



Inspection Details

<b>Name</b>	Test Pharmacy	<b>Case #</b>		<b>Permit</b>	14549
<b>Address</b>	123 Apple St. Chapel Hill, NC 27516	<b>Person</b>		<b>Inspection Date</b>	06/25/2024
<b># RPhs</b>	2	<b>Providing Info</b>		<b>Inspection User</b>	Brashears, Krystal
<b># Techs</b>	3	<b>Person In</b>	Jack William	<b>Inspection</b>	DISTRICT3
<b>Follow-Up CAP</b>	No	<b>Charge</b>	Campbell, IV	<b>District</b>	
<b>CAP Requested</b>	No	<b>Rx Volume/Date</b>	500		
<b>CAP</b>	No	<b>Hours</b>			
<b>Documentation</b>	No	<b>Office</b>	No		
<b>Received</b>	No	<b>Commercial Use</b>	No		
<b>Additional</b>	Yes	<b>Ship to Other</b>	No		
<b>Documents</b>		<b>States</b>			
<b>Office Use</b>	No	<b>States Shipped</b>			
<b>Office Use</b>		<b>To</b>			
<b>Comments</b>		<b>Commercial Use</b>	No		
		<b>Documented</b>			
		<b>Clinical</b>			
		<b>Indication</b>			

Non-Sterile Compounding

<b>Non-Sterile</b>	Yes
<b>Does the pharmacy engage in Occasional Basic Non-Sterile Compounding?</b>	Yes
<b>Does facility engage in moderate or complex sterile compounding?</b>	Yes
<b>Does facility engage in Hazardous Drug Compounding?</b>	Yes
<b>Is there documented clinical indication for the approved medication?</b>	

Sterile Compounding

<b>Sterile Compounding</b>	Yes
<b>Does facility compound Immediate Use CSP?</b>	Yes
<b>Does facility compound Category 1 Sterile Compounding?</b>	Yes
<b>Does facility compound Category 2 Sterile Compounding?</b>	Yes
<b>Does facility compound Category 3 Sterile Compounding?</b>	Yes
<b>Does facility compound hazardous medications?</b>	Yes
<b>Does facility compound Allergenic Extracts?</b>	Yes

Pharmacy Staffing

<b>How many pharmacists are employed at the pharmacy:</b> 2	<b>How many technicians are employed at the pharmacy:</b> 3
<b>What is the P:T ratio at the time of inspection:</b> 1:4	<b>How often is there only one pharmacist on duty:</b>
<b>If ratio is above 1:2 at the time of inspection, how many certified technicians are on shift:</b> 3	<b>How many technicians are usually on shift at a time:</b>
<b>What is the approved Pharmacist: Technician ratio?</b> N/A	<b>Are pharmacists asked to do any duties outside of the pharmacy :</b>

Pharmacy Volume

<b>What is the average daily prescription volume of the pharmacy:</b> 500	<b>Does pharmacy conduct any point of care testing such as COVID:</b> No
<b>Does pharmacy administer vaccines:</b> No	<b>What is the daily average of testing:</b>
<b>What is the daily average of vaccines:</b>	<b>What staff is responsible for administering test and what is testing procedure:</b>
<b>What staff members are administering vaccines and what type of vaccines:</b>	<b>Are administered vaccines reported to the appropriate vaccine registry:</b>
<b>How far behind is the pharmacy on filling and verifying prescriptions:</b> N	<b>Please explain:</b>
<b>How long has this backlog persisted:</b>	

Comments

None

General Pharmacy Regulations

Answer	Question
1) <b>Unanswered</b>	NCGS 90-85.15A (a) - tech must register with the Board within 30 days after the date of completing the training program.
2) <b>Unanswered</b>	NCGS 90-85.15A (c) - 2:1 ratio, if ratio above provide waiver documentation. Any technician above the 2:1 ratio must be certified.
3) <b>Unanswered</b>	NCGS 90-85.23- PM license, permit and current renewal shall be posted. Licenses and renewals of each RPh. are readily available for inspection.
4) <b>Unanswered</b>	NCGS 90-85.25 (b) - PM shall report within 10 days any disaster, accident, theft.
5) <b>Unanswered</b>	NCGS 90-85.26 (a) - prescriptions preserved for 3 years. (b) - Documentation of alleged medication errors.
6) <b>Unanswered</b>	NCGS 90-85.29 (1) - prescription label shall contain a discard date that is earlier of 1 yr. from date dispensed or manuf's exp. date, whichever is earlier. (2) - not obscure exp. date and storage statement when product dispensed in manuf's original container.
7) <b>Unanswered</b>	NCGS 90-85.32 (a) - prescriptions marked PRN not refilled more than 1 yr. after issue date.
8) <b>Unanswered</b>	NCGS 90-85.47 - Quality Assurance Program
9) <b>Unanswered</b>	NCGS 90-93 (3)(d): Sch. V log book or record of disposition.
10) <b>Unanswered</b>	NCGS 90-106.1 (a) - documentation system of photo ID. Kept on premises or central location for 3 years.
11) <b>Unanswered</b>	NCGS 90-113.52 (b) - pseudoephedrine Products kept behind counter. (c) - record of every purchaser, amount of product in grams. (d) - records kept for two 2 years.
12) <b>Unanswered</b>	NCGS 90-113.54 - posting of sign prohibiting sale of more than 2 pkgs (3.6grams total) of pseudoeph. /day, no more than 3 pkgs (9grams total) within 30- day period.
13) <b>Unanswered</b>	NCGS 90-640 (b) - ID badge
14) <b>Unanswered</b>	21CFR 201.17- Misbranded drugs: Medications stored in pharmacy should be labeled with an expiration date and manufacturer lot number. Note: Return to stock prescription vial with the pharmacy's own label affixed will not be deemed misbranded
15) <b>Unanswered</b>	21 NCAC 46.106-134.1 (4)(b)- label lacks any requirement listed in the subsection. (px name, name/add. of pharmacy, disp. rph's name, rx #, fill date of rx, prescriber name, dir. for use, name & strength of drug.)
16) <b>Unanswered</b>	21 NCAC 46.1601 (a)(2)- posted Pharmacy hours. (4)(A-E)- reference library, hard copy or electronic. (5)- lavatory facilities w/ hot and cold running water; clean, orderly and sanitary. (b)(1)- records are readily retrievable. (b)(2)- toll free number on labels of dispensed medications. (e)- pharmacy permit is countersigned by rphmgr. as represented in the application.
17) <b>Unanswered</b>	21 NCAC 46.1802 (a) - refills limited to prescriber's orders.
18) <b>Unanswered</b>	21 NCAC 46.1803 - All records pertaining to the filling and refilling of prescriptions shall be available to designated employees of the Board during normal business hours.
19) <b>Unanswered</b>	21 NCAC 46.1806 - proper documentation and handling of transferred rxs
20) <b>Unanswered</b>	21 NCAC 46.1818 - label shall list generic name of drug, even if unavailable to dispense or generic is not authorized.
21) <b>Unanswered</b>	21 NCAC 46.2302 (a)(1-5) - records of dispensing shall be kept for 3 years.
22) <b>Unanswered</b>	21 NCAC 46.2303 - records of prescription filling and refilling shall be kept for 3 yrs.
23) <b>Unanswered</b>	21 NCAC 46.2304 (1) - produce sight-readable documents. (3) - RPh. responsible for completeness and accuracy of entries, provides documentation that prescription information entered is correct. (5) - pharmacy has auxiliary recordkeeping system. (7) - current version of drug interactions software is utilized
24) <b>Unanswered</b>	21 NCAC 46.2305 - To maintain the confidentiality of patients' prescription orders, there must be adequate safeguards or security of the records.
25) <b>Unanswered</b>	21 NCAC 46.2502 (a) - PM shall assure that rx meds & cs meds are safe/secure within the pharmacy. (b) - PM is present one-half the hrs. the pharmacy is open or 32 hrs. /wk., whichever is less. (d) - system of inventory recordkeeping and control to detect any shortage or discrepancies of cs meds. (e) - control of all keys to pharmacy. (j) - written disaster plan. (k) - separate from the dispensing stock all drugs more than 6 months out of date.
26) <b>Unanswered</b>	21 NCAC 46.2504 (a) - effective communication of information to the patient(s). (b) - offer to counsel for all new

General Pharmacy Regulations

Answer	Question
	and transfer prescriptions. (g) - Documentation of refusals.
27) <b>Unanswered</b>	21 NCAC 46.3001 (a) - policy/procedure for all out dated, improperly labeled, adulterated damaged or unwanted drugs or drug containers are destroyed or disposed.
28) <b>Unanswered</b>	21 NCAC 46.3301 (b) - Current registration of a pharmacy tech shall be readily available for inspection.
29) <b>Unanswered</b>	21CFR 1301.75 (b) - controlled substances listed in II, III, IV, and V shall be stored in a substantially constructed cabinet, or disbursed throughout the non-controlled substances
30) <b>Unanswered</b>	21CFR 1304.04 (2)(h)(1) - inventories and records of Sch. I & II substances maintained separate from all other records (2)(h)(2)- paper prescriptions for Sch. II substances maintained in separate file.
31) <b>Unanswered</b>	21CFR 1304.11 (a) - complete/accurate inventory of all cs meds and maintained at the registered location. (c) - Biennial inventory.
32) <b>Unanswered</b>	21CFR 1305.05 (a) - power of attorney on file at registered location.
33) <b>Unanswered</b>	21CFR 1305.12 (b) - purchaser shall record 1 item on each numbered line. (c) - name/address of supplier on form. Only 1 supplier on any form. (d)- DEA Form 222 properly signed and dated.
34) <b>Unanswered</b>	21CFR 1305.13 (e) - purchaser must record the number of commercial or bulk containers furnished on each item and dates on which the containers are received.
35) <b>Unanswered</b>	21CFR 1305.22 Procedure for filling electronic orders. (g) - purchaser receives shipment, purchaser must create a record of the quantity of each item received and date received. Record must be electronically linked to the original order and archived.
36) <b>Unanswered</b>	21CFR 1305.27 Preservation of electronic orders. (a) purchaser must, for each order filled, retain the original signed order and all linked records for that order for 2 years. Purchaser must also retain all copies of each unaccepted or defective order and each linked statement. (b) supplier must retain each original order filled and the linked records . (Note: 2yrs for Federal Law; 3yrs for NC Law) (c) If electronic order records are maintained on a central server, records must be readily retrievable at the registered location. (Note: 2yrs for Federal Law; 3yrs for NC Law)
37) <b>Unanswered</b>	21CFR 1306.05 (a) - all cs prescriptions shall bear full name and address of the patient along with date, drug, strength, dosage form, quantity, dirs. for use, and name, address and registration number of practitioner. (d) - computer generated prescription that is printed or faxed must be manually signed
38) <b>Unanswered</b>	21CFR 1306.08 (3)(b) - pharmacy may fill electronically transmitted prescription for a cs med provided the pharmacy complies with all requirements. A Sch. II order signed by the practitioner.
39) <b>Unanswered</b>	21CFR 1306.14 (a) - prescription vials labeled for Sch. II display pharmacy name and address, rx #, initial fill date, patient name, practitioner name, dirs. for use and any cautionary statements.
40) <b>Unanswered</b>	21CFR 1306.21 (a) - order for Sch. III, IV, or V that is a facsimile is signed by practitioner.
41) <b>Unanswered</b>	21CFR 1306.22 (b) - cs refills entered on a medication record or electronic record must be uniformly maintained and readily retrievable.
42) <b>Unanswered</b>	21CFR 1306.24 (a) - prescription vials labeled for Sch. III, IV, or V display pharmacy name and address, rx #, initial fill date, patient name, practitioner name, dirs. for use and any cautionary statements.
43) <b>Unanswered</b>	21CFR 1306.26 (b) - not more than 8oz. of any cs containing opium, nor more than 4oz. of any other cs; not more than 48 dosage units of any such cs containing opium, nor more than 24 dosage units of any other such cs to the same purchaser in any 48-hr. period. (c) - purchaser at least 18 yoa (d) - furnish suitable ID (e) - maintain log containing name and address of purchaser, name and qty. of cs, date of purchase, name or initials of RPh. who dispensed the substance.
44) <b>Unanswered</b>	21CFR 1311.10 Eligibility to obtain a CSOS digital certificate. (a) - person who signed the most recent DEA registration application or renewal application and a person authorized to sign a registration application. (b) - person granted power of attorney by a DEA registrant to sign orders for one or more schedules of controlled substances.
45) <b>Unanswered</b>	21CFR 1311.30 Requirements for storing and using a private key for digitally signing orders. (a) - Only the certificate holder may access or use his or her digital certificate and private key. (b) - The certificate holder must provide FIPS approved secure storage for the private key, as discussed by FIPS 140-2, 180-2, 186-2, and accompanying change notices and annexes, as incorporated by reference in §1311.08. (c) - A certificate holder must ensure that no one else uses the private key. While the private key is activated, the certificate holder must prevent unauthorized use of that private key.
46) <b>Unanswered</b>	21CFR 1311.35 Number of CSOS digital certificates needed. A purchaser of Schedule I and II controlled substances must obtain a separate CSOS certificate for each registered location for which the purchaser will

## General Pharmacy Regulations

Answer	Question
	order these controlled substances.
47) <input type="checkbox"/> Unanswered	21CFR 1311.60 Recordkeeping. (a) - supplier and purchaser must maintain records of CSOS electronic orders and any linked records for 2 years. Records may be maintained electronically. Records regarding controlled substances that are maintained electronically must be readily retrievable from all other records. (Note: 2yrs for Federal Law; 3yrs for NC Law) (b) - Electronic records must be easily readable or easily rendered into a format that a person can read. Must be made available to the Administration upon request. (c) - CSOS certificate holders must maintain a copy of the subscriber agreement that the Certification Authority provides for the life of the certificate.

## Section A: OCCASIONAL BASIC NON-STERILE COMPOUNDING:

Answer	Question
3) <input type="checkbox"/> Unanswered	Occasional Basic Non-Sterile Compounding means combining one or more conventionally manufactured products pursuant to an individual prescription on an occasional basis. This includes but is not limited to: Magic Mouthwash, GI Cocktail, creams or ointments using only conventionally manufactured products. Documentation includes the following:
4) <input type="checkbox"/> Unanswered	a) Official name, strength, and dosage of preparation.
5) <input type="checkbox"/> Unanswered	b) Name and quantities of all components.
6) <input type="checkbox"/> Unanswered	c) Sources, lot numbers, and expiration dates of components.
7) <input type="checkbox"/> Unanswered	d) Name of the person who compounded and the person who verified the preparation.
8) <input type="checkbox"/> Unanswered	e) Date preparation.
9) <input type="checkbox"/> Unanswered	f) Assigned BUD.
10) <input type="checkbox"/> Unanswered	g) Description of final preparation.
11) <input type="checkbox"/> Unanswered	h) Description of Compounding Steps

## Section B: PERSONNEL TRAINING AND EVALUATION:

Answer	Question
1) <input type="checkbox"/> Unanswered	Facility has a written SOP for knowledge and competency of core skills.
2) <input type="checkbox"/> Unanswered	Personnel are able to demonstrate knowledge of principles and competency of skills for performing non-sterile manipulations that include:
3) <input type="checkbox"/> Unanswered	a) Hand hygiene
4) <input type="checkbox"/> Unanswered	b) Garbing
5) <input type="checkbox"/> Unanswered	c) Cleaning and sanitizing
6) <input type="checkbox"/> Unanswered	d) Handling and transporting components and CNSPs
7) <input type="checkbox"/> Unanswered	e) Measuring and mixing
8) <input type="checkbox"/> Unanswered	f) Proper use of equipment and devices used to compound CNSPs
9) <input type="checkbox"/> Unanswered	g) Documentation of the compounding process (e.g., master formulation and compounding records)
10) <input type="checkbox"/> Unanswered	Steps in the training procedure must include:
11) <input type="checkbox"/> Unanswered	a) Read and understand USP<795>, all referenced standards, and other relevant literature.
12) <input type="checkbox"/> Unanswered	b) Understand and interpret Safety Data Sheets (SDSs) and Certificates of Analysis (COAs).
13) <input type="checkbox"/> Unanswered	c) Read and understand facility compounding procedures related to staff duties.
14) <input type="checkbox"/> Unanswered	All personnel who conduct compounding activities or have direct oversight must be trained in the facility's SOPs.
15) <input type="checkbox"/> Unanswered	Initial and annual training documentation present for compounding personnel observed and verified by Designated Person(s) or Assigned Trainer(s).
16) <input type="checkbox"/> Unanswered	Proficiency and competency demonstrated every twelve (12) months. Any deficiencies identified must be addressed, corrective actions applied, and documented.

## Section B HD: USP <800> TRAINING PROGRAM

Answer	Question
1) <input type="button" value="Unanswered"/>	USP<800>: Facility has a written HD Training Program which includes:
2) <input type="button" value="Unanswered"/>	a) Review of facility's HD list and their assessment of risks.
3) <input type="button" value="Unanswered"/>	b) Review of facility's SOPs related to HDs. SOPs must be reviewed every twelve (12) months and must be documented in accordance with this chapter, OSHA standard (1910.120) and other applicable laws and regulations.
4) <input type="button" value="Unanswered"/>	c) Proper receiving, handling, and storage of HDs.
5) <input type="button" value="Unanswered"/>	d) Proper Use of PPE.
6) <input type="button" value="Unanswered"/>	e) Proper use of equipment and devices (e.g. engineering controls).
7) <input type="button" value="Unanswered"/>	f) Response to HD exposure – known or suspected.
8) <input type="button" value="Unanswered"/>	g) Spill Management.
9) <input type="button" value="Unanswered"/>	h) Proper disposal of HDs and trace-contaminated materials.
10) <input type="button" value="Unanswered"/>	Initial and annual training documentation present for all personnel who handle HDs observed and verified by Designated Person or Assigned Trainer.
11) <input type="button" value="Unanswered"/>	Proficiency and competency demonstrated every twelve (12) months.
12) <input type="button" value="Unanswered"/>	Personnel of reproductive capability must confirm in writing that they understand the risk of handling HDs.
13) <input type="button" value="Unanswered"/>	Qualified Personnel must be available for spill management at all times while HDs are handled.

#### Section C: PERSONAL HYGIENE AND GARBING:

Answer	Question
1) <input type="button" value="Unanswered"/>	Prior to entering a compounding area, staff:
2) <input type="button" value="Unanswered"/>	a) Removes personal outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests).
3) <input type="button" value="Unanswered"/>	b) Removes all hand, wrist, and other exposed jewelry including piercings.
4) <input type="button" value="Unanswered"/>	c) Not wear earbuds or headphones.
5) <input type="button" value="Unanswered"/>	Garbing requirements and order of donning and doffing must be documented in facility SOPs.
6) <input type="button" value="Unanswered"/>	Hand Hygiene: wash hands and forearms up to the elbows, for at least 30 seconds, using soap and water.
7) <input type="button" value="Unanswered"/>	Reusable garb (e.g. goggles) should be cleaned and sanitized with 70% IPA before each use.

#### Section C HD: USP <800>: Personal Protective Equipment:

Answer	Question
1) <input type="button" value="Unanswered"/>	Facility has written SOPs for PPE use based on risk of exposure and activities performed that include:
2) <input type="button" value="Unanswered"/>	a) Receipt
3) <input type="button" value="Unanswered"/>	b) Storage
4) <input type="button" value="Unanswered"/>	c) Transport
5) <input type="button" value="Unanswered"/>	d) Compounding (sterile and nonsterile)
6) <input type="button" value="Unanswered"/>	e) Deactivation/decontamination, cleaning, and disinfecting
7) <input type="button" value="Unanswered"/>	f) Spill control
8) <input type="button" value="Unanswered"/>	g) Waste disposal
9) <input type="button" value="Unanswered"/>	h) Contaminated clothing must not go home under any circumstances
10) <input type="button" value="Unanswered"/>	Two pairs of powder free chemotherapy gloves (ASTM D6978 or successor) must be used when compounding.
11) <input type="button" value="Unanswered"/>	Changed every thirty (30) minutes, according to manufacturer recommendation, torn, punctured, or suspected contamination.
12) <input type="button" value="Unanswered"/>	Hands must be washed with soap and water after doffing gloves.
13) <input type="button" value="Unanswered"/>	Coated disposable gowns that are impermeable to liquids.
14) <input type="button" value="Unanswered"/>	a) Open in back.
15) <input type="button" value="Unanswered"/>	b) Long sleeved with cuffs.
16) <input type="button" value="Unanswered"/>	c) Changed per manufacturer's information or every two (2) to three (3) hours.

Section C HD: USP <800>: Personal Protective Equipment:

Answer	Question
17) <input type="checkbox"/> Unanswered	Head, hair and shoe covers that:
18) <input type="checkbox"/> Unanswered	a) Protect against HDs.
19) <input type="checkbox"/> Unanswered	b) Second pair of shoe covers donned before entering C-SEC and doffed before exiting C-SEC.
20) <input type="checkbox"/> Unanswered	Goggles:
21) <input type="checkbox"/> Unanswered	a) Worn when risk for spill or splashes outside of a C-PEC.
22) <input type="checkbox"/> Unanswered	b) Best practice – goggles with face shield.
23) <input type="checkbox"/> Unanswered	Respiratory protection:
24) <input type="checkbox"/> Unanswered	a) Fit-tested NIOSH certified N-95 respirator – sufficient but offers not protection from gases and vapors or direct splash.
25) <input type="checkbox"/> Unanswered	b) Evidence of fit testing for workers of N95 mask or other respirator by an occupational health practitioner.
26) <input type="checkbox"/> Unanswered	c) Full face-piece chemical cartridge respirator or Powered Air-Purifying Respirator (PAPR) should be worn when there is a risk of respiratory exposure to HD.
27) <input type="checkbox"/> Unanswered	Gloves and sleeve covers in C-PEC – removed and discarded in container or sealed bag before exiting C-PEC.
28) <input type="checkbox"/> Unanswered	All waste disposed of accordance with local, state and federal regulation.

Section D: BUILDING AND FACILITIES:

Answer	Question
1) <input type="checkbox"/> Unanswered	Area is specifically designated for non-sterile compounding & method of designation is identified in facility SOP.
2) <input type="checkbox"/> Unanswered	Compounding space is well lighted.
3) <input type="checkbox"/> Unanswered	Clean, orderly, sanitary, in good repair. It allows for orderly placement of equipment and minimizes cross-contamination.
4) <input type="checkbox"/> Unanswered	Temperatures monitored daily and documented on temperature log. Documentation from electronic recording device must be retrievable.
5) <input type="checkbox"/> Unanswered	Temperature monitoring equipment is calibrated or verified per manufacturer recommendation (or every 12 months if not specified).
6) <input type="checkbox"/> Unanswered	Compounding components, equipment, and containers are stored off the floor to prevent contamination and promote cleaning.
7) <input type="checkbox"/> Unanswered	Sink with hot and cold water is easily accessible.
8) <input type="checkbox"/> Unanswered	Sink is emptied of all items not related to compounding & cleaned when visibly soiled.
9) <input type="checkbox"/> Unanswered	Plumbing system free of defects that could contribute to the contamination of any CNSP.

Section D HD: USP <800> FACILITIES & ENGINEERING CONTROLS:

Answer	Question
10) <input type="checkbox"/> Unanswered	HD Handling areas located away from breakrooms, refreshment areas for personnel, patients, or visitors.
11) <input type="checkbox"/> Unanswered	Designated areas for: receipts & unpacking of HD in neutral or negative pressure relative to surrounding areas.
12) <input type="checkbox"/> Unanswered	All HD API's and HDs requiring manipulation other than counting/repackaging of final dosage forms or reconstitution according to the manufacturer's directions in the FDA approved labeled stored in externally vented, negative pressure with 12ACPH (Non-antineoplastic, reproductive risk only, may be stored with other inventory if facility policy & Assessment of Risk allows).
13) <input type="checkbox"/> Unanswered	HDs stored off the floor in a manner that prevents spillage or container breakage in negative pressure with 12 ACPH. (e.g low to the floor; use of resealable plastic bag if appropriate for small container, etc).
14) <input type="checkbox"/> Unanswered	C-SEC where compounding activities occur and storage area for HDs is externally vented, physically separated, has minimum 12 ACPH, and negative pressure 0.01-0.03 in water column relative to adjacent areas.
15) <input type="checkbox"/> Unanswered	Facility has signs and spill kits readily available to identify and contain spills.

Section E: CLEANING AND SANITIZING:

Answer	Question
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## Section E: CLEANING AND SANITIZING:

Answer	Question
16) <input type="checkbox"/> Unanswered	Work surfaces and floors are cleaned and sanitized at the beginning of each shift on days compounding occurs, after spills, and when contamination is known or suspected.
17) <input type="checkbox"/> Unanswered	Walls are visible soiled, after spills, and when contamination known or suspected.
18) <input type="checkbox"/> Unanswered	Ceilings cleaned and sanitized when visibly soiled or contaminated.
19) <input type="checkbox"/> Unanswered	Storage areas cleaned and sanitized quarterly.
20) <input type="checkbox"/> Unanswered	Cleaning and sanitizing agents must be selected and used with consideration of compatibilities, effectiveness, and to minimize the potential to leave residues. If performed as separated steps, cleaning occurs prior to sanitizing.

## Section E HD: USP <800> DEACTIVATING, DECONTAMINATING, CLEANING, DISINFECTING:

Answer	Question
21) <input type="checkbox"/> Unanswered	Reusable equipment and areas are deactivated, decontaminated, and cleaned according to facility's written procedures.
22) <input type="checkbox"/> Unanswered	Procedures include agents used, dilutions (if applicable), frequency, and documentation requirements.
23) <input type="checkbox"/> Unanswered	Agents used are compatible with facility surfaces and appropriate for the documented task(s) (List Agents used).
24) <input type="checkbox"/> Unanswered	C-PEC Deactivation, decontamination, and cleaning occurs daily and is documented.
25) <input type="checkbox"/> Unanswered	Underside of C-PEC work tray is deactivated and decontaminated, cleaned at least monthly and is documented.

## Section F: EQUIPMENT AND COMPONENTS:

Answer	Question
<b>Equipment:</b>	
1) <input type="checkbox"/> Unanswered	Equipment and supplies are suitable for the specific compounding process. Must not be reactive, additive, sorptive, or alter quality of non-sterile preparations. Storage prevents risk of contamination
2) <input type="checkbox"/> Unanswered	Equipment and devices used in compounding or testing compounded preparations are inspected before use and verified for accuracy per manufacturer recommendation or every 12 months, whichever is more frequent
3) <input type="checkbox"/> Unanswered	Equipment is cleaned after each preparation to prevent cross-contamination
4) <input type="checkbox"/> Unanswered	Weighing, measuring, and manipulating components that could generate airborne particles is assessed to determine if the activity requires closed system processing device (e.g. CVE, BSC, or single-use containment glove bag). Must be documented.
5) <input type="checkbox"/> Unanswered	CVE or BSC is certified at least every 12 months
6) <input type="checkbox"/> Unanswered	CVE is cleaned and sanitized at the beginning and end of each shift, between compounds with different components, after spills, and when contamination is suspected.
7) <input type="checkbox"/> Unanswered	Equipment and devices are cleaned and sanitized before use, and between compounds using different components.
<b>Components:</b>	
8) <input type="checkbox"/> Unanswered	Compounding personnel follow SOP that addresses the selection, receipt, evaluation, handling, storage, and documentation of all CNSP components, including ingredients, containers, and closures.
9) <input type="checkbox"/> Unanswered	CNSP components meet the following criteria:
10) <input type="checkbox"/> Unanswered	a) An active ingredient in an FDA approved drug
11) <input type="checkbox"/> Unanswered	b) Comply with an applicable USP-NF monograph if one exists:
12) <input type="checkbox"/> Unanswered	c) Have a COA that includes specifications and testing results.
13) <input type="checkbox"/> Unanswered	d) Obtained from a registered FDA facility or selected from a acceptable reliable source.
14) <input type="checkbox"/> Unanswered	Certificates of Analysis (COA) are examined at the time of receipt of the API. Information from the COA is noted and used as appropriate in the compounding process to ensure quality compounds.
15) <input type="checkbox"/> Unanswered	The receipt date, quantity received, supplier name, lot number, expiration date, and any in-house or third-party testing performed must be documented for all components.
16) <input type="checkbox"/> Unanswered	Components are examined for deterioration and other aspects of unacceptable quality when received and re-inspected before use.

## Section F: EQUIPMENT AND COMPONENTS:

Answer	Question
17) <input type="checkbox"/> Unanswered	Unacceptable components are clearly labeled and segregated for disposal.
18) <input type="checkbox"/> Unanswered	Date of receipt is marked or added on each API that lacks expiration date. An conservative expiration date that does not exceed 3 years is noted on API packaging.
19) <input type="checkbox"/> Unanswered	Components stored under appropriate conditions according to manufacture requirements.
20) <input type="checkbox"/> Unanswered	Facility maintains SDS and updates chemical hazard & disposal information every 12 months.
21) <input type="checkbox"/> Unanswered	Waste is disposed in accordance with applicable laws & regulations (e.g. USP 800, EPA, OSHA, etc).

## Section F HD: USP <800> EQUIPMENT AND COMPONENTS

Answer	Question
1) <input type="checkbox"/> Unanswered	USP <800>: C-PEC used for compounding HD CNSP is externally vented to the outside or has a redundant HEPA filter in series. The C-PEC is placed within the C-SEC under negative pressure.

## Section G: MASTER FORMULATION AND COMPOUNDING RECORD:

Answer	Question
Master Formulation Record:	
1) <input type="checkbox"/> Unanswered	Master Formulation Record created for each unique formulation CNSP.
2) <input type="checkbox"/> Unanswered	The Master formulation record includes name, strength, activity, and dosage form of CNSP.
3) <input type="checkbox"/> Unanswered	Identities and amounts of all components.
4) <input type="checkbox"/> Unanswered	Container Closure system
5) <input type="checkbox"/> Unanswered	Complete instructions for preparing the CNSP, including:
6) <input type="checkbox"/> Unanswered	Equipment
7) <input type="checkbox"/> Unanswered	Supplies
8) <input type="checkbox"/> Unanswered	Description of compounding steps
9) <input type="checkbox"/> Unanswered	Physical description for expected appearance of final CNSP.
10) <input type="checkbox"/> Unanswered	Assigned BUD and storage requirements with referenced sources.
11) <input type="checkbox"/> Unanswered	Calculation to determine and verify quantities and/or concentration of components.
12) <input type="checkbox"/> Unanswered	Labeling requirements
13) <input type="checkbox"/> Unanswered	QC procedures and expected results (pH testing, visual inspection)
14) <input type="checkbox"/> Unanswered	Other information needed to describe the compounding process (ie: adjusting pH and temperature, adjustment for assay, loss on drying of or waters of hydration of the API.)
15) <input type="checkbox"/> Unanswered	Source for stability-indicating study or USP monograph that allows extension of BUDs beyond <795> defaults. Make sure they are performing all required tests in the USP Compounded Preparation Monograph. (e.g. pH).
16) <input type="checkbox"/> Unanswered	Any changes or alterations to the MFR must be approved and documented according to facility's SOP.

## Compounding Record:

17) <input type="checkbox"/> Unanswered	Compounding Record includes name, strength, activity, and dosage form of CNSP.
18) <input type="checkbox"/> Unanswered	Date and time of preparation of the CNSP.
19) <input type="checkbox"/> Unanswered	Assigned identification number (Rx number, Lot number, order number, etc).
20) <input type="checkbox"/> Unanswered	Identity of personnel involved in compounding and verifying the CNSP.
21) <input type="checkbox"/> Unanswered	Name, vendor or manufacturer, lot number, and expiration date of each component.
22) <input type="checkbox"/> Unanswered	Weigh or measurement of each component.
23) <input type="checkbox"/> Unanswered	Total quantity compounded.
24) <input type="checkbox"/> Unanswered	Assigned BUD and storage requirements.
25) <input type="checkbox"/> Unanswered	Physical description of appearance for final CNSP.
26) <input type="checkbox"/> Unanswered	QC results (pH testing and visual inspection).

## Section G: MASTER FORMULATION AND COMPOUNDING RECORD:

Answer	Question
27) <input type="button" value="Unanswered"/>	Master Formulation Reference.

## Section H: RELEASE INSPECTION:

Answer	Question
1) <input type="button" value="Unanswered"/>	1. CNSP visually inspected to determine physical appearance meet expectations.
2) <input type="button" value="Unanswered"/>	2. Checks, inspections, and test conducted in accordance to the Master Formulation Record.
3) <input type="button" value="Unanswered"/>	3. Checks, inspections, and test documented in Compounding Record.
4) <input type="button" value="Unanswered"/>	4. Pre-Release inspection includes visual inspection of container closure integrity (ie: check of leakage, cracks, or improper packaging).
5) <input type="button" value="Unanswered"/>	5. Inspection confirm the CSNP and its label match Compounding Record and prescription order.

## Section I: LABELING:

Answer	Question
1) <input type="button" value="Unanswered"/>	Labeling for each CNSP contains at minimum:
2) <input type="button" value="Unanswered"/>	a) Identification number (ie: prescription number, lot number, barcode).
3) <input type="button" value="Unanswered"/>	b) Active components, amounts, activities, or concentrations (no abbreviations).
4) <input type="button" value="Unanswered"/>	c) Dosage form.
5) <input type="button" value="Unanswered"/>	d) Amount or volume in each container.
6) <input type="button" value="Unanswered"/>	e) Storage condition if other than controlled room temperature.
7) <input type="button" value="Unanswered"/>	f) Beyond Use Date.
8) <input type="button" value="Unanswered"/>	g) Route of administration.
9) <input type="button" value="Unanswered"/>	h) Indication that the preparation is compounded.
10) <input type="button" value="Unanswered"/>	i) Any special handling instructions.
11) <input type="button" value="Unanswered"/>	j) Any warning statements if applicable.
12) <input type="button" value="Unanswered"/>	k) Name, address, and contact information of the compounding facility if the CNSP is to be sent outside of a healthcare facility.
13) <input type="button" value="Unanswered"/>	l) Compounded medications for Veterinary application labeled to indicate "Veterinary Use".
14) <input type="button" value="Unanswered"/>	Labeling procedures followed as described in facility SOP to prevent mix-ups and errors.
15) <input type="button" value="Unanswered"/>	Label verified to ensure it conforms to prescription/medication order, MFR, and compounding record.

## Section I HD: USP <800>

Answer	Question
1) <input type="button" value="Unanswered"/>	HD handling precautions must be clearly labeled at all times during transport.
2) <input type="button" value="Unanswered"/>	Personnel ensure that the labeling process for compounded preparation do not introduce contamination into the non-HD areas.

## Section J: ESTABLISHING BEYOND USE DATING:

Answer	Question
Parameters for Establishing a BUD:	
1) <input type="button" value="Unanswered"/>	The chemical and physical stability properties of the API and any added substance in the preparation (e.g. if the API and added substance in the preparation are known to degrade over time and/or under certain storage conditions, which would reduce strength and/or produce harmful impurities).
2) <input type="button" value="Unanswered"/>	The compatibility of the container closure system with the finished preparation (e.g. leachables, interactions, adsorption, and storage conditions).
3) <input type="button" value="Unanswered"/>	Degradation of the container closure system, which can lead to reduction in integrity of the CNSP.
4) <input type="button" value="Unanswered"/>	The potential for microbial proliferation in the CNSP.

## Section J: ESTABLISHING BEYOND USE DATING:

Answer	Question
BUD limits in absence of a USP-NF Compound monograph or specific stability information or BUDs that are known to be shorter due to instability:	
5) <input type="checkbox"/>	Non-preserved aqueous (water activity greater than 0.60) dosage form BUD is 14 days refrigerated.
6) <input type="checkbox"/>	Preserved aqueous dosage form BUD is 35 days at controlled room temperature or refrigerated.
7) <input type="checkbox"/>	Nonaqueous dosage form (water activity less than 0.6) BUD is 90 days at controlled room temperature or refrigerated.
8) <input type="checkbox"/>	Solid dosage forms BUD is 180 days at controlled room temperature or refrigerated.
Shorter Beyond Use Dates:	
9) <input type="checkbox"/>	If the API or any other components in the CNSP have an expiration date that is earlier than the BUD that could be assigned in the absence of a USP-NF compounded preparation monograph or CNSP- specific stability information., the expiration date supersedes the BUD and must be the assigned shortest date.
10) <input type="checkbox"/>	If the CNSP includes components from conventionally manufactured products, the BUD of the CNSP must not exceed the shortest remaining expiration date of any of those products.
11) <input type="checkbox"/>	If the CNSP includes components from other compounded preparations, the BUD of the final CNSP must not exceed the shortest remaining BUD of any of those compounded preparations.
12) <input type="checkbox"/>	If the formulation is known to require a shorter BUD.
Extended Beyond Use Dates:	
13) <input type="checkbox"/>	If there is a USP-NF compounded preparation monograph for the CNSP, the BUD must not exceed the BUD specified in the monograph.
14) <input type="checkbox"/>	The BUD for aqueous dosage forms and nonaqueous dosage forms may be extended up to a maximum of 180 days if there is a stability study (Stability indicating assay USP <1163> Potency over time not acceptable).
15) <input type="checkbox"/>	Aqueous formulations that are extended must be tested for antimicrobial effectiveness (USP<51>).
16) <input type="checkbox"/>	When using peer reviewed source compounding process must follow all aspects documented in source to include exact ingredients and container closures and tests performed.

## Section K: QUALITY ASSURANCE AND QUALITY CONTROL:

Answer	Question
1) <input type="checkbox"/>	Facility has written SOP Quality Assurance and Quality Control Program for non-sterile compounding procedures. The Program must be able to identify the following:
2) <input type="checkbox"/>	a) That procedures were followed
3) <input type="checkbox"/>	b) Prevention and Detection of Errors and other quality problems.
4) <input type="checkbox"/>	c) Evaluation of Complaints and Adverse Events with documentation.
5) <input type="checkbox"/>	d) Appropriate Investigations and Corrective Actions
6) <input type="checkbox"/>	Facility has a designated person(s) responsible for QA and QC program for non-sterile compounding.
7) <input type="checkbox"/>	Designated QA and QC person has documented training for non-sterile compounding.
8) <input type="checkbox"/>	QA and QC program reviewed annually and documented.

## Section L: CNSP PACKAGING AND TRANSPORTING

Answer	Question
9) <input type="checkbox"/>	SOP for packaging CNSPs.
10) <input type="checkbox"/>	Materials used for packaging maintain physical and chemical integrity and stability of the CNSPs.
11) <input type="checkbox"/>	Materials used for packaging protect the CNSPs from damage, leakage, contamination, and degradation.

## Section L HD: USP <800>

Answer	Question
12) <input type="checkbox"/>	Packaging materials must protect the healthcare worker from exposure.
13) <input type="checkbox"/>	Facility does not use pneumatic tubes to transport HDs.

**Section M: COMPLAINT HANDLING AND ADVERSE EVENT REPORTING:**

Answer	Question
14) <input type="checkbox"/> Unanswered	Facility has an SOP for Complaint handling and adverse Event reporting.
15) <input type="checkbox"/> Unanswered	Facility has a designated person who is responsible for reviewing complaints to determine if the complaint indicates a potential quality problem with CNSP.
16) <input type="checkbox"/> Unanswered	Facility does an investigation into the complaint if a quality problem is identified.
17) <input type="checkbox"/> Unanswered	Facility has a readily retrievable record-keeping system of all complaints with CNSPs that include
18) <input type="checkbox"/> Unanswered	a) name of patient,
19) <input type="checkbox"/> Unanswered	b) prescription number,
20) <input type="checkbox"/> Unanswered	c) name and strength of CNSP,
21) <input type="checkbox"/> Unanswered	d) date of complaint,
22) <input type="checkbox"/> Unanswered	e) nature of complaint,
23) <input type="checkbox"/> Unanswered	f) results of the investigation and follow up.
24) <input type="checkbox"/> Unanswered	The compounding record permits traceability, and the facility can initiate recall.

**Section A: IMMEDIATE USE CSP:**

Answer	Question
1) <input type="checkbox"/> Unanswered	The facility has an SOP that describes CSPs made for immediate use and includes information on how to avoid contamination and mix-ups.
2) <input type="checkbox"/> Unanswered	Aseptic Technique, processes, and procedures are followed.
3) <input type="checkbox"/> Unanswered	Prepared using evidence that proves the CSP is stable up to BUD or for 4 hours (e.g. package insert, Trissell's, stability studies) whichever is less.
4) <input type="checkbox"/> Unanswered	Prepared with no more than 3 different sterile products.
5) <input type="checkbox"/> Unanswered	Single-dose containers are not used on more than one patient . unused single-dose components are discarded after preparation.
6) <input type="checkbox"/> Unanswered	CSPs are administered within 4 hours of the start of preparation.
7) <input type="checkbox"/> Unanswered	Unless directly administered by the person who prepared the immediate use CSP, the CSP is labeled with the names and amounts of all active ingredients, the name or initials of the person who prepared the preparation, and the exact 4-hour time period within which administration must begin.
8) <input type="checkbox"/> Unanswered	A compounding record for immediate use CSPs that are made for more than one patient.

**Section A HD: USP <800>**

Answer	Question
1) <input type="checkbox"/> Unanswered	For Immediate Use HD CSPs USP <800> requirements are followed.

**Section B: PERSONNEL TRAINING AND EVALUATION:**

Answer	Question
<b>Demonstrate Knowledge and Competency of Core Skills</b>	
1) <input type="checkbox"/> Unanswered	Facility has a written SOP for knowledge and competency of core skills. Personnel are able to demonstrate knowledge of principles and competency of skills for performing sterile manipulations that include:
2) <input type="checkbox"/> Unanswered	a) Hand hygiene
3) <input type="checkbox"/> Unanswered	b) Garbing
4) <input type="checkbox"/> Unanswered	c) Cleaning and disinfection
5) <input type="checkbox"/> Unanswered	d) Calculations, measuring, and mixing
6) <input type="checkbox"/> Unanswered	e) Aseptic technique
7) <input type="checkbox"/> Unanswered	f) Achieving and/or maintaining sterility and apyrogenicity
8) <input type="checkbox"/> Unanswered	g) Use of equipment
9) <input type="checkbox"/> Unanswered	h) Documentation of the compounding process (e.g., master formulation and compounding records)

## Section B: PERSONNEL TRAINING AND EVALUATION:

Answer	Question
10) <input type="checkbox"/> Unanswered	i) Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area
11) <input type="checkbox"/> Unanswered	j) Proper use of primary engineering controls (PECs)
12) <input type="checkbox"/> Unanswered	k) Principles of movement of materials and personnel within the compounding area
13) <input type="checkbox"/> Unanswered	Documentation present for initial training and competency assessment of skills for compounding personnel or personnel who have direct oversight.
14) <input type="checkbox"/> Unanswered	Documentation present for training and competency completed every 12 months.
15) <input type="checkbox"/> Unanswered	Documentation present for training and competency for any other personnel accessing the compounding area (e.g cleaning staff/companies).

### Garbing and Hand Hygiene Competency

16) <input type="checkbox"/> Unanswered	Facility has SOP for Garbing and Hand Hygiene Competency which includes procedures, documentation, incubation, and interpreting results.
17) <input type="checkbox"/> Unanswered	Garbing and Hand Hygiene Competency (Gloved Fingertip Testing) observed and documented for compounding personnel or personnel who have direct oversight initially in the classified area or Segregated Compounding Area (SCA).
18) <input type="checkbox"/> Unanswered	Hand Hygiene, Garbing, and Gloved Fingertip Testing is completed three (3) separate times in succession.
19) <input type="checkbox"/> Unanswered	All failures of Gloved Fingertip Testing documented along with corrective action taken that includes retesting the entire process.
20) <input type="checkbox"/> Unanswered	Documentation must include:
21) <input type="checkbox"/> Unanswered	a) Name of the person evaluated.
22) <input type="checkbox"/> Unanswered	b) Evaluation date/time.
23) <input type="checkbox"/> Unanswered	c) Manufacturer, lot, and expiration numbers of media and components used.
24) <input type="checkbox"/> Unanswered	d) Incubation temperature intervals (30-35 degrees C for first 48 hours 20-25 degrees C for no less than 5 days) .
25) <input type="checkbox"/> Unanswered	e) Dates of incubation.
26) <input type="checkbox"/> Unanswered	f) Results.
27) <input type="checkbox"/> Unanswered	g) Name of observer and the person who reads/documents the results.
28) <input type="checkbox"/> Unanswered	All failures of Gloved Fingertip Testing documented along with corrective action taken that includes retesting the entire process.
29) <input type="checkbox"/> Unanswered	Garbing and Gloved Fingertip observations and testing are completed every six (6) months in the classified areas or SCA.
30) <input type="checkbox"/> Unanswered	Garbing and GFT observations and testing are completed every three (3) months.

### Aseptic Manipulation Competency Testing

31) <input type="checkbox"/> Unanswered	Facility has SOP for Aseptic Manipulation Competency Testing which includes procedures, documentation, incubation, and interpreting results.
32) <input type="checkbox"/> Unanswered	Aseptic Manipulation Competency which included observation, media fill testing, gloved fingertip testing, and surface sampling performed initially for compounding personnel or personnel who have direct oversight.
33) <input type="checkbox"/> Unanswered	Testing simulates the most challenging compounding procedures.
34) <input type="checkbox"/> Unanswered	Documentation includes:
35) <input type="checkbox"/> Unanswered	a) Name of the person evaluated.
36) <input type="checkbox"/> Unanswered	b) Evaluation date/time.
37) <input type="checkbox"/> Unanswered	c) Manufacturer, lot, and expiration numbers of media and components used.
38) <input type="checkbox"/> Unanswered	d) Incubation temperature intervals (20-25 degrees C for 7 days then 30-35 degrees C for 7 days).
39) <input type="checkbox"/> Unanswered	e) Dates of incubation.
40) <input type="checkbox"/> Unanswered	f) Results.
41) <input type="checkbox"/> Unanswered	g) Name of observer and the person who reads/documents the results.
42) <input type="checkbox"/> Unanswered	All failures of the Aseptic Manipulation Competency Testing documented along with corrective action taken that includes retesting the entire process.

## Section B: PERSONNEL TRAINING AND EVALUATION:

Answer	Question
43) <input type="checkbox"/> Unanswered	Certificate of Analysis is present for commercial growth media.
44) <input type="checkbox"/> Unanswered	In-house media demonstrates growth promotion in accordance with USP<71>.
45) <input type="checkbox"/> Unanswered	Aseptic Manipulation Competency is completed every 6 months.
46) <input type="checkbox"/> Unanswered	Aseptic Manipulation Competency is completed every 3 months.

## Section B HD: USP <800> TRAINING PROGRAM

Answer	Question
1) <input type="checkbox"/> Unanswered	Facility has a written Training Program and Competency assessment which includes:
2) <input type="checkbox"/> Unanswered	a. Review of facility's HD list, dosage form, and risks .
3) <input type="checkbox"/> Unanswered	b. Review of facility's SOPs related to HDs.
4) <input type="checkbox"/> Unanswered	c. Proper Use of PPE.
5) <input type="checkbox"/> Unanswered	d. Proper use of equipment and devices (e.g engineering controls).
6) <input type="checkbox"/> Unanswered	e. Response to HD exposure – known or suspected.
7) <input type="checkbox"/> Unanswered	f. Spill Management.
8) <input type="checkbox"/> Unanswered	g. Proper disposal of HDs and trace-contaminated materials.
9) <input type="checkbox"/> Unanswered	h. Personnel of reproductive capability must confirm in writing that they understand the risk of handling HDs.
10) <input type="checkbox"/> Unanswered	Initial and annual training documentation present for all personnel who handle HDs observed by Designated Person or Assigned Trainer, with proficiency demonstrated every twelve (12) months.

## Section C: PERSONAL HYGIENE AND GARBING:

Answer	Question
1) <input type="checkbox"/> Unanswered	Facility has written SOP on personal hygiene and garbing procedure logically based on location of hand hygiene sink (e.g. outside of ante room, dirty side of ante room, clean side of ante room).
2) <input type="checkbox"/> Unanswered	Prior to entering a compounding area, staff:
3) <input type="checkbox"/> Unanswered	a. Removes personal outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests).
4) <input type="checkbox"/> Unanswered	b. Removes all cosmetics because they shed flakes and particles.
5) <input type="checkbox"/> Unanswered	c. Removes all hand, wrist, and other exposed jewelry including piercings. Cover any jewelry that cannot be removed.
6) <input type="checkbox"/> Unanswered	d. Not wear earbuds or headphones.
7) <input type="checkbox"/> Unanswered	e. Not bring electronic devices that are not necessary for compounding or other required tasks into the compounding area.
8) <input type="checkbox"/> Unanswered	f. Keep nails clean and neatly trimmed to minimize particle shedding and avoid glove punctures. Nail products (e.g. polish, artificial nails, and extenders) must not be worn.
9) <input type="checkbox"/> Unanswered	g. Wipe eyeglasses, if worn
10) <input type="checkbox"/> Unanswered	h. Documentation by designated person for any permissible excursion that do not compromise the quality of the classified environment.
11) <input type="checkbox"/> Unanswered	Hand Hygiene:
12) <input type="checkbox"/> Unanswered	a. Wash hands and forearms up to the elbows, for at least 30 seconds, using soap containers that cannot be refilled.
13) <input type="checkbox"/> Unanswered	b. Use of nail picks.
14) <input type="checkbox"/> Unanswered	c. No scrub brush used in hand hygiene.
15) <input type="checkbox"/> Unanswered	d. Dry hands and elbows using low-lint towels or wipes (no hand dryers).
16) <input type="checkbox"/> Unanswered	e. Hands sanitized with alcohol based hand rub.
17) <input type="checkbox"/> Unanswered	Facility SOPs for hand hygiene/garbing address cleanroom suite sink placement
18) <input type="checkbox"/> Unanswered	Facility has SOP for garbing order and garbing materials.

**Section C: PERSONAL HYGIENE AND GARBING:**

<b>Answer</b>	<b>Question</b>
19) <input type="checkbox"/>	Garbing materials if Category 1 or 2 include
20) <input type="checkbox"/>	a. Face mask and Beard cover, if applicable.
21) <input type="checkbox"/>	b. Low-lint garb such as gowns/coveralls, disposable covers for shoes, head, and facial hair.
22) <input type="checkbox"/>	Garbing Materials for Category 3 include:
23) <input type="checkbox"/>	a. Face Mask and Beard Cover, if applicable
24) <input type="checkbox"/>	b. Low lint garb that is sterile and not reused without resterilization.
25) <input type="checkbox"/>	c. No exposed skin (fully garbed).
26) <input type="checkbox"/>	Gloves must be powder free and sterile, donned inside SCA or Classified area.
27) <input type="checkbox"/>	a. Sterile 70% IPA applied regularly throughout the compounding process.
28) <input type="checkbox"/>	RABS (CACI and CAI) – Disposable gloves worn inside gloves attached to RABS sleeves, and sterile gloves donned over gloves attached to RABS.
29) <input type="checkbox"/>	RABS sleeves changed per manufacturers' recommendations/SOPs.

**Section C HD: USP <800>: Personal Protective Equipment:**

<b>Answer</b>	<b>Question</b>
1) <input type="checkbox"/>	Facility has written SOPs for PPE use based on the risk of exposure and activities performed.
2) <input type="checkbox"/>	a. Receipt
3) <input type="checkbox"/>	b. Storage
4) <input type="checkbox"/>	c. Transport
5) <input type="checkbox"/>	d. Compounding (sterile and nonsterile)
6) <input type="checkbox"/>	e. Deactivation/decontamination, cleaning, and disinfecting
7) <input type="checkbox"/>	f. Spill Control
8) <input type="checkbox"/>	g. Waste disposal
9) <input type="checkbox"/>	Two pairs of powder-free chemotherapy gloves (ASTM D6978 or successor) must be used when compounding with the outer pair sterile when performing sterile compounding.
10) <input type="checkbox"/>	a. Gloves are changed every thirty (30) minutes or according to the manufacturer's recommendation.
11) <input type="checkbox"/>	b. Hands must be washed with soap and water after doffing gloves.
12) <input type="checkbox"/>	Coated disposable gowns.
13) <input type="checkbox"/>	a. Open in back
14) <input type="checkbox"/>	b. Long-sleeved with cuffs
15) <input type="checkbox"/>	c. Changed per manufacturer's information or every two (2) to three (3) hours or immediately after spill/splash
16) <input type="checkbox"/>	Contaminated clothing must not go home under any circumstances.
17) <input type="checkbox"/>	Head, hair, and shoe covers
18) <input type="checkbox"/>	a. Protect against contact with HD residues
19) <input type="checkbox"/>	b. Second pair of shoe covers donned before entering C-SEC and doffed before exiting C-SEC
20) <input type="checkbox"/>	Goggles
21) <input type="checkbox"/>	a. Must be worn when the risk for spill or splashes outside of a C-PEC
22) <input type="checkbox"/>	b. Best practice – goggles with face shield

**Section D: FACILITIES AND ENGINEERING CONTROLS:**

<b>Answer</b>	<b>Question</b>
Segregated Compounding Area (SCA)	
1) <input type="checkbox"/>	The SCA and all surfaces in the SCA are clean, uncluttered, and dedicated to compounding.
2) <input type="checkbox"/>	Surfaces are smooth, impervious, free from cracks and crevices, easily cleanable, and resistant to damage from

Section D: FACILITIES AND ENGINEERING CONTROLS:

Answer	Question
	cleaning and disinfecting agents.
3) <input type="checkbox"/> Unanswered	SCA is located away from unsealed windows and doors that connect to the outside and away from high-traffic flow areas. Must not be near restrooms, warehouses, or food preparation areas.
4) <input type="checkbox"/> Unanswered	SCA has a visible perimeter.
5) <input type="checkbox"/> Unanswered	SCA is clear of free-standing humidifiers/dehumidifiers or air conditioners .
6) <input type="checkbox"/> Unanswered	Sink located more than 1 meter from PEC .
Cleanroom Suite (Buffer and Ante Rooms)	
7) <input type="checkbox"/> Unanswered	ISO-classified Anterooms and buffer rooms are separated from unclassified areas by fixed walls, doors, etc.
8) <input type="checkbox"/> Unanswered	Buffer room maintains at least ISO 7 air quality.
9) <input type="checkbox"/> Unanswered	Anteroom providing access to a positive pressure ISO 7 buffer room maintains at least ISO 8.
10) <input type="checkbox"/> Unanswered	Anteroom providing access to a negative pressure ISO 7 buffer room maintains at least ISO 7.
11) <input type="checkbox"/> Unanswered	Primary Engineering Control (PEC) is located within ISO 7 positive pressure, provides unidirectional HEPA-filtered airflow, and maintains ISO 5 or better air quality during dynamic operating conditions.
12) <input type="checkbox"/> Unanswered	Sterile compounding facilities are well-light and comfortable (USP<1066>)
13) <input type="checkbox"/> Unanswered	Temperature and Humidity are monitored and documented in each room of the cleanroom suite each day compounding is performed (should maintain 20 degrees C or cooler and relative humidity below 60% to provide comfortable conditions for personnel who are garbed).
14) <input type="checkbox"/> Unanswered	Electronic documentation of Temperature and Humidity must be retrievable.
15) <input type="checkbox"/> Unanswered	Temperature and Humidity readings reviewed per facility SOPs.
16) <input type="checkbox"/> Unanswered	ISO-classified areas are clear of free-standing humidifiers/dehumidifiers or air conditioners
17) <input type="checkbox"/> Unanswered	Air supplied to the cleanroom suite is introduced by HEPA filters located in the ceilings of ante and buffer rooms.
18) <input type="checkbox"/> Unanswered	Air returns are located low on wall.
19) <input type="checkbox"/> Unanswered	a. Visual smoke study demonstrates no stagnant airflow if returns are not located low on walls.
20) <input type="checkbox"/> Unanswered	b. Visual smoke study and environmental monitoring is repeated when equipment placement is changed, HVAC alterations are made, or HEPA filters are changed .
21) <input type="checkbox"/> Unanswered	All ISO classified rooms are equipped with pressure-differential monitoring, and electronic records are readily retrievable.
22) <input type="checkbox"/> Unanswered	Room pressures are documented at least daily.
23) <input type="checkbox"/> Unanswered	Room pressures are reviewed at least daily.
24) <input type="checkbox"/> Unanswered	Minimum 0.020-inch water column positive pressure differential between buffer room and anteroom.
25) <input type="checkbox"/> Unanswered	Pressure differential between anteroom and unclassified area not less than 0.020-inch water column .
26) <input type="checkbox"/> Unanswered	Anteroom has a line of demarcation that indicates a clean side for garbing.
27) <input type="checkbox"/> Unanswered	Procedures are in place to minimize the influx of lower-quality air ISO-classified areas.
28) <input type="checkbox"/> Unanswered	Both doors of pass-throughs are not opened at the same time.
29) <input type="checkbox"/> Unanswered	No tacky mats in ISO-classified areas.
30) <input type="checkbox"/> Unanswered	If compounding both sterile and nonsterile preparations (e.g weighing and mixing):
32) <input type="checkbox"/> Unanswered	a. PECs must be placed in separate rooms unless ISO 7 can be continuously maintained.
33) <input type="checkbox"/> Unanswered	b. If in the same room, respective PECs for sterile and nonsterile must be 1 meter apart and no particle-generating activities occur during sterile compounding.
34) <input type="checkbox"/> Unanswered	Surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, worksurfaces, counters, and cabinets in classified areas are smooth, impervious, free from cracks and crevices, and non-shedding.
35) <input type="checkbox"/> Unanswered	Anteroom does not contain a floor drain.
36) <input type="checkbox"/> Unanswered	Buffer room does not include plumbed water sources (sinks, eye washes, showers or floor drains)
37) <input type="checkbox"/> Unanswered	All surfaces are resistant to damage by cleaning agents, disinfectants, sporicidal agents, and tools used for cleaning.
38) <input type="checkbox"/> Unanswered	Walls are constructed of or covered with durable material (e.g. epoxy painted walls, heavy-gauge polymers)

## Section D: FACILITIES AND ENGINEERING CONTROLS:

Answer	Question
39) <input type="checkbox"/>	Junctures between ceilings and walls, and walls and floors are sealed to eliminate cracks and crevices.
40) <input type="checkbox"/>	Floors include coving to the sidewall or juncture between floor and wall is caulked
41) <input type="checkbox"/>	Ceiling panels caulked on all sides.
42) <input type="checkbox"/>	Dust-collecting overhangs, pipes, and/or ledges are minimized. All such areas are easily cleanable, and cleaning is documented.

### Facilities Preparing CSPs from Nonsterile Ingredients/Components:

43) <input type="checkbox"/>	Weighing and mixing before sterilization completed in ISO 8 or better environment (e.g. anteroom or buffer room) and in a single-use containment glove bag, containment ventilated enclosure (CVE), BSC, or CACI.
44) <input type="checkbox"/>	CVE, BSC, CACI used for weighing and mixing must be certified at least every six months.
45) <input type="checkbox"/>	Secondary engineering control used for weighing and mixing is certified under dynamic conditions.

### Placement and Movement of Materials:

46) <input type="checkbox"/>	Classified area or SCA contain only furniture, equipment, and materials necessary for compounding which are low-shedding, promote easy cleaning & disinfecting, and do not impact environmental air quality
47) <input type="checkbox"/>	Equipment removed from the classified area or SCA is cleaned and wiped with SIPA (or appropriate disinfectant) before returning to the area. (Should not be removed except for calibration, servicing, or required maintenance activity).
48) <input type="checkbox"/>	No cartons, corrugated cardboard, or uncoated cardboard in classified areas or SCA
49) <input type="checkbox"/>	Carts or equipment in classified areas are non-porous with cleanable casters and wheels. Carts do not cross to the opposite side of the line of demarcation unless the entire cart is cleaned and disinfected.
50) <input type="checkbox"/>	Only equipment necessary for compounding is located in the PEC. Placement is verified by a dynamic airflow smoke pattern test initially and repeated if the equipment is moved.

## Section D HD: USP <800> FACILITIES & ENGINEERING CONTROLS:

Answer	Question
1) <input type="checkbox"/>	HD Handling areas located away from breakrooms, and refreshment areas for personnel, patients, or visitors.
2) <input type="checkbox"/>	Designated areas for: receipts & unpacking of HD in neutral or negative pressure relative to surrounding areas.
3) <input type="checkbox"/>	HDs stored off the floor in a manner that prevents spillage or container breakage in negative pressure with 12 ACPH.
4) <input type="checkbox"/>	Refrigerated antineoplastic HDs stored in a dedicated refrigerator in negative pressure with at least 12 ACPH (consideration of exhaust adjacent to refrigerator compressor).
5) <input type="checkbox"/>	Facility has signs and spill kits readily available to identify and contain spills.
6) <input type="checkbox"/>	C-PECs used for sterile compounding are externally vented and maintain ISO 5 or better-quality air (e.g. Class II BSC, Class III BSC, or CACI; Class II BSC types A2, B1, B2, and C acceptable ).
7) <input type="checkbox"/>	ISO 5 C-PEC is located in ISO 7 C-SEC with ISO 7 anteroom.
8) <input type="checkbox"/>	ISO 7 Buffer is externally vented with fixed walls, HEPA filtered air with minimum 30 ACPH, and negative pressure -0.01 to -0.03 inches water column relative to all adjacent areas.
9) <input type="checkbox"/>	ISO 7 anteroom has fixed walls, HEPA filtered air with minimum 30 ACPH, and positive pressure at least 0.02 inches water column relative to adjacent unclassified areas.
10) <input type="checkbox"/>	ISO 7 handwashing sink is at least 1 meter away from ISO 7 buffer entry.
11) <input type="checkbox"/>	Facility has negative pressure HD buffer entered from positive pressure non-HD buffer
14) <input type="checkbox"/>	C-SCA is externally vented, has fixed walls, negative pressure between 0.01 and 0.03 in water column relative to all adjacent areas, and min 12 ACPH. The handwashing sink must be at least 1 meter away from C-PEC.
15) <input type="checkbox"/>	Non-HD preparations made in BSC or CACI used for HD compounding are placed in protective wrappers and labeled to require PPE handling precautions.

### CONTAINMENT SUPPLEMENTAL ENGINEERING CONTROLS

16) <input type="checkbox"/>	CSTD used if it is physically and chemically compatible with the HD.
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## Section E: CERTIFICATION AND RECERTIFICATION:

Answer	Question
1) <input type="checkbox"/> Unanswered	PEC is certified initially and every six months under dynamic conditions.
2) <input type="checkbox"/> Unanswered	Certification report contains Airflow Testing, HEPA Filter Integrity Testing, Total Particle Count Testing, and Dynamic Airflow Smoke Pattern Test
3) <input type="checkbox"/> Unanswered	Certification report contains Airflow Testing, HEPA Filter Integrity Testing, Total Particle Count Testing, Dynamic Airflow Smoke Pattern Test, and when applicable, manufacturer specifications.
4) <input type="checkbox"/> Unanswered	All ISO Classified rooms and PECs are certified initially, at least every six months, and when changes occur (e.g. redesign, construction, relocation and/or replacement of PECs and any changes affecting airflow or air quality).
5) <input type="checkbox"/> Unanswered	Airflow testing is performed and documented under dynamic operating conditions.
6) <input type="checkbox"/> Unanswered	ISO 7 rooms maintain $\geq 30$ ACPH during dynamic operating conditions.
7) <input type="checkbox"/> Unanswered	Minimum of 15 ACPH are supplied by HVAC via ceiling HEPA filters.
8) <input type="checkbox"/> Unanswered	PEC used to meet minimum ACPH is not turned off except for maintenance (rooms & PEC must be recertified following maintenance).
9) <input type="checkbox"/> Unanswered	Total ACPH, ACPH contributed from PEC, and ACPH from HVAC are documented in the certification report
10) <input type="checkbox"/> Unanswered	ISO 8 rooms maintain $\geq 20$ ACPH during dynamic operating conditions.
11) <input type="checkbox"/> Unanswered	HEPA filter integrity testing is performed after installation and as part of recertification.
12) <input type="checkbox"/> Unanswered	Total Particle Count Testing is performed under dynamic conditions using calibrated equipment.
13) <input type="checkbox"/> Unanswered	ISO 8 $\leq 3,520,000$
14) <input type="checkbox"/> Unanswered	ISO 7 $\leq 352,000$
15) <input type="checkbox"/> Unanswered	ISO 5 $\leq 3,520$
16) <input type="checkbox"/> Unanswered	All sampling sites and procedures are documented in facility SOPs
17) <input type="checkbox"/> Unanswered	Dynamic airflow smoke pattern tests performed in each PEC and demonstrated unidirectional airflow and sweeping action over & away from preparations (Video documentation required).
18) <input type="checkbox"/> Unanswered	Number of personnel in PECs and SECs during total particle counts & dynamic smoke pattern tests are documented.
19) <input type="checkbox"/> Unanswered	Certification and recertifications are reviewed by the designated person(s).
20) <input type="checkbox"/> Unanswered	Corrective Action Plan is documented in response for out-of-range results. Corrective Actions are reviewed for effectiveness and documented.

#### Section F: MICROBIAL AIR AND SURFACE MONITORING:

Answer	Question
1) <input type="checkbox"/> Unanswered	Facility has developed and implemented written SOPs for microbiological air and surface monitoring
2) <input type="checkbox"/> Unanswered	A diagram of sampling locations is included in SOP
3) <input type="checkbox"/> Unanswered	Procedures for collecting samples included in SOP
4) <input type="checkbox"/> Unanswered	Size of samples (e.g. surface area, volume of air) is defined in SOP
5) <input type="checkbox"/> Unanswered	Time of day of sampling is included in SOP
6) <input type="checkbox"/> Unanswered	CFU counts that trigger corrective action
7) <input type="checkbox"/> Unanswered	a. Air (ISO 5 > 1/ISO 7 >10/ISO 8 >100)
8) <input type="checkbox"/> Unanswered	b. Surface (ISO 5 >3/ISO 7 >5/ISO 8 >50)
9) <input type="checkbox"/> Unanswered	The facility documents all microbiological air and surface monitoring test results
10) <input type="checkbox"/> Unanswered	Results are reviewed along with personnel data to assess state of control and identify potential risks for contamination
11) <input type="checkbox"/> Unanswered	Corrective action taken is documented in response to out-of-range results.
12) <input type="checkbox"/> Unanswered	Corrective actions are reviewed for effectiveness when completed and documented.
13) <input type="checkbox"/> Unanswered	Impaction samplers are serviced and calibrated as recommended by the manufacturer.
14) <input type="checkbox"/> Unanswered	Facility has access to C of A for media used during sampling.
15) <input type="checkbox"/> Unanswered	Facility personnel who perform sampling are trained and demonstrate competency in air and surface sampling .

Section F: MICROBIAL AIR AND SURFACE MONITORING:

Answer	Question
16) <input type="checkbox"/> Unanswered	Volumetric active air sampling is performed at least every six months in all classified areas (ISO 5 PEC, ISO 7 and 8 rooms) during dynamic operating conditions.
17) <input type="checkbox"/> Unanswered	Volumetric active air sampling is performed within 30 days prior to starting Category 3 compounding and at least monthly in all classified areas (ISO 5 PEC, ISO 7 and 8 rooms) during dynamic operating conditions regardless of the frequency of Category 3 compounding.
18) <input type="checkbox"/> Unanswered	Volume of air sampled is 1 cubic meter (1000 L) for each sample location.
19) <input type="checkbox"/> Unanswered	Action levels for Viable Airborne Particles Sampling:
20) <input type="checkbox"/> Unanswered	a. >1 CFU for ISO 5 PECs;
21) <input type="checkbox"/> Unanswered	b. >10 CFU for ISO 7 rooms;
22) <input type="checkbox"/> Unanswered	c. >100 for ISO 8 rooms
23) <input type="checkbox"/> Unanswered	CFUs exceeding action levels are identified to the genus level (USP <1113>) and corrective actions documented.
24) <input type="checkbox"/> Unanswered	Results are reviewed and documented as described in facility SOPs.
25) <input type="checkbox"/> Yes	Does Facility Perform its own Viable Air Samples?
26) <input type="checkbox"/> Unanswered	Facility has SOP for how Viable Air Samples are conducted in-house which includes procedures, documentation, incubation, and interpreting results.
27) <input type="checkbox"/> Unanswered	Documentation that personnel can demonstrate knowledge and competency of sample collection completed annually.
28) <input type="checkbox"/> Unanswered	Incubate Inverted samples at 30°-35° C for at least 48 hours, (growth is recorded) then 20°-25° C for at least 5 additional days (growth is recorded).
29) <input type="checkbox"/> Unanswered	If two sampling media are used, (e.g TSA and TSA) incubate Inverted samples in separate incubators at 30°-35° C for at least 48 hours, then 20°-25° C for additional 5 days).
30) <input type="checkbox"/> Unanswered	If fungal media (e.g. MEA or SDA) are second media, incubate inverted at 20° to 25° C for no less than 5 days
31) <input type="checkbox"/> Unanswered	Incubation temperature is monitored and recorded during incubation periods.
32) <input type="checkbox"/> Unanswered	Incubator is located outside the sterile compounding area.
33) <input type="checkbox"/> Unanswered	C of A from media manufacturer verifies expected growth promotion, pH, and sterilization requirements.
34) <input type="checkbox"/> Unanswered	Media supports growth of bacteria and fungi.
Monitoring Surfaces for Viable Particles:	
35) <input type="checkbox"/> Unanswered	Surface sampling is performed at least monthly for all classified areas (ISO 5 PECs, ISO 7 and 8 rooms) and pass-throughs.
36) <input type="checkbox"/> Unanswered	Surface Sampling is performed on a regular schedule at least weekly for all classified areas (ISO 5 PECs, ISO 7 and 8 rooms) and pass-throughs (see USP<1116>: and
37) <input type="checkbox"/> Unanswered	Surface Sampling is performed for all classified areas (ISO 5 PECs, ISO 7 and 8 rooms) and pass-throughs before assigning a BUD longer than the limits set in Table 13
38) <input type="checkbox"/> Unanswered	Surface sampling is conducted in the PEC at the end of each batch before cleaning and disinfection occur (unless a self-enclosed robotic device is used)
39) <input type="checkbox"/> Unanswered	Surface sampling is conducted at least once daily at the end of compounding operations and before cleaning and disinfection for any PEC that is a self-enclosed robotic device
40) <input type="checkbox"/> Unanswered	All sampling sites and procedures are described in facility SOPs.
41) <input type="checkbox"/> Unanswered	Action Levels for Surface Sampling:
42) <input type="checkbox"/> Unanswered	a. >3 CFU for ISO 5 PECs;
43) <input type="checkbox"/> Unanswered	b. >5 CFU for ISO 5 rooms;
44) <input type="checkbox"/> Unanswered	c. >50 for ISO 8 rooms.
45) <input type="checkbox"/> Unanswered	CFU exceeding action levels are identified to the genus level (USP <1113>) and corrective action is documented.
46) <input type="checkbox"/> Unanswered	Results are reviewed and documented as described in facility SOPs
47) <input type="checkbox"/> Yes	Does perform its own Viable Surface Sampling?

## Section F: MICROBIAL AIR AND SURFACE MONITORING:

Answer	Question
48) <input type="checkbox"/> Unanswered	Facility has SOP for how Surface Samples are conducted in-house which includes procedures, documentation, incubation, and interpreting results.
49) <input type="checkbox"/> Unanswered	Documentation that personnel can demonstrate knowledge and competency of sample collection completed annually.
50) <input type="checkbox"/> Unanswered	Surface sampling devices (e.g. plates, paddles, slides) have a raised, convex surface for sampling flat surfaces. May use swabs for irregular surfaces.
51) <input type="checkbox"/> Unanswered	Incubate Inverted samples at 30°-35° C for at least 48 hours, (growth is recorded) then 20°-25° C for at least 5 additional days (growth is recorded).
52) <input type="checkbox"/> Unanswered	If two sampling media are used, (e.g TSA and TSA) incubate Inverted samples in separate incubators at 30°-35° C for at least 48 hours, then 20°-25° C for additional 5 days).
53) <input type="checkbox"/> Unanswered	If fungal media (e.g. MEA or SDA) are second media, incubate inverted at 20° to 25° C for no less than 5 days
54) <input type="checkbox"/> Unanswered	Incubation temperature is monitored and recorded during incubation periods.
55) <input type="checkbox"/> Unanswered	Media supports growth of bacteria and fungi and contains a neutralizing agent
56) <input type="checkbox"/> Unanswered	C of A from media manufacturer verifies expected growth promotion, pH, and sterilization requirements.

## Section G : CLEANING, DISINFECTING, AND APPLYING SPORICIDAL AGENTS IN COMPOUNDING:

Answer	Question
1) <input type="checkbox"/> Unanswered	Surfaces are cleaned prior to being disinfected unless an EPA registered one step disinfectant cleaner is used to accomplish both cleaning and disinfection in one step.
2) <input type="checkbox"/> Unanswered	A sporicidal agent is applied to destroy bacterial and fungal spores.
3) <input type="checkbox"/> Unanswered	Cleaning and disinfecting surfaces and applying a sporicidal occurs at the minimum frequencies as described in the facility's SOP or, if compounding is not performed daily, cleaning and disinfecting is completed before initiating compounding.
4) <input type="checkbox"/> Unanswered	All cleaning and disinfecting activities are performed by trained and appropriately garbed personnel using facility-approved agents and procedures, which is described in SOPs. Personnel are trained if there is any changes in the cleaning and disinfecting procedures.
5) <input type="checkbox"/> Unanswered	Cleaning is performed in the direction of clean to dirty areas. The frequency, method(s), and location(s) of cleaning, disinfecting, and sporicidal agent use is established in written SOPs, in accordance with the manufacturer's instructions, and followed by all cleaning personnel.
6) <input type="checkbox"/> Unanswered	All cleaning, disinfecting, and application of sporicidal agents is documented accordingly to facility SOPs.

### Daily Cleaning, Disinfecting, and applying Sterile IPA

7) <input type="checkbox"/> Unanswered	Equipment and all interior surfaces of the PEC and when surface contamination is known or suspected.
8) <input type="checkbox"/> Unanswered	The surface of the workbench tray inside PEC.
9) <input type="checkbox"/> Unanswered	Pass-through(s), Floor(s), and work surfaces(s) outside the PEC.
10) <input type="checkbox"/> Unanswered	Apply sterile 70% IPA to the horizontal work surface at least every 30 minutes if the compounding process takes 30 minutes or less.
11) <input type="checkbox"/> Unanswered	a. If the compounding process takes longer than 30 minutes, compounding not disrupted and the work surface of the PEC is disinfected immediately after compounding.

### Monthly Cleaning and Disinfecting

12) <input type="checkbox"/> Unanswered	Floor(s)Wall(s), door(s), door frame(s), and ceiling(s).
13) <input type="checkbox"/> Unanswered	Storage shelving and bins.
14) <input type="checkbox"/> Unanswered	Equipment outside the PEC(s).
15) <input type="checkbox"/> Unanswered	Underside of the workbench tray inside the PEC.

### Applying Sporocidal- Monthly

16) <input type="checkbox"/> Unanswered	PEC(s) and equipment inside the PEC(s)
17) <input type="checkbox"/> Unanswered	Surface of the workbench tray
18) <input type="checkbox"/> Unanswered	All surfaces and the area underneath the workbench tray
19) <input type="checkbox"/> Unanswered	Pass-Through(s)

## Section G : CLEANING, DISINFECTING, AND APPLYING SPORICIDAL AGENTS IN COMPOUNDING:

Answer	Question
20) <input type="checkbox"/> Unanswered	Work surfaces outside the PEC
21) <input type="checkbox"/> Unanswered	Floor(s)Wall(s), door(s), door frame(s), and ceiling(s)
22) <input type="checkbox"/> Unanswered	Storage shelving and bins
23) <input type="checkbox"/> Unanswered	Equipment outside the PEC(s)

### Cleaning Supplies

24) <input type="checkbox"/> Unanswered	All cleaning supplies (e.g., wipers, sponges, and mop heads) with the exception of tool handles and holders are low lint.
25) <input type="checkbox"/> Unanswered	Cleaning supplies used in PEC must be sterile.
26) <input type="checkbox"/> Unanswered	If disposable cleaning supplies are used, they are discarded after each cleaning activity.
27) <input type="checkbox"/> Unanswered	Reusable cleaning tools are made of cleanable materials (e.g., no wooden handles) and cleaned and disinfected before and after each use.
28) <input type="checkbox"/> Unanswered	Reusable cleaning tools are dedicated for use in the classified areas or SCA and not removed from these areas except for disposal.
29) <input type="checkbox"/> Unanswered	Cleaning, disinfecting, and sporicidal agents used in the PEC must be sterile.

## Section G HD: USP <800> DEACTIVATING, DECONTAMINATING, CLEANING, DISINFECTING

Answer	Question
1) <input type="checkbox"/> Unanswered	Reusable equipment and areas are deactivated, decontaminated, and cleaned according to facility's written procedures
2) <input type="checkbox"/> Unanswered	Procedures include agents used, dilutions (if applicable), frequency, and documentation requirements
3) <input type="checkbox"/> Unanswered	Agents used are compatible with facility surfaces and appropriate for the documented task(s) (List Agents used)
4) <input type="checkbox"/> Unanswered	C-PEC Deactivation, decontamination, and cleaning occurs daily and is documented
5) <input type="checkbox"/> Unanswered	C-PEC work tray is deactivated and decontaminated, cleaned at least monthly and is documented

## Section H: INTRODUCING ITEMS INTO THE SEC AND PEC:

Answer	Question
6) <input type="checkbox"/> Unanswered	All items are wiped with a sporicidal agent, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipes before they are introduced to the clean side of ante-rooms, pass-throughs, or brought inside the perimeter of the SCA. (Must adhere to contact time for sporicidal/disinfectant; sterile 70% IPA must be allowed to dry).
7) <input type="checkbox"/> Unanswered	All items are wiped with sterile 70% IPA and allowed to dry before entry to the PEC.
8) <input type="checkbox"/> Unanswered	Critical sites (e.g. vial stoppers, ampule necks, IV bag septum) are wiped with sterile 70% IPA is allowed to dry before entering or puncturing the container.
9) <input type="checkbox"/> Unanswered	Wiping of items does not render product labels unreadable.

## Section I: EQUIPMENT, SUPPLIES, AND COMPONENTS:

Answer	Question
Equipment and Supplies:	
1) <input type="checkbox"/> Unanswered	Equipment brought into classified space must be wiped down with a sporicidal agent, disinfectant, or sterile 70% IPA using low lint wipers.
2) <input type="checkbox"/> Unanswered	SOP's for calibration, maintenance, cleaning, and use of equipment based in manufacturer's recommendations are followed by compounding personnel
3) <input type="checkbox"/> Unanswered	Documentation of equipment calibration, verification, and maintenance is at the facility.
4) <input type="checkbox"/> Unanswered	Personnel conduct and record accuracy assessments on ACDs and similar equipment before the first use and again each day the equipment is used.
5) <input type="checkbox"/> Unanswered	Corrective action documented for accuracy measurements outside of manufacturers specifications
6) <input type="checkbox"/> Unanswered	Supplies (beakers, utensils, needles, syringes, filters, and tubing sets) that are in direct contact with CSPs are sterile and depyrogenated.

## Section I: EQUIPMENT, SUPPLIES, AND COMPONENTS:

Answer	Question
Components:	
7) <input type="checkbox"/> Unanswered	Compounding personnel follow SOP that addresses the selection, receipt, evaluation, handling, storage, and documentation of all CSP components, including ingredients, containers, and closures.
8) <input type="checkbox"/> Unanswered	API meets the following criteria:
9) <input type="checkbox"/> Unanswered	a. Comply with USP-NF monograph if one exists
10) <input type="checkbox"/> Unanswered	b. COA that includes specifications and test results showing API meets expected quality.
11) <input type="checkbox"/> Unanswered	c. In the United States, API must be manufactured by an FDA registered facility (If obtained from a non-FDA registered source the compounding facility is responsible for establishing identity, strength, purity, and quality of the ingredients by visual inspection, evaluation of COA, verification by testing a sample to determine conformance with COA. USP<1197>)
12) <input type="checkbox"/> Unanswered	Suitability for sterile compounding is assessed. API is not labeled with "not for pharmaceutical use", "not for injectable use", "not for human use"(unless the CSP is for non-human patients), etc.
13) <input type="checkbox"/> Unanswered	If facility uses commercially available sterile vials and container closure systems; a COA is on file for each lot.
14) <input type="checkbox"/> Unanswered	If facility sterilizes and depyrogenates its own vials and container closure systems; the efficacy of each process is verified and documented. (USP<1229>).
15) <input type="checkbox"/> Unanswered	Components are examined for deterioration and other aspects of unacceptable quality a when received and re-inspected before use.
16) <input type="checkbox"/> Unanswered	Unacceptable components are immediately disposed of or clearly labeled and segregated for disposal.
17) <input type="checkbox"/> Unanswered	Date of receipt is marked or added on each API that lacks expiration date. A conservative expiration date that does not exceed 1 year added to API packaging.
18) <input type="checkbox"/> Unanswered	Components are stored according to the official monograph or as specified by the manufacturer. (proper temperature, humidity, and lighting)
19) <input type="checkbox"/> Unanswered	Temperature in storage areas is monitored and documented at least once daily when facility is open. Documentation is readily retrievable

## Section J: STERILIZATION AND DEPYROGENTATION:

Answer	Question
1) <input type="checkbox"/> Yes	Does facility compound CSPs from one or more non-sterile components or nonsterile supplies or devices?
2) <input type="checkbox"/> Unanswered	Sterilization methods used do not degrade physical/chemical stability of CSPs (USP <1229>)
3) <input type="checkbox"/> Unanswered	SOPs include training and competency of personnel on all sterilization methods used at the facility
4) <input type="checkbox"/> Unanswered	SOPs describe the terminal sterilization and depyrogenation process that includes: temperature, pressure (if applicable), duration, permissible load, conditions, and use of Biological Indicators (BI) and endotoxin challenge vials (ECV).
5) <input type="checkbox"/> Unanswered	SOPs include a schedule and method for verifying the effectiveness of the terminal sterilization and depyrogenation methods selected and also includes methods for maintaining and cleaning the sterilization and depyrogenation equipment.
6) <input type="checkbox"/> Unanswered	Injectable CSPs that contain nonsterile components or that come into contact with nonsterile devices (e.g. containers or tubing) are sterilized within 6 hours after completing the preparation.

### Depyrogenation: (USP<1228.1>)

7) <input type="checkbox"/> Unanswered	The effectiveness of the dry heat depyrogenation cycle is established initially and verified annually using endotoxin challenge vials (ECV) and documented. (USP<85>)
8) <input type="checkbox"/> Unanswered	The effectiveness of the depyrogenation cycle is re-established and documented if there are changes to the depyrogenation cycle described in facility SOPs (e.g. changes in load conditions, duration, or temperature)
9) <input type="checkbox"/> Unanswered	Items that are not thermostable (physically or chemically unaffected by high temperatures) are depyrogenated by multiple rinses with sterile water, drained, and dried before use in compounding. (USP<1228.4>)

### Sterilization by Filtration: (USP<1229.4>)

10) <input type="checkbox"/> Unanswered	Facility has SOP that addresses Sterilization by Filtration which includes, responsible personnel, procedures, and documentation.
11) <input type="checkbox"/> Unanswered	Filters used for sterilization are sterile, 0.22 µm nominal pore size or smaller, and labeled for pharmaceutical use.

## Section J: STERILIZATION AND DEPYROGENTATION:

Answer	Question
12) <input type="checkbox"/> Unanswered	Designated person ensures filters are chemically and physically compatible with all ingredients in the CSP, chemically stable at temperature and pressure that will be used and have enough capacity to filter required volumes.
13) <input type="checkbox"/> Unanswered	All filters used are subjected to manufacturers' recommended integrity test (e.g. bubble point test) and documented.
14) <input type="checkbox"/> Unanswered	If a filter failed integrity testing, the cause is investigated and the CSP is refiltered for sterilization not more than one additional time.

### Sterilization by Steam Heat: (USP<1229.1>)

15) <input type="checkbox"/> Unanswered	The effectiveness of steam sterilization is verified and documented with each sterilization run or load using appropriate biological indicators (BI). (USP<1229.5>)
16) <input type="checkbox"/> Unanswered	Steam supplied is contaminant free and generated using water per manufacturer's recommendation.
17) <input type="checkbox"/> Unanswered	A calibrated data recorder or chart used to monitor each steam sterilization cycle.
18) <input type="checkbox"/> Unanswered	Date, run, and load numbers of steam sterilizer documented in compounding record.

### Sterilization by Dry Heat: (USP<1229.8>)

19) <input type="checkbox"/> Unanswered	Immediately before filling ampules or vials, CSP solutions are filtered using 1.2 µm pore size or less.
20) <input type="checkbox"/> Unanswered	The effectiveness of dry heat sterilization verified and documented with each sterilization run using appropriate BI.
21) <input type="checkbox"/> Unanswered	A calibrated data recorder or chart is used to monitor each dry heat sterilization cycle. Data is reviewed.
22) <input type="checkbox"/> Unanswered	Date, run, and load numbers of dry heat sterilizer documented in compounding record.

## Section K: MASTER FORMULATION RECORD AND COMPOUNDING RECORDS:

Answer	Question
<b>Master Formulation Records:</b>	
1) <input type="checkbox"/> Unanswered	Facility has Master Formulation records (MFR) for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s).
2) <input type="checkbox"/> Unanswered	Master Formulation Record includes name, strength or activity, and dosage form of the CSP.
3) <input type="checkbox"/> Unanswered	Identities and amounts of all ingredients.
4) <input type="checkbox"/> Unanswered	Type and size of container-closure systems(s).
5) <input type="checkbox"/> Unanswered	Documentation of complete instructions for preparing the CSP, including equipment, supplies, a description of the compounding steps, and any special precautions.
6) <input type="checkbox"/> Unanswered	Physical description of the final CSP.
7) <input type="checkbox"/> Unanswered	BUD and storage requirements.
8) <input type="checkbox"/> Unanswered	Reference source to support the stability of the CSP.
9) <input type="checkbox"/> Unanswered	Quality control (QC) procedures (e.g., pH testing, filter integrity testing).
10) <input type="checkbox"/> Unanswered	Other information as needed to describe the compounding process and ensure repeatability (e.g., adjusting pH and tonicity, sterilization method (e.g., steam, dry heat, irradiation, or filter).
11) <input type="checkbox"/> Unanswered	An SOP that describes who is responsible for making changes to the MFR
<b>Compounding Record:</b>	
12) <input type="checkbox"/> Unanswered	A Compounding Record must be created for all CSPs.
13) <input type="checkbox"/> Unanswered	Compounding Record includes Name, strength or activity, and dosage form of the CSP.
14) <input type="checkbox"/> Unanswered	Date and time of preparation of the CSP.
15) <input type="checkbox"/> Unanswered	Assigned internal identification number (e.g., prescription, order, or lot number).
16) <input type="checkbox"/> Unanswered	A method to identify the individuals involved in the compounding process and verifying the final CSP.
17) <input type="checkbox"/> Unanswered	Name of each component.
18) <input type="checkbox"/> Unanswered	Vendor, lot number, and expiration date for each component for SCP's prepared for more than 1 patient and for CSPs prepared from nonsterile ingredient(s).

## Section K: MASTER FORMULATION RECORD AND COMPOUNDING RECORDS:

Answer	Question
19) <input type="button" value="Unanswered"/>	Weight or volume of each component.
20) <input type="button" value="Unanswered"/>	Strength or activity of each component.
21) <input type="button" value="Unanswered"/>	Total quantity compounded.
22) <input type="button" value="Unanswered"/>	Assigned BUD and storage requirements.
23) <input type="button" value="Unanswered"/>	Results of QC procedures (e.g., visual inspection, filter integrity testing, pH testing).
24) <input type="button" value="Unanswered"/>	Master Formulation (MF) reference for the CSP and any deviations from MF are approved.
25) <input type="button" value="Unanswered"/>	Calculation made to determine and verify quantities and/or concentrations of components.

## Section L: ESTABLISHING BEYOND USE DATES (BUD):

Answer	Question
<b>Parameters to Consider in Establishing a BUD</b>	
1) <input type="button" value="Unanswered"/>	When establishing a BUD for a CSP, compounders must consider factors that may affect stability, including but not limited to:
1) <input type="button" value="Unanswered"/>	a. The chemical and physical properties of the drug and/or its formulation
1) <input type="button" value="Unanswered"/>	b. The compatibility of the container-closure system with the finished preparation (e.g., leachables, interactions, and storage conditions).
<b>Establishing a BUD for a CSPs</b>	
2) <input type="button" value="Unanswered"/>	A shorter BUD assigned when the stability of the CSP or its components is less than the hours or days stated above.
3) <input type="button" value="Unanswered"/>	The BUD does not exceed the shortest remaining expiration date or BUD of any of the starting components, regardless of the source.
4) <input type="button" value="Unanswered"/>	BUD Controlled Room Temperature (20-25 degree Celsius) ≤ 12 hours or refrigerator (2-8 degree Celsius) ≤ 24 hours. Prepared in a Segregated Compounding Area.
<b>No Sterility Test Performed</b>	
5) <input type="button" value="Unanswered"/>	Aseptically processed, no sterility testing, prepared from one or more non-sterile starting components: 1 day at controlled room temperature, 4 days refrigerated, 45 days frozen.
6) <input type="button" value="Unanswered"/>	Aseptically processed, no sterility testing, prepared from only sterile starting components: 4 days at controlled room temperature, 10 days refrigerated, 45 days frozen.
7) <input type="button" value="Unanswered"/>	Terminally sterilized, no sterility testing: 14 days at controlled room temperature, 28 days refrigerated, 45 days frozen.
<b>Sterility Test Performed and Passed</b>	
8) <input type="button" value="Unanswered"/>	Aseptically processed, with sterility testing: 30 days at controlled room temperature, 45 days refrigerated, 60 days frozen.
9) <input type="button" value="Unanswered"/>	Terminally sterilized, sterility testing: 45 days at controlled room temperature, 60 days refrigerated, 90 days frozen.
10) <input type="button" value="Unanswered"/>	Aseptically processed, sterility tested, and pass all applicable tests for Category 3: 60 days at controlled room temperature, 90 days refrigerated, 120 days frozen
11) <input type="button" value="Unanswered"/>	Terminally sterilized, sterility tested, and passing all applicable tests for Category 3: 90 days at controlled room temperature, 120 days refrigerated, 180 days frozen.
12) <input type="button" value="Unanswered"/>	Category 3 CSP must be prepared using the exact formulation from which stability data was derived.
13) <input type="button" value="Unanswered"/>	Documentation of the stability study, including methodology, validation of the method, stability-indicating analytical method, container closure, and all results of the study.
14) <input type="button" value="Unanswered"/>	If Category 3 is an injection or ophthalmic, particulate matter testing is conducted in accordance with USP <788> or <789>.
15) <input type="button" value="Unanswered"/>	CSP Category 3 that are prepared are sterility tested and if required endotoxin tested .

## Section M: RELEASE INSPECTIONS AND TESTING:

Answer	Question
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## Section M: RELEASE INSPECTIONS AND TESTING:

Answer	Question
1) <input type="checkbox"/> Unanswered	All release testing procedures (e.g., visual inspections and testing) must be included in the facility's SOP documentation. Any out-of-specification results must be investigated, and a corrective action plan must be implemented and documented as part of the quality assurance (QA) and QC program.
Visual Inspection:	
2) <input type="checkbox"/> Unanswered	Before release and dispensing, the CSP is visually inspected for visible particulates, other foreign matter, discoloration, or other defects.
3) <input type="checkbox"/> Unanswered	The CSP and its labeling match the prescription or medication order.
4) <input type="checkbox"/> Unanswered	Container-closure integrity inspected for leakage, cracks in the container, or improper seals.
5) <input type="checkbox"/> Unanswered	(any observed defect must be discarded, or marked and segregated from acceptable units in a manner that presents them from being released or dispensed.)
6) <input type="checkbox"/> Unanswered	When a CSP will not be released or dispensed on the day of preparation, a visual inspection must be conducted before it is released or dispensed.
Sterility Testing :	
7) <input checked="" type="checkbox"/> Yes	Does facility perform sterility testing Y or N.
8) <input type="checkbox"/> Unanswered	Sterility testing performed in accordance to USP <71> or a validated alternative method.
9) <input type="checkbox"/> Unanswered	a. Units between 1 and 39 CSPs in a single batch, number of units equal to 10% rounded up to the next whole number.
10) <input type="checkbox"/> Unanswered	b. Units 40 or more CSPs in a single batch must comply with Table 3 USP <71> .
11) <input type="checkbox"/> Unanswered	c. Batch size is less than 250 units.
12) <input type="checkbox"/> Unanswered	Method Suitability Test performed for each formulation tested.
13) <input type="checkbox"/> Unanswered	Failures are investigated for:
14) <input type="checkbox"/> Unanswered	a. causes
15) <input type="checkbox"/> Unanswered	b. identification of microorganisms.
16) <input type="checkbox"/> Unanswered	Investigations and resulting corrective actions documented.
Bacterial Endotoxins Testing	
17) <input type="checkbox"/> Unanswered	Injectable CSPs made from one or more non-sterile component(s) and assigned a BUD that requires sterility testing are tested in accordance to USP <85> to ensure that they do not contain excessive bacterial endotoxins.
18) <input type="checkbox"/> Unanswered	CSPs endotoxin testing is performed with every batch , if using non-sterile ingredients or components.
19) <input type="checkbox"/> Unanswered	In the absence of a bacterial endotoxins limit in an official monograph or other CSP formula source, the CSP must not exceed the endotoxins limit calculated as described for the appropriate route of administration for humans.
20) <input type="checkbox"/> Unanswered	CSPs for non-human species must not exceed the endotoxin reference limits based on the weight of the target animal unless a different limit is scientifically supported.

## Section N: LABELING:

Answer	Question
1) <input type="checkbox"/> Unanswered	The label on the immediate container of the CSP must, at a minimum, display prominently and legibly the following information:
2) <input type="checkbox"/> Unanswered	a. Assigned internal identification number (e.g., barcode, prescription, order, or lot number)
3) <input type="checkbox"/> Unanswered	b. Active ingredient(s) and their amounts, activities, or concentrations
4) <input type="checkbox"/> Unanswered	c. Storage conditions if other than controlled room temperature
5) <input type="checkbox"/> Unanswered	d. BUD
6) <input type="checkbox"/> Unanswered	e. Dosage form
7) <input type="checkbox"/> Unanswered	f. Route of administration
8) <input type="checkbox"/> Unanswered	g. If it is a single dose container (if space permitting)
9) <input type="checkbox"/> Unanswered	h. If it is a multidose container (if space permitting)
10) <input type="checkbox"/> Unanswered	i. Special Hanging instructions, (if applicable)

## Section N: LABELING:

Answer	Question
11) <input type="checkbox"/>	j. Warning statements, (if applicable)
12) <input type="checkbox"/>	k. Compounding facility and contact information if sent outside of facility
13) <input type="checkbox"/>	l. Labeling indicates it is a compounded preparation.

## Section N HD: USP <800>

Answer	Question
14) <input type="checkbox"/>	USP <800>: HD handling precautions must be clearly labeled at all times during transport.
15) <input type="checkbox"/>	Personnel ensure that the labeling process for compounded preparation do not introduce contamination into the non HD areas.

## Section O: USE OF COVENTIONALLY MANUFACTURED PRODUCTS AS COMPONENTS:

Answer	Question
Single-Dose Containers:	
1) <input type="checkbox"/>	Single-dose vial entered or punctured in only ISO 5 or cleaner air.
2) <input type="checkbox"/>	Single-dose vial used within 12 hours after initial entry or puncture.(e.g.: labeled with date and time)
3) <input type="checkbox"/>	Opened single-use ampules are used immediately and not stored for any time period once opened.
Multiple Dose Containers:	
4) <input type="checkbox"/>	Once entered or punctured not used for more than 28 days (e.g labeled with date and time) unless otherwise specified by the manufacturer on the labeling. (USP<51>)
Use of Conventionally Manufactured Pharmacy Bulk Packages:	
5) <input type="checkbox"/>	Contents of conventionally manufactured Bulk Packages punctured only in ISO 5 PEC.
6) <input type="checkbox"/>	Used according to manufacturer's labeling. (USP<659>)
7) <input checked="" type="checkbox"/>	Does the facility use CSPs as components for final CSPs?
Use of Compounded Multiple- Dose CSPs	
8) <input type="checkbox"/>	Multiple-Dose CSP meets antimicrobial effectiveness testing and meet requirements of USP<51> and Multi-dose CSPs 14.5.
9) <input type="checkbox"/>	Multi-Dose CSPs not used longer than assigned BUD or 28 days, whichever is shorter.
Use of Compounded Single-Dose CSP and CSP Stock Solutions:	
10) <input type="checkbox"/>	Compounded single-dose CSPs and CSP stock Solution entered or punctured in ISO 5 PEC and stored under conditions upon which its BUD is based.
11) <input type="checkbox"/>	For Stock Solutions ,used for no more than 12 hours after puncturing or duration of assigned BUD, whichever is shorter, and remainder discarded.

## Section P: QUALITY ASSURANCE AND QUALITY CONTROL:

Answer	Question
1) <input type="checkbox"/>	Facility has written SOP Quality Assurance and Quality Control Program for non-sterile compounding procedures. The Program must be able to identify the following:
2) <input type="checkbox"/>	a. That procedures were followed
3) <input type="checkbox"/>	b. Prevention and Detection of Errors and other quality problems.
4) <input type="checkbox"/>	c. Evaluation of Complaints and Adverse Events
5) <input type="checkbox"/>	d. Appropriate Investigations and Corrective Actions
6) <input type="checkbox"/>	Facility has a designated person(s) responsible for QA and QC program for non-sterile compounding.
7) <input type="checkbox"/>	Designated QA and QC person has documented training for non-sterile compounding.
8) <input type="checkbox"/>	QA and QC program reviewed annually and documented.

## Notification About and Recall of Out -of – Specifications Dispensed CSPs:

9) <input type="checkbox"/>	Facility has procedures in place to immediately notify prescriber of a failure of specifications with the potential to
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## Section P: QUALITY ASSURANCE AND QUALITY CONTROL:

Answer	Question
	cause patient harm (sterility, strength, purity, bacterial, endotoxin, or other quality attributes).
10) <input type="checkbox"/>	Facility has procedures to determine whether a recall is necessary.
11) <input type="checkbox"/>	Facility has SOP for recall of out-of- specification dispensed CSPs that contain:
12) <input type="checkbox"/>	a. Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall.
13) <input type="checkbox"/>	b. Procedures to determine the distribution of any affected CSP, including the date and quality of distribution.
14) <input type="checkbox"/>	c. Procedures to identify patients who have received the CSP.
15) <input type="checkbox"/>	d. Procedures for disposition and reconciliation of the recalled CSP
16) <input type="checkbox"/>	Facility documents the implementation of the recall procedures.
17) <input type="checkbox"/>	Facility reports recalls to state board of pharmacy.

### Complaint Handling and Adverse Event Reporting:

18) <input type="checkbox"/>	Facility has an SOP for Complaint handling and adverse Event reporting.
19) <input type="checkbox"/>	Facility has a designated person who is responsible for reviewing of complaints to determine if the complaint indicates a potential quality problem with CNSP.
20) <input type="checkbox"/>	Facility does an investigation into the complaint if a quality problem is identified.
21) <input type="checkbox"/>	Facility has a readily retrievable record keeping system of all complaints with CNSPs that include:
22) <input type="checkbox"/>	a. name of patient
23) <input type="checkbox"/>	b. prescription number
24) <input type="checkbox"/>	c. name and strength of CNSP
25) <input type="checkbox"/>	d. date of complaint
26) <input type="checkbox"/>	e. nature of complaint
27) <input type="checkbox"/>	f. results of the investigation and follow-up

## Section Q: CSP HANDLING, STORAGE, PACKING, SHIPPING, AND TRANSPORT:

Answer	Question
1) <input type="checkbox"/>	Facility has SOPs for handling, storing, packaging, and transporting CSPs
2) <input type="checkbox"/>	Facility staff trained in accordance with SOPs; this is documented

### Handling and Storing CSPs:

5) <input type="checkbox"/>	Facility monitors storage conditions for temperature daily and is documented. (USP<659>)
6) <input type="checkbox"/>	Temperature and monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer.

### Packaging of CSPs:

7) <input type="checkbox"/>	Facility selects appropriate shipping containers and packing materials based on information from vendors and modes of transport to protect CSPs from damage, leakage, contamination, degradation, and absorption
8) <input type="checkbox"/>	IF USP <800>: Packaging materials must protect the healthcare worker from exposure.

### Shipping and Transporting CSPs:

9) <input type="checkbox"/>	Facility selects modes of transportation expected to deliver properly packed CSPs in an undamaged, sterile, and stable condition.
10) <input type="checkbox"/>	Special handling instructions included on exterior of container when applicable.

## Section R: COMPOUNDING ALLERGENIC EXTRACT:

Answer	Question
Personnel Qualifications	
1) <input type="checkbox"/>	A designated person, trained and has expertise in allergen immunotherapy, is responsible for training, evaluation and supervision.
2) <input type="checkbox"/>	Personnel demonstrate knowledge of principles and skills for sterile compounding before being allowed to

## Section R: COMPOUNDING ALLERGENIC EXTRACT:

Answer	Question
	compound. This training and competency include passing written or electronic testing before they can be allowed to compound allergenic extract prescription sets.
3) <input type="checkbox"/> Unanswered	Annual personnel training and competency must be documented. Personnel who have not compounded in more than six months retrained and tested on core competencies.
4) <input type="checkbox"/> Unanswered	Garbing and Hand Hygiene Competency (Gloved Fingertip Testing) observed and documented initially and every twelve (12) months. Documentation must include:
5) <input type="checkbox"/> Unanswered	a. Name of person evaluated.
6) <input type="checkbox"/> Unanswered	b. Evaluation date/time.
7) <input type="checkbox"/> Unanswered	c. Manufacturer, lot and expiration numbers of media and components used.
8) <input type="checkbox"/> Unanswered	d. Starting temperature for each interval of incubation.
9) <input type="checkbox"/> Unanswered	e. Dates of incubation.
10) <input type="checkbox"/> Unanswered	f. Results.
11) <input type="checkbox"/> Unanswered	g. Name of observer and person who reads/documents the results.
12) <input type="checkbox"/> Unanswered	Aseptic Manipulation Competency (Media Fills) performed initially and every 12 months.
13) <input type="checkbox"/> Unanswered	a. Testing simulates the most challenging compounding procedures
14) <input type="checkbox"/> Unanswered	b. COAs present for commercial growth media
15) <input type="checkbox"/> Unanswered	c. In-house media must demonstrate growth promotion in accordance with USP<71>
16) <input type="checkbox"/> Unanswered	All failures documented along with corrective actions taken.

### Personnel Hygiene and Garbing

17) <input type="checkbox"/> Unanswered	Before beginning compounding of allergen immunotherapy prescription sets, personnel perform hand hygiene and garbing procedures according to facility SOPs.
18) <input type="checkbox"/> Unanswered	Hand hygiene procedures include:
19) <input type="checkbox"/> Unanswered	a. Wash hands and forearms up to the elbows, for at least 30 seconds, using closed system soap and nail picks.
20) <input type="checkbox"/> Unanswered	b. No scrub brush used in hand hygiene.
21) <input type="checkbox"/> Unanswered	c. Dry hands and forearms to elbows completely with low lint disposable towels.
22) <input type="checkbox"/> Unanswered	The minimum garb requirements include:
25) <input type="checkbox"/> Unanswered	a. Low-lint garment with sleeves that fit snugly around the wrists and that is enclosed at the neck (e.g., gowns or coveralls).
26) <input type="checkbox"/> Unanswered	b. Low-lint, disposable covers for head that cover the hair, ears and facial hair.
27) <input type="checkbox"/> Unanswered	c. Face mask.
28) <input type="checkbox"/> Unanswered	d. Sterile powder-free gloves.
29) <input type="checkbox"/> Unanswered	Sterile 70% IPA rubbed onto all surfaces of the gloves and allowed to dry thoroughly throughout the compounding process.

### Facilities for Compounding Allergenic Extract Prescription Sets

30) <input type="checkbox"/> Unanswered	The compounding occurs in an ISO Class 5 PEC or in a dedicated allergenic extracts compounding area (AECA). Located away from unsealed windows, doors that connect to the outdoors, restrooms, warehouses, food preparation areas, and traffic flow.
31) <input type="checkbox"/> Unanswered	The PEC or the work surfaces in the AECA located at least 1 meter away from a sink.
32) <input type="checkbox"/> Unanswered	PEC if used is certified every 6 months.
33) <input type="checkbox"/> Unanswered	A visible perimeter establishing the boundaries of the AECA.
34) <input type="checkbox"/> Unanswered	Access to the AECA during compounding restricted to authorized personnel and no other activity is permitted in the AECA.
35) <input type="checkbox"/> Unanswered	The surfaces of walls, floors, fixtures, shelving, counters, and cabinets in the AECA are cleanable. No carpet in AECA.
36) <input type="checkbox"/> Unanswered	Surfaces in the AECA used to prepare allergenic extract prescription sets are prepared must be smooth, impervious, free from cracks and crevices, and non-shedding to allow for easy cleaning and disinfecting.

## Section R: COMPOUNDING ALLERGENIC EXTRACT:

Answer	Question
37) <input type="checkbox"/> Unanswered	If ledges are present, they must be easily cleanable.
38) <input type="checkbox"/> Unanswered	AECA must be well-lit with temperature and humidity controls.
Cleaning and Disinfecting	
39) <input type="checkbox"/> Unanswered	PEC cleaned and disinfected daily and when surface contamination is known or suspected.
40) <input type="checkbox"/> Unanswered	Sterile 70% IPA applied to the horizontal work surface between each prescription set.
41) <input type="checkbox"/> Unanswered	Work surfaces in the AECA where direct compounding is occurring cleaned and disinfected daily and when surface contamination is known or suspected. Sterile 70% IPA applied to the horizontal work surface between each prescription set.
42) <input type="checkbox"/> Unanswered	Walls, doors, and door frames within the perimeter of the AECA cleaned and disinfected monthly and when surface contamination is known or suspected.
43) <input type="checkbox"/> Unanswered	Ceilings within the perimeter of the AECA cleaned and disinfected when visibly soiled and when surface contamination is known or suspected.
44) <input type="checkbox"/> Unanswered	Vial stoppers on packages of conventionally manufactured sterile ingredients wiped with sterile 70% IPA and allowed to dry before they are used to compound allergenic extracts prescription sets.
Establishing BUDs	
45) <input type="checkbox"/> Unanswered	BUD for the prescription set no later than the earliest expiration date of any allergenic extract or any diluent in the prescription set. BUD must not exceed 1 year from the date the prescription set is mixed or diluted.
46) <input type="checkbox"/> Unanswered	Prescription Set stored in vials not syringe.
Labeling	
47) <input type="checkbox"/> Unanswered	The label of each vial of an allergenic extract prescription set displays:
48) <input type="checkbox"/> Unanswered	a. Patient name
49) <input type="checkbox"/> Unanswered	b. Type and fractional dilution of each vial, with a corresponding vial number
50) <input type="checkbox"/> Unanswered	c. BUD
51) <input type="checkbox"/> Unanswered	d. Storage conditions
Shipping and Transport	
52) <input type="checkbox"/> Unanswered	Allergenic extract prescription sets are shipped and transported in an undamaged, sterile, and stable condition.
53) <input type="checkbox"/> Unanswered	Allergenic extract prescription sets that require special handling during shipping or transport, include specific handling instructions on the exterior of the container.
Documentation	
54) <input type="checkbox"/> Unanswered	SOPs describing all aspects of the compounding process
55) <input type="checkbox"/> Unanswered	Personnel training records, competency assessments, and qualification records including corrective actions for any failures
56) <input type="checkbox"/> Unanswered	Certification reports of the PEC, if used, and any corrective actions for failures
57) <input type="checkbox"/> Unanswered	Temperature logs for refrigerator(s)
58) <input type="checkbox"/> Unanswered	Information related to complaints and adverse events including corrective actions taken
59) <input type="checkbox"/> Unanswered	Investigations and corrective actions
Compounding Records:	
60) <input type="checkbox"/> Unanswered	Compounding Record includes Name, strength or activity, and dosage form of the CSP.
61) <input type="checkbox"/> Unanswered	Date and time of preparation of the CSP.
62) <input type="checkbox"/> Unanswered	Assigned internal identification number (e.g., prescription, order, or lot number).
63) <input type="checkbox"/> Unanswered	A method to identify the individuals involved in the compounding process and verifying the final CSP.
64) <input type="checkbox"/> Unanswered	Name of each component
65) <input type="checkbox"/> Unanswered	Vendor, lot number, and expiration date for each component for SCP's prepared for more than 1 patient and for CSPs prepared from nonsterile ingredient(s).
66) <input type="checkbox"/> Unanswered	Weight or volume of each component
67) <input type="checkbox"/> Unanswered	Strength or activity of each component

Section R: COMPOUNDING ALLERGENIC EXTRACT:

	<b>Answer</b>	<b>Question</b>
68)	Unanswered	Total quantity compounded
69)	Unanswered	Assigned BUD and storage requirements
70)	Unanswered	Results of QC procedures (e.g., visual inspection, filter integrity testing, pH testing)
71)	Unanswered	Master Formulation (MF) reference for the CSP and any deviations from MF are approved.
72)	Unanswered	Calculation made to determine and verify quantities and/or concentrations of components.