom, placed into a pass-through chamber, and/or brought into the SCA. ***Inspector note: The wiping procedure or agents used should not compromise the packaging integrity or render the product label unreadable. Disinfectant dwell time minimums, as specified by the manufacturer, are to be followed.***	☐	☐	☐	☐		8.1
58.5	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use. ***Inspector note: Per USP, "When sterile items are received in sealed containers designed to keep them sterile until opening, the sterile items may be removed from the covering as the supplies are introduced into the ISO Class 5 PEC without the need to wipe the individual sterile supply items with sterile 70% IPA. The wiping procedure must not render the product label unreadable."***	☐	☐	☐	☐		8.2
58.6	Aseptic processes and manipulations are performed in a manner intended to minimize the risk of contamination. ***Inspector note: Observe the compounder's technique to ensure proper aseptic technique is utilized such as: preparation occurs in the direct compounding area (DCA); the compounder does not interrupt first air during the compounding process; proper set up of equipment, supplies, and components that ensure first air is not interrupted; the compounder handles the syringe in a manner that does not introduce contaminates (touch contamination on the plunger rod); proper entry and exit of materials in ISO Class 5 PEC; and frequent sanitization of gloves.***	☐	☐	☐	☐		2.3
58.7	All critical sites (e.g., vial stoppers, ampule necks, and IV bag septums) are wiped with sterile 70% IPA in the PEC and allowed to dry before puncturing.	☐	☐	☐	☐		7, 8.3
58.8	Gloves are disinfected with sterile 70% IPA immediately before compounding and regularly throughout the compounding process. ***Inspector note: Per USP, best practice is to re-sanitize each time hands re-enter the PEC. This may not occur when compounder is staging the next batch.***	☐	☐	☐	☐		3.3

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
58.9	Gloves are regularly inspected for holes, punctures, or tears, and are replaced immediately if such defects are detected.	☐	☐	☐	☐		3.3
59.0	Do compounding personnel adhere to the USP established time limits for components after initial puncture or entry in compliance with USP <797> standards? ***Look at punctured, stored containers and confirm if puncture time or BUD is noted on the container and stored within time limits.***	☐	☐	☐	☐		15
59.1	Single dose containers (entered or punctured only in an ISO Class 5 air or cleaner air) are not used beyond 12 hours after initial puncture or entry or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured single-dose vials, compounded single-dose CSPs used as components, and CSP stock solutions. The labeled storage requirements during that 12-hour period must be maintained. Additionally, per USP, "This time limit for entering or puncturing (a single-dose CSP or CSP stock solution) is not intended to restrict the BUD of the final CSP."***	☐	☐	☐	☐		15.1, 16.2
59.2	Multiple-use containers are not used for more than 28 days after initial puncture or entry, manufacturer specifications, or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured multiple-dose vials and compounded multiple-dose CSPs used as components. Multiple-dose CSPs are required to meet the criteria for antimicrobial effectiveness testing (USP <51>) and must be stored under the conditions upon which its BUD is based (e.g., refrigerator or controlled room temperature).***	☐	☐	☐	☐		14.5, 15.2, 16.1
59.3	The remaining contents of opened single-dose ampules (or vials where container closure system has been removed) are discarded immediately. ***Inspector note: Ampules or vials where the container closure system has been removed must not be stored for any time period.***	☐	☐	☐	☐		15.1

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
59.4	Pharmacy bulk package containers of sterile drugs for parenteral use are only entered or punctured in an ISO Class 5 PEC. ***Inspector note: Per USP, the pharmacy bulk package system must be used according to the manufacturer's labeling.***	☐	☐	☐	☐		15.3
60.0	**Inspect several different finished compounded sterile preparations.** Are all the finished compounded sterile preparations free from any evidence of particulates, filaments, floaters, or signs ofcontamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately. Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (e.g., filament or floater); number of preparations affected (e.g., two of the five vials on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	☐	☐	☐	☐		12
61.0	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 or high risk drugs or high risk populations (e.g., neonates). These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. Documentation of the compounding accuracy is recommended to be performed by someone other than the compounder to ensure proper measurement, reconstitution, and component usage. Some checks may be done retrospectively and with the assistance of technology.***	☐	☐	☐	☐		2 Table 2, Table 3

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
62.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and disinfection activities in compliance with USP <797> standards? ***If inspector is unable to observe cleaning activities (due to timing of compounding activities observed), inspector should interview compounder(s) to have them walk through their normal process. If this occurs, inspector should record in notes column "process only."***	☐	☐	☐	☐		7
62.1	All cleaning and disinfection activities are performed by appropriately garbed personnel.	☐	☐	☐	☐		7
62.2	Cleaning and disinfection are performed on all surfaces in the classified area and SCA.	☐	☐	☐	☐		7
62.3	Cleaning is performed in the direction of clean to dirty areas.	☐	☐	☐	☐		7
62.4	Reusable cleaning tools are disinfected prior to and after each use.	☐	☐	☐	☐		7.1.2
62.5	Only sterile cleaning, disinfecting, and sporicidal agents are permitted for use in the PEC. ***Inspector note: If pharmacy utilizes non-ready to use (RTU) agents, they must be diluted with sterile water. Per USP, "Once opened, sterile cleaning and disinfecting agents and supplies (e.g., closed containers of sterile wipers) and sterile 70% IPA may be reused for a time period specified as by the manufacturer and/or described in the facility written SOPs."***	☐	☐	☐	☐		7.1.1, 7.1.2
62.6	Only sterile supplies and equipment are permitted for use in the PEC. ***Inspector notes: Non-disposable cleaning tools or handles must be properly disinfected prior to entering the PEC and prior to use.***	☐	☐	☐	☐		7.1.1, 7.1.2
62.7	Compounding personnel are using the appropriate sterile cleaning, disinfecting, and sporicidal agents within the PEC.	☐	☐	☐	☐		7.1.1

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
62.8	Compounding personnel are using the appropriate cleaning and disinfecting procedures and techniques within the PEC. ***Inspector note: Per USP, "All cleaning, disinfecting, and application of sporicidal disinfectants must be documented according to the facility's SOPs"; "Cleaning must be performed in the direction of clean to dirty areas"; and when 70% sterile IPA is used, it is used last and allowed to dry. There are differing opinions on the best order of cleaning.*** ***Procedure includes using a sterile low-lint wiper to all surfaces. Allow surfaces to dry completely before beginning compounding.***	☐	☐	☐	☐		7.1.2 Box 7, Box 8
62.9	The manufacturer's directions or published data for the minimum contact time is followed for each of the cleaning, disinfecting, and sporicidal disinfectant used. ***Per USP, contact times should be included in the SOP based on the agent used.***	☐	☐	☐	☐		7.1.1 Box 7, Box 8
62.10	Sterile 70% IPA is applied to all surfaces in the ISO Class 5 PEC at the frequencies specified by USP during active compounding. ***Inspector note: Per USP <797>, sterile 70% IPA must be applied: immediately before initiating compounding procedures, to the work surface of the PEC at least every 30 minutes (if the compounding process takes 30 minutes or less), to the work surface of the PEC immediately after compounding (when the compounding process takes more than 30 minutes), after each batch or lot is completed, and after cleaning and disinfecting.***	☐	☐	☐	☐		7
	Sterilization and Depyrogenation						**10**
63.0	Does the pharmacy compound preparations with any nonsterile starting components?	☐	☐	☐	☐		10

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
64.0	Are injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (e.g., containers, tubing) during any phase of the compounding procedure, sterilized within six hours after completing the preparation? ***If no, describe observations and collect a copy of the master formulation record, a copy of the compounding record, and a copy of the process for sterilization.*** ***If the pharmacy does not compound with nonsterile components or devices, or they only compound sterile ophthalmic and/or sterile drugs administered by inhalation, inspector should answer question as N/A.***	☐	☐	☐	☐		10
65.0	**Filter Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***View compounding records for CSPs sterilized by filtration to verify.*** ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (e.g., affecting its strength, purity, or quality) or the packaging integrity.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	☐	☐	☐	☐		10.2 USP <1229.4>
65.1	Sterilization by filtration is performed in an ISO 5 environment.	☐	☐	☐	☐		4.1.2, 10.2
65.2	Filters used have enough capacity to filter the required volumes. ***Inspector note: Per USP, "The filter dimensions and the CSP to be sterilized by filtration should permit the sterilization process to be completed without the need for replacement of the filter during the process."***	☐	☐	☐	☐		10.2

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
65.3	The 0.2 micron sterile micro-porous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP. ***Inspector note: Per USP <797>, sterilizing filters must be appropriate for pharmaceutical use. Sterilizing filters labeled "for laboratory use" or equivalent must not be used. "Sterilizing filters must be certified by the manufacturer to retain at least 10^7 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be filtered (ie, pressure, flow rate, and volume filtered)."***	☐	☐	☐	☐		10.2
65.4	Confirmation of filter integrity (bubble testing) is performed and documented for each filter used with each batch sterilized by filtration. ***Inspector note: If multiple filters are required for the compounding process, each of the filters must be tested.*** ***If no, collect a copy of the master formulation record and compounding record.***	☐	☐	☐	☐		10.2
65.5	A prefiltration step is performed for any CSPs that are known to contain excessive particulate matter. ***Inspector note: The prefiltration step consists of using a filter with a larger nominal pore size (e.g., 1.2 micron) or a separate filter of larger nominal pore size should be placed upstream of (i.e., prior to) the sterilizing filter to remove gross particulate contaminants before the CSP is passed through the sterilizing-grade filter.***	☐	☐	☐	☐		10.2
65.6	CSPs that are prepared using a filter that failed integrity tests are either discarded or, after investigating the cause of the failure and selection of an appropriate filter, refiltered for sterilization not more than one additional time. ***If no, collect a copy of the master formulation record and compounding record.***	☐	☐	☐	☐		10.2
65.7	Single-use filters are only used once.	☐	☐	☐	☐		4.1.2, 10.2

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
66.0	**Steam Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment (autoclave), documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (e.g., affecting its strength, purity, or quality) or the packaging integrity.*** ***View documentation on compounding records for CSPs sterilized by steam to confirm.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	☐	☐	☐	☐		10.3 USP <1229.1>
66.1	The pharmacy has evaluated if steam sterilization would cause degradation of the drug. ***Inspector note: Per USP, compounded preparations that are degraded by moisture, pressure, or temperatures used may not be sterilized by steam heat.***	☐	☐	☐	☐		10.3
66.2	Steam supplied is free of contaminants and generated using water per manufacturer's specifications.	☐	☐	☐	☐		10.3
66.3	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	☐	☐	☐	☐		10.3
66.4	Items are placed in the autoclave in a manner that allows steam to reach them without entrapment of air. ***Inspector note: The pharmacy should have the autoclave cycle validated for the size of the batch, sterilization temperature, and sterilization time to ensure the load will be sterile.***	☐	☐	☐	☐		10.3 USP <1229.1>
66.5	Sealed containers used are able to generate steam internally (e.g., small amount of water in empty crimped vials).	☐	☐	☐	☐		10.3

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
66.6	The appropriate biological indicators (USP <1229>) are used to verify the effectiveness of each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of steam sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Geobacillus stearothermophilus (ATCC 12980, ATCC 7953, or equivalent; see Biological Indicators for Sterilization USP <1229.5>), and other confirmation methods such as physicochemical indicators (see Physicochemical Integrators and Indicators for Sterilization USP <1229.9>). The date, run, and load numbers of the steam sterilizer used to sterilize a CSP is documented in the compounding record."***	☐	☐	☐	☐		10.3 USP <1229.5> USP <1229.9>
66.7	All items are directly exposed to steam under adequate pressure for the length of time necessary as determined by use of appropriate biological indicators to render the items sterile. ***Inspector note: Per USP <797>, the duration of the exposure period must include sufficient time for the entire contents of the CSP and other items to reach the sterilizing temperature. The CSP and other items must remain at the sterilizing temperature for the duration of the sterilization period (an example provided in the chapter is 20-60 minutes at 121°C saturated steam under a pressure of 15 psi, depending on the volume or size of the CSP being sterilized).*** ***Any parameters for the autoclave must be set through validation.***	☐	☐	☐	☐		10.3 USP <1229.1>
66.8	A calibrated data recorder or chart is used to monitor each cycle and to examine for cycle irregularities (e.g., deviations in temperature or pressure) and results documented on the CR.	☐	☐	☐	☐		10.3, 20

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
67.0	**Dry Heat Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (e.g., affecting its strength, purity, or quality) or the packaging integrity. USP <1229.8> also applies.*** ***View documentation on compounding records for CSPs sterilized by dry heat to confirm.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	☐	☐	☐	☐		10.4 USP <1229.8>
67.1	The pharmacy has the appropriate dry heat sterilization equipment. ***Inspector note: Dry heat sterilization is usually performed in an oven designed for sterilization at 160°C or higher. The dry heat oven should be able to get to the appropriate temperature and pressure, for example, not be a toaster oven.***	☐	☐	☐	☐		10.4
67.2	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	☐	☐	☐	☐		10.4
67.3	During sterilization, sufficient space is left between materials to allow for circulation of hot air.	☐	☐	☐	☐		10.4
67.4	CSPs and other items are exposed to dry heat for the length of time necessary for all items to reach sterilizing temperature of 160°C or higher. ***Inspector note: Per USP <797>, if lower temperatures are used, they are validated by biological indicators (see USP <1229.8>, Validation of Dry Heat Sterilization, Biological Indicators). The calibrated oven must be equipped with temperature controls and a timer.***	☐	☐	☐	☐		10.4

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
67.5	The appropriate biological indicators are used to verify the effectiveness of each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of dry heat sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Bacillus atrophaeus (ATCC 9372; see Biological Indicators for Sterilization USP <1229.5>) and other confirmation methods (e.g., temperature-sensing devices). The date, run, and load numbers of the dry heat oven used to sterilize a CSP must be documented in the CR."***	☐	☐	☐	☐		10.4 USP <1229.5>
67.6	A calibrated data recorder or chart is used to monitor each cycle and the data is reviewed to identify cycle irregularities (e.g., deviations in temperature or exposure time) and results documented on the CR.	☐	☐	☐	☐		10.4, 20
68.0	**Dry Heat Depyrogenation:** Is the appropriate depyrogenation method used and documented in compliance with USP <797> standards? ***View documentation records of items depyrogenated to confirm.*** ***If the pharmacy does not use this method, inspector should answer question as N/A.***	☐	☐	☐	☐		10.1 USP <1228.1>
68.1	Glassware, metal, and other thermostable containers are exposed to dry heat for the length of time necessary for all items to be rendered pyrogen free.	☐	☐	☐	☐		10.1
68.2	The effectiveness of the dry heat depyrogenation cycle is established and documented. ***Inspector note: Per USP <797>, this must be done initially, re-established any time there are changes made to the cycle (e.g., load conditions, duration, temperature), and verified at least annually by using endotoxin challenge vials (ECVs) to demonstrate that the cycle is capable of achieving a ≥ 3-log reduction in endotoxins (see Bacterial Endotoxins Test USP <85>). The verification must be documented.***	☐	☐	☐	☐		10.1 USP <1228.1> USP <85>

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
68.3	Items that are not thermostable are depyrogenated by multiple rinses with sterile, nonpyrogenic water (e.g., sterile water for injection or sterile water for irrigation) and then thoroughly drained or dried immediately before use in compounding. ***Inspector note: USP <1228.4> Depyrogenation by Rinsing also applies.***	☐	☐	☐	☐		10.1 USP <1228.4>
	Master Formulation and Compounding Records **Inspector should review a minimum of five (5) master formulation records and five (5) compounding records.**						**11**
69.0	Are **Master Formulation Records (MFRs)** created and maintained in compliance with USP <797> standards?	☐	☐	☐	☐		11.1
69.1	The pharmacy creates and maintains MFRs for CSPs that are prepared for more than one patient.	☐	☐	☐	☐		11.1, 20
69.2	MFR changes and alterations are approved and documented according to the pharmacy's SOPs.	☐	☐	☐	☐		11.1
69.3	The pharmacy creates and maintains MFRs for CSPs that are prepared from nonsterile ingredients.	☐	☐	☐	☐		11.1, 20
69.4	The MFR includes the name, strength or activity, and dosage form of the sterile compounded preparation.	☐	☐	☐	☐		11.1, 20
69.5	The MFR includes the identities and amounts of all ingredients.	☐	☐	☐	☐		11.1, 20
69.6	The MFR includes the type and size of container closure.	☐	☐	☐	☐		11.1, 20

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
69.7	The MFR includes complete instructions for preparing the sterile compounded preparation, including equipment, supplies, a description of the compounding steps, and any special precautions.	☐	☐	☐	☐		11.1, 20
69.8	The MFR includes a physical description of the final CSP.	☐	☐	☐	☐		11.1, 20
69.9	The MFR includes the BUD and storage requirements.	☐	☐	☐	☐		11.1, 14.2, 20
69.10	The MFR includes the reference source to support the stability of the CSP.	☐	☐	☐	☐		11.1, 20
69.11	The MFR includes quality control procedures (e.g., pH testing, filter integrity testing).	☐	☐	☐	☐		11.1, 20
69.12	The MFR includes other information as needed to describe the compounding process and ensure repeatability (e.g., adjusting pH and tonicity, sterilization method).	☐	☐	☐	☐		11.1, 20
69.13	The MFR includes all required release tests, and if applicable, sterility test methods, process, number and endotoxin test and limits.	☐	☐	☐	☐		11.1, 12, 20
70.0	Are **Compounding Records (CR)** created and maintained in compliance with USP <797> standards? ***Inspector note: Per USP, a prescription or medication order or label may serve as the CR. Also, a copy of the MFR can be made that contains spaces for recording the information needed to complete the CR (e.g., both the MFR and CR are on the same document/form). A CR may be kept electronically, if readily retrievable, as long as it contains all required information.***	☐	☐	☐	☐		11.2 Box 10

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
70.1	The pharmacy creates and maintains CRs for all for immediate-use CSPs prepared for more than one patient. ***Inspector note: if pharmacy does not prepare any CSPs for immediate-use, inspector should answer compliance statement as N/A.***	☐	☐	☐	☐		11.2 Box 10
70.2	The pharmacy creates and maintains CRs for all Category 1, Category 2, and Category 3 CSPs.	☐	☐	☐	☐		11.2 Box 10
70.3	The CR includes the name, strength or activity, dosage form of the CSP, and (if applicable) the MFR reference.	☐	☐	☐	☐		11.2 Box 10
70.4	The CR includes the date and time of preparation.	☐	☐	☐	☐		11.2 Box 10
70.5	The CR includes an assigned internal identification number (e.g., prescription, order, or lot number).	☐	☐	☐	☐		11.2 Box 10
70.6	The CR includes the identity of the individual(s) involved in the compounding process.	☐	☐	☐	☐		11.2 Box 10
70.7	The CR includes identity of the individual(s) verifying the final CSP.	☐	☐	☐	☐		11.2 Box 10
70.8	The CR includes the name of each component.	☐	☐	☐	☐		11.2 Box 10
70.9	The CR includes the vendor/manufacturer, lot number, and expiration date for each component. ***Inspector note: this is required for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s).***	☐	☐	☐	☐		11.2 Box 10
70.10	The CR includes the weight or volume of each component.	☐	☐	☐	☐		11.2 Box 10
70.11	The CR includes the strength or activity of each component.	☐	☐	☐	☐		11.2 Box 10
70.12	The CR includes the total quantity compounded.	☐	☐	☐	☐		11.2 Box 10

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70.13	The CR includes the final yield (e.g., quantity, containers, number of units).	☐	☐	☐	☐		11.2 Box 10
70.14	The CR includes the assigned BUD and storage requirements.	☐	☐	☐	☐		11.2 Box 10
70.15	The CR includes results of quality-control procedures (e.g., visual inspection, filter integrity testing, pH testing).	☐	☐	☐	☐		11.2, 12 Box 10
70.16	The CR includes calculations made to determine and verify quantities and/or concentrations of components. ***Inspector note: Per USP, "If applicable, the CR must also include…Calculations."***	☐	☐	☐	☐		11.2 Box 10
70.17	The CR is verified by the pharmacist for appropriateness and accuracy with in-process and final checks. ***Inspector note: "Documentation must comply with all laws and regulations of the applicable regulatory jurisdiction."***	☐	☐	☐	☐		2, 11.2, 12.1, 13, 20 Box 10
71.0	Are the pharmacy's labels for CSPs in compliance with USP <797> standards and display all requiredinformation?	☐	☐	☐	☐		13 USP <7>
71.1	Information on the label is prominently and legibly displayed. ***Inspector note: Definition of labeling includes other accompanying materials with the CSP, which includes, "written, printed, or graphic matter on the immediate container or on or inside any package or wrapper in which it is enclosed." The shipping container is not included in the definition of the "label."***	☐	☐	☐	☐		13

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
71.2	Labeling meets any state or federal regulatory requirements.	☐	☐	☐	☐		13
71.3	Labeling on the immediate container includes an assigned internal identification number (e.g., barcode, prescription, order, or lot number).	☐	☐	☐	☐		13
71.4	Labeling on the immediate container includes the active ingredients and their amounts, activity, or concentration.	☐	☐	☐	☐		13
71.5	Labeling on the immediate container includes the storage conditions, if other than controlled room temperature.	☐	☐	☐	☐		13
71.6	Labeling on the immediate container includes the BUD. Per USP, "Each CSP label must state the date, or the hour and date, beyond which the preparation must not be used and must be discarded (i.e., the BUD)."	☐	☐	☐	☐		13, 14.1
71.7	The compounded CSP label does not use the term "expiration date" or equivalent.	☐	☐	☐	☐		13, 14.1 USP <7>
71.8	Labeling on the immediate container includes the dosage form.	☐	☐	☐	☐		13
71.9	Labeling on the immediate container includes the total amount or volume when not obvious from the container.	☐	☐	☐	☐		13
71.10	Labeling on the immediate container states that the CSP is a single-dose container (when space permits).	☐	☐	☐	☐		13
71.11	Labeling on the immediate container states that the CSP is a multiple-dose container.	☐	☐	☐	☐		13

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
71.12	Labeling includes the route of administration, as applicable.	☐	☐	☐	☐		13
71.13	Labeling includes any special handling instructions and/or warning statements, as applicable.	☐	☐	☐	☐		13
71.14	Labeling includes the compounding facility name and contact information if the CSP is to be sent outside of the facility or health care system in which it was compounded.	☐	☐	☐	☐		13
72.0	Does the label contain information identifying the CSP is a compounded preparation? ***Inspector note: Per USP, this is a recommendation/should.***	☐	☐	☐	☐		13 USP <7>
	Establishing BUDs						**14**
73.0	**Category 1 and Category 2 CSPs:** Does the pharmacy assign BUDs for Category 1 and Category 2 CSPs in compliance with USP <797> standards?	☐	☐	☐	☐		14, 14.1, 14.2
73.1	The assigned BUD does not exceed the shortest expiration date of any of the individual commercially available starting components.	☐	☐	☐	☐		14.3
73.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and that its packaging maintains its integrity for the duration of the assigned BUD.	☐	☐	☐	☐		14.3

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
73.3	**Category 1 CSPs:** BUDs for **Category 1 CSPs** prepared in an SCA do not exceed the limits established in Table 12. ***Inspector note: Per USP <797> Table 12, BUD maximum limits for Category 1 CSPs are defined as 12 hours at controlled room temperature (CRT 20°C-25°C) or 24 hours refrigerated (2°C-8°C).*** ***If no Category 1 CSPs are prepared, inspector should answer statement as N/A.***	☐	☐	☐	☐		14.3, Table 12
73.4	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs using one or more nonsterile starting components are defined as: one day CRT; four days refrigerator; and 45 days freezer. Aseptically processed Category 2 CSPs using only sterile starting components are defined as: four days CRT; 10 days refrigerator; and 45 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***	☐	☐	☐	☐		14.3, Table 13
73.5	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs, that were sterility tested and passed, regardless of starting components being sterile or nonsterile, are defined as: 30 days CRT; 45 days refrigerator; and 60 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***	☐	☐	☐	☐		14.3, 14.2.1, 14.2.3, Table 13

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
73.6	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to probability of nonsterile unit (PNSU) of 10^{-6} (e.g., dry heat, steam, irradiation) Category 2 CSPs are defined as: 14 days CRT; 28 days refrigerator; and 45 days freezer.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***	☐	☐	☐	☐		14.3, 14.2.1, Table 13
73.7	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to PNSU of 10^{-6} (e.g., dry heat, steam, irradiation) Category 2 CSPs are defined as: 45 days CRT; 60 days refrigerator; and 90 days freezer. Endotoxin testing is required for Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing.*** ***USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components are also endotoxin tested.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***	☐	☐	☐	☐		14.3, 14.2.1, 14.2.3, Table 13

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
74.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest beyond use date of any individual compounded components? ***Inspector note: Per USP, "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 CSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP must not be negatively impacted." Other examples where this may occur: formula within a formula, preservative-free compounded component used in a preserved final CSP, "in-use" times for pharmacy bulk packages, and cyclosporine ophthalmic stock solution.*** ***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.***	☐	☐	☐	☐		14.3
75.0	Are BUDs for **Category 3 CSPs** assigned in compliance with all conditions outlined in USP <797> standards and do not exceed the maximum limits established in Table 14? ***Inspector note: If all of the conditions described for Category 3 CSPs are not met, the applicable BUD must not exceed the established maximum limits in Table 13 for Category 2 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer question as N/A.***	☐	☐	☐	☐		14.3, 14.4., 14.4.1, 14.4.2, 14.4.3, 14.4.4, Table 14
75.1	The assigned BUD does not exceed the shortest expiration date of any of the individual starting components.	☐	☐	☐	☐		14.3 Table 14
75.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and its packaging maintains its integrity for the duration of the assigned BUD.	☐	☐	☐	☐		14.3 Table 15

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
75.3	BUDs for **Category 3 CSPs** do not exceed the maximum limits for aseptically processed (e.g., filtered) established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits for aseptically processed Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 60 days CRT; 90 days refrigerator; and 120 days frozen.***	☐	☐	☐	☐		14.4.1 Table 14
75.4	BUDs for **Category 3 CSPs** do not exceed the maximum limits for terminally sterilized established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits terminally sterilized Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 90 days CRT; 120 days refrigerator; and 180 days frozen.***	☐	☐	☐	☐		14.4.1 Table 14
75.5	**Category 3 CSPs** are supported by stability data obtained using methods described in USP <1225> or a validated noninferior stability-indicating analytical method. ***Inspector note: Per USP <797>, Category 3 CSPs must prepared according to the EXACT formulation (API and other ingredients of identical grade and procedures) from which the stability data is derived. Category 3 CSPs must be packaged and stored in container closure of the same materials of composition as used in study and the facility must have documentation of the stability study.*** ***View records to verify the preparation exactly matches the preparation cited in the documentation including concentration of all active ingredients, excipients, etc.***	☐	☐	☐	☐		14.4.3 Table 14 USP <1225>
75.6	**Category 3 CSPs** undergo sterility testing. ***Inspector note: Sterility testing is performed on all Category 3 CSPs.***	☐	☐	☐	☐		14.4.4 Table 14 USP <71>
75.7	**Category 3 CSPs** undergo bacterial endotoxin testing. ***If all compounds prepared are ophthalmics and/or drug administered by inhalation, bacterial endotoxin is not required, inspector should answer statement as N/A.***	☐	☐	☐	☐		12.3, 14.4.4 Table 14 USP <85>

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
75.8	**Category 3 CSPs** undergo particulate matter testing. ***Inspector note: If the Category 3 CSP is an injection or an ophthalmic solution, particulate matter testing is also conducted once per formulation with acceptable results (See USP <788> Particulate Matter in Injections and USP <789> Particulate Matter in Ophthalmic Solutions).***	☐	☐	☐	☐		14.4.3 Table 14 USP <788>, <789>
75.9	**Category 3 CSPs** undergo an evaluation for the container closure system. ***Inspector note: The container closure system used is evaluated for and conforms to container closure integrity to the end of the BUD (see USP <1207> Package Integrity Evaluation— Sterile Products). Evaluation must be done once for each formulation and for each container closure system in which it will be packaged.***	☐	☐	☐	☐		14.4.3 Table 14 USP <1207>
76.0	Are **multiple-dose CSPs prepared** in compliance with USP <797> standards? ***If the pharmacy does not prepare multiple-dose CSPs, inspector should answer question as N/A.***	☐	☐	☐	☐		14.5
76.1	Multiple-dose CSPs are prepared as a Category 2 or Category 3 CSP only.	☐	☐	☐	☐		14.5
76.2	When preservatives are used, they are appropriate for the CSP formulation and the route of administration. Inspector note: Per USP <797>, "The preservative must not be inactivated by any ingredients in the CSP, and some preservatives are not always appropriate for the patient (e.g., neonates) or route of administration (e.g., intrathecal or ophthalmic injection)."	☐	☐	☐	☐		14.5

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
76.3	Aqueous multiple-dose CSPs pass antimicrobial effectiveness testing in accordance with USP <51>. ***Inspector note: Per USP <797>, a test can be one test done for each formulation in the particular container-closure system in which it will be packaged, or test results provided by an FDA-registered facility or in appropriate peer-reviewed literature, provided the sterile compounded preparation formulation and container-closure system used are exactly the same as those tested, unless a bracketing study is performed. The concentration of all other ingredients (including preservatives) must be the same throughout the bracketing study.*** ***Additionally, multiple-dose, nonpreserved, aqueous topical, and topical ophthalmic CSPs prepared as a Category 2 or Category 3 CSP are not required to pass antimicrobial effectiveness testing if the preparation is: For use by a single patient, labeled (in the label or labeling) to indicate that, once opened, it must be discarded after 24 hours when stored at controlled room temperature and/or that, once opened, it must be discarded after 72 hours when stored under refrigeration.***	☐	☐	☐	☐		14.5 USP <51>
76.4	Multiple-dose CSPs are labeled to indicate the beyond use date of the CSP once it is opened or punctured. ***Inspector note: Labeling on the CSP should indicate that once the CSP container is entered or punctured, it must not be used for longer than the assigned BUD or 28 days (if supported by antimicrobial effectiveness testing results), whichever is shorter.*** ***Inspector should review the CR or final compounded preparation to verify the label contains this information.***	☐	☐	☐	☐		14.5
76.5	Container-closure systems used are evaluated for maintaining integrity (USP <1207>) for each formulation and fill volume. ***Inspector note: Per USP <797>, the container closure integrity test needs to be conducted only once on each formulation and on fill volume in the particular container closure system in which the multiple-dose CSP will be packaged.***	☐	☐	☐	☐		14.5 USP <1207>

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
	Finished Preparation Release Checks and Tests						12
77.0	Are all CSPs visually inspected for quality prior to release or dispensing in compliance with USP <797> standards?	☐	☐	☐	☐		12.1
77.1	The CSP label is visually inspected to confirm that the CSP and its labeling match the prescription or medication order.	☐	☐	☐	☐		12.1
77.2	CSPs are visually inspected for quality characteristics such as discoloration, visible particulates, or cloudiness.	☐	☐	☐	☐		12.1
77.3	CSPs are visually inspected to verify container closure integrity (e.g., checking for leakage, cracks in the container, or improper seals).	☐	☐	☐	☐		12.1
77.4	A visual inspection is also repeated prior to release or dispense for CSPs that have been stored in the pharmacy and not released or dispensed on the day of preparation.	☐	☐	☐	☐		12.1
77.5	Any CSPs found to be of unacceptable quality (e.g., observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	☐	☐	☐	☐		12.1

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
78.0	For any CSPs assigned beyond use dates that require sterility testing, does the pharmacy ensure that all testing is performed, evaluated, and documented in accordance with USP <71> or a validated alternative method that is noninferior to USP <71> testing and USP <797> standards? ***Inspector note: Alternative testing methods may not be accepted in all regulatory jurisdictions that the pharmacy conducts business.*** ***If the pharmacy does not prepare any CSPs that require sterility testing, inspector should mark as N/A.***	☐	☐	☐	☐		12.2
78.1	The required number of sterile compounded preparation units, as described in USP <71> and USP <797>, are tested. ***Inspector note: Per USP <71> Table 3, the minimum number of items to be tested for each medium is:*** ***Parenterals*** ***Not more than 100 containers = 10% or four containers, whichever is greater*** ***More than 100, but not more than 250 containers = 10 containers*** ***Large volume parenterals*** ***2% or 10 containers, whichever is less*** ***Non-parenterals (eye drops, inhalation, pellets, etc.)*** ***Not more than 200 containers = 5% or two containers, whichever is greater*** ***More than 200, but not more than 250 containers = 10 containers*** ***Per USP <797>, if the number of CSPs compounded in a single batch is less than what is needed for testing as specified in USP <71> Table 3, additional units must be compounded to be able to perform testing as follows:*** ****If 1-39 CSPs are compounded in a single batch, the sterility testing must be performed on a number of units equal to 10% of the number of CSPs prepared, rounded up to the next whole number.*** ****If more than 40 CSPs are prepared in a single batch, the sample sizes specified in USP <71> Table 3 must be used.***	☐	☐	☐	☐		12.2, 14.2.3 USP <71>

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78.2	Batch sizes of sterile CSPs do not exceed 250. ***Inspector Note: Per USP <797>, the maximum batch size for all sterile compounded preparation requiring sterility testing is limited to 250 final yield units.***	☐	☐	☐	☐		12.2, 14.2.3
78.3	Pharmacy is utilizing an alternative method for sterility assurance testing (other than USP <71>). ***Inspector note: Per USP, "If an alternative method is used for sterility testing, the method must be validated (see USP <1223>) and demonstrated to be suitable for that CSP formulation."*** ***If an alternative method is used, describe the method used and how the pharmacy ensures they are compliant with state-specific regulations.***	☐	☐	☐	☐		12.2 USP <71>, <1223>
78.4	When sterility testing identifies a failure, the pharmacy has processes to investigate and identify any contributing factors. ***Inspector note: Per USP, "Sterility tests resulting in failures must prompt an investigation into the possible causes and must include identification of the microorganism, as well as an evaluation of the sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. The source(s) of the contamination, if identified, must be corrected, and the facility must determine whether the conditions causing the sterility failure affect other CSPs. The investigation and resulting corrective actions must be documented."*** ***Additionally, some rapid sterility test methods do not allow for the identification of the recovered microorganisms. If one of these methods is used, the pharmacy is not in compliance with the chapter, as the investigation must include identification of the recovered microorganism.***	☐	☐	☐	☐		12.2

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79.0	For any CSPs assigned BUDs that require **bacterial endotoxin testing**, does the pharmacy ensure that all testing is performed and documented in compliance with USP <85> and USP <797> standards? ***Inspector note: Endotoxin limits reflect limits in an official monograph, or calculated as described in USP Chapter <85> for the route of administration for humans, and for animals based on weight.*** ***Although USP <797> refers to USP <85> Bacterial Endotoxins Test for calculating endotoxin limits for the appropriate route of administration, it does not address products administered epidurally or administered directly into the central nervous system. CSPs administered epidurally should have the same endotoxin limit as that of intrathecally administered CSPs.*** ***If the pharmacy does not prepare CSPs that require bacterial endotoxin testing, inspector should answer question as N/A.***	☐	☐	☐	☐		12.3 USP <85>
79.1	The pharmacy has an appropriate procedure for calculating/determining endotoxin limits. ***Per USP, there are endotoxin limits listed in USP product and compounded preparation monographs. The laboratory may be performing the calculation rather than the pharmacy; however, if done in house, this should be included in the pharmacy SOPs.*** ***If the dosage form does not require, inspector should answer statement as N/A.***	☐	☐	☐	☐		12.3
79.2	The pharmacy collects patient weight to make bacterial endotoxin calculation for an animal patient. ***If the dosage form does not require or the pharmacy does not compound sterile preparations for animals, inspector should answer statement as N/A.***	☐	☐	☐	☐		12.3

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79.3	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 2 CSPs** compounded from one or more nonsterile components that are assigned a BUD requiring sterility testing per Table 13. ***Inspector note: USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components is also endotoxin tested.***	☐	☐	☐	☐		12.3 Table 13 USP <85>
79.4	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 3 CSPs** compounded from one or more nonsterile components.	☐	☐	☐	☐		12.3 Table 13 USP <85>
79.5	Any CSPs with failed endotoxin testing are quarantined, not further released, and action is taken for any product released prior to receipt of failed test results. ***View testing records and note any products with failed results and actions taken.***	☐	☐	☐	☐		12.2, 12.3
	CSP Packaging, Shipping and Transport						**19**
80.0	Are processes and techniques for packaging and transporting CSPs in compliance with USP <797> standards?	☐	☐	☐	☐		19.1, 19.2, 19.3
80.1	The pharmacy uses the appropriate shipping containers and packaging materials (e.g., coolers and light-resistant packaging) based on the product specifications.	☐	☐	☐	☐		19.2
80.2	CSPs are appropriately packaged to protect against damage, leakage, contamination, degradation, and adsorption during storage and transport. ***Inspector should look at packaging materials used to ensure cushioning to prevent breakage of glass vials and ensure that container is generally clean without non-microbial growth that would come in direct contact with CSPs.***	☐	☐	☐	☐		19.2
80.3	Specific handling instructions when applicable, are included on the exterior of the container.	☐	☐	☐	☐		19.3

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
80.4	The pharmacy selects transport modes that ensure CSPs are delivered properly in undamaged, sterile, and stable conditions (e.g., no undue exposure to heat, cold, or light). ***Inspector note: Transport modes include pneumatic tube transport systems and should not be used if the CSP is sensitive to shaking.***	☐	☐	☐	☐		19.3
	Quality Assurance and Quality Control						**18**
81.0	**Quality Assurance and Quality Control (QA/QC):** Does the pharmacy's SOP on quality assurance and quality control meet the requirements in compliance with USP <797> standards?	☐	☐	☐	☐		18 USP <1163>
81.1	Description of procedures for complaint handling, adverse events, and recalls that include corrective action, investigation, reporting, and documentation requirements.	☐	☐	☐	☐		18.1, 18.2
81.2	**QA/QC Out-Of-Specification (OOS) SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the severity of the problem and the urgency for implementation and completion of the recall.	☐	☐	☐	☐		18.1
81.3	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the distribution of any affected CSP, including the date and quantity of distribution.	☐	☐	☐	☐		18.1
81.4	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to identify patients who have received the CSP.	☐	☐	☐	☐		18.1
81.5	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process for the disposal and documentation of the recalled CSP.	☐	☐	☐	☐		18.1
81.6	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to investigate and document the reason for failure.	☐	☐	☐	☐		18.1

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Sterile Compounding Inspection for USP <797>

Facility Name: «Name»,«DBA_Name»
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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
82.0	Does the pharmacy ensure that QA and QC programs are conducted in compliance with USP <797> standards?	☐	☐	☐	☐		18, 20
82.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "Designated person(s) must ensure that the facility has formal, written QA and QC programs that establish a system of: adherence to procedures; prevention and detection of errors and other quality problems; evaluation of complaints and adverse events; and appropriate investigations and corrective actions."***	☐	☐	☐	☐		18
82.2	The pharmacy's QA/QC program is reviewed at least once every 12 months by the designated person(s) and the results of the review are documented.	☐	☐	☐	☐		18
82.3	The designated person(s) reviews all complaints to determine whether the complaint indicates a potential quality problem with the CSP.	☐	☐	☐	☐		18.2, 20
82.4	All complaints and adverse events are thoroughly investigated. ***Inspector note: Per USP <797>, the timeframe is specified in the facility SOP. Additionally, USP states, "The investigation must consider whether the quality problem extends to other CSPs."*** ***If facility SOP permits a long investigation period, include in the inspector notes the SOP's expected time frame to complete an investigation. State may have a more aggressive time frame to complete an investigation and report quality events to the state.***	☐	☐	☐	☐		18.2, 18.3, 20

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82.5	The record of each complaint is maintained by the pharmacy regardless of the source of the complaint (e.g., email, telephone, or mail) and includes the minimum required information. ***Inspector note: Per USP <797>, the complaint record must contain the following information:*** ***-Name of the complainant or other unique identifier;*** ***-Date the complaint was received;*** ***-Nature of the complaint;*** ***-The response to the complaint; and*** ***-Results of any investigation and any follow-up.*** ***In addition, to the extent that the information is known, the following should be recorded:*** ***-The name and strength of the CSP and the assigned internal identification number (e.g., prescription, order, or lot number).*** ***If no, inspector should document what is missing in the notes column.***	☐	☐	☐	☐		18.2, 20
82.6	The pharmacy's QA/QC program includes documentation of steps necessary for completing a recall, including reporting the recall to appropriate regulatory agencies. ***Inspector note: Per USP, "The recall must be reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction."***	☐	☐	☐	☐		18.1, 18.2
83.0	If a CSP is dispensed or administered **before the results of release testing are known**, does the pharmacy ensure procedures for recalls and out-of-specification notifications are conducted and documented in compliance with USP <797> standards? ***Inspector note: Per USP <797>, if a CSP is dispensed or administered before the results of release testing are known, the facility must have procedures in place to notify, recall, and investigate.***	☐	☐	☐	☐		18.1, 20
83.1	The pharmacy has a process in place to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (e.g., sterility, strength, purity, bacterial endotoxin, or other quality attributes).	☐	☐	☐	☐		18.1

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	Observation	Yes	No	N/A	Unknown	Inspector Notes	USP Reference
83.2	The pharmacy has a process in place to recall any unused dispensed CSPs and quarantine any stock remaining in the pharmacy.	☐	☐	☐	☐		18.1
83.3	The pharmacy has a process in place to investigate if other lots are affected and recall if necessary.	☐	☐	☐	☐		18.1
	Personnel Training and Evaluation - **Verify records of all compounding personnel (up to 10). Use the records tab to document records reviewed.**						**2**
84.0	Is the pharmacy's documented hand hygiene and garbing competency evaluations compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet (columns G-J) for details.***	☐	☐	☐	☐		2.2, 20 Box 1, Table 1
85.0	Is the pharmacy's documented aseptic manipulation competency evaluation compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet (columns K-O) for details.***	☐	☐	☐	☐		2.3, 20 Box 2, Table 1
86.0	Is the pharmacy's documented training program and ongoing competency evaluation compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet (columns P-S) for details.***	☐	☐	☐	☐		2, 2.1, 17 Table 2, Table 3

PIC Signature _____ Date _____ Inspector Signature _____ Date _____